CHAPTER 33.1-10-01

GENERAL PROVISIONS

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33.1-10-01-01. Purpose.

It is the purpose of this article to state such requirements as shall be applied in the use of all sources of ionizing radiation within North Dakota. This article provides for the protection of public health and maximum safety to all persons at, or in the vicinity of the place of use and storage of sources of ionizing radiation and in addition with respect to radioactive materials, or devices containing radioactive materials, the disposal thereof. This article is intended to be consistent with the best use of ionizing radiation.

History: Effective January 1, 2019.
General Authority: NDCC 28-32-02; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

33.1-10-01-02. Scope.

Except as otherwise specifically provided, this article applies to all persons who receive, possess, use, transfer, own, or acquire any source of radiation, provided, however, that nothing in this article shall apply to any person to the extent such person is subject to regulation by the United States nuclear regulatory commission. Attention is directed to the fact that regulation by this state of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between this state and the United States nuclear regulatory commission and to part 150 of the commission's regulations [10 CFR part 150].

History: Effective January 1, 2019.
General Authority: NDCC 28-32-02; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

33.1-10-01-03. Authority.

The department of environmental quality has been authorized to provide and administer this article under the provisions of North Dakota Century Code chapter 23.1-03.

History: Effective January 1, 2019.
General Authority: NDCC 28-32-02; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

33.1-10-01-04. Definitions.

As used in this article, these terms have the definitions set forth below. Additional definitions used only in a certain section will be found in that section. Terms not defined in this article shall have the meaning given them in North Dakota Century Code chapter 23.1-03.

1. "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

2. "Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

3. "Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to one disintegration or transformation per second (dps or tps).

4. "Byproduct material" means:

   a. Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

   b. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

5. "Calibration" means the determination of:

   a. The response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

   b. The strength of a source of radiation relative to a standard.

6. "CFR" means Code of Federal Regulations.

7. "Chelating agent" means amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxycarboxylic acids, and polycarboxylic acids (e.g., citric acid, carbolic acid, and gluconic acid).

8. "Curie" means a unit of measurement of activity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} disintegrations or transformations per second (dps or tps).

9. "Department" means the department of environmental quality.

10. "Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these rules, "radiation dose" is an equivalent term.

11. "Dose equivalent (H_T)" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

12. "Dose limits" means the permissible upper bounds of radiation doses established in accordance with these rules. For purposes of these rules, "limits" is an equivalent term.

13. "Exposure" means being exposed to ionizing radiation or to radioactive material.

14. "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram [100 rad].

15. "Hazardous waste" means those wastes designated as hazardous by United States environmental protection agency regulations in 40 CFR part 261 and article 33.1-24 of the North Dakota Administrative Code.

16. "Healing arts" means diagnostic or healing treatment of human and animal maladies including, but not limited to, the following which are duly licensed by the state of North Dakota for the lawful practice of: medicine and its associated specialties, dentistry, veterinary medicine, osteopathy, chiropractic, and podiatry.

17. "Human use" means the internal or external administration of radiation or radioactive material to human beings.

18. "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the department.

19. "License" means a general or specific license issued by the department in accordance with the regulations adopted by the department.

20. "Licensee" means any person who is licensed by the department in accordance with this article and North Dakota Century Code chapter 23.1-03.

21. "Licensing state" means any state with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the conference of radiation control program directors, incorporated.

22. "Major processor" means a user processing, handling, or manufacturing radioactive material exceeding type A quantities as unsealed sources or material, or exceeding four times type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. The terms "type A quantity" and "type B quantity" are defined in chapter 33.1-10-13.1.

23. "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material, and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

24. "Natural radioactivity" means radioactivity of naturally occurring nuclides.

25. "Nuclear regulatory commission (NRC)" means the United States nuclear regulatory commission or its duly authorized representatives.

26. "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, other than the commission, or any successor thereto and other than federal government agencies licensed by the commission or any successor thereto.

27. "Protective apron" means an apron made of radiation-attenuating materials used to reduce exposure to radiation.

28. "Quality factor" (Q) means the modifying factor, listed in tables I and II of section 33.1-10-01-14, that is used to derive dose equivalent from absorbed dose.

29. "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of one hundred erg per gram or one one-hundredths joule per kilogram [0.01 gray].

30. "Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these rules, ionizing radiation is an equivalent term. Radiation, as used in these rules, does not include nonionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

31. "Radiation exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg). (See section 33.1-10-01-14 units of radiation exposure, dose, and activity for the special unit equivalent "roentgen" (R).)

32. "Radiation exposure rate" means the radiation exposure per unit of time, such as R/min, mR/h, etc.

33. "Radiation machine" means any device capable of producing radiation except, those devices with radioactive material as the only source of radiation.

34. "Radiation safety officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection requirements.

35. "Radioactive material" means any material (solid, liquid, or gas) which emits radiation spontaneously.

36. "Radioactivity" means the disintegration of unstable atomic nuclei by the emission of radiation.

37. "Registrant" means any person who is registered with the department and is legally obligated to register with the department pursuant to this article and North Dakota Century Code chapter 23.1-03.

38. "Registration" means the notification of the department of possession of a source of radiation and the furnishing of information with respect thereto, in accordance with North Dakota Century Code chapter 23.1-02.

39. "Regulations of the United States department of transportation" means the regulations in 49 CFR part 100-189.

40. "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert (Sv)).

41. "Roentgen" (R) means the special unit of exposure. One roentgen equals two hundred fifty-eight millionths of a coulomb per kilogram of air. (See "exposure")

42. "Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

43. "SI" means the abbreviation for the international system of units.

44. "Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv= 100 rems).

45. "Source material" means: (a) uranium or thorium, or any combination thereof, in any physical or chemical form; or (b) ores that contain by weight one-twentieth of one percent (0.05 percent) or more of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

46. "Source material milling" means any activity that results in the production of byproduct material as defined in subdivision b of subsection 17.

47. "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.

48. "Special nuclear material" means:

    a. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the United States nuclear regulatory commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determined to be special nuclear material, but does not include source material; or

    b. Any material artificially enriched by any of the foregoing but does not include source material.

49. "Test" means a method for determining the characteristics or condition of sources of radiation or components thereof. "Test" may also mean the process of verifying compliance with this article.

50. "These rules" means all parts of this article and any subsequent changes or additions thereto.

51. "Uranium fuel cycle" means the operations of milling of uranium ore, chemical conversion of uranium, isotopic enrichment of uranium, fabrication of uranium fuel, generation of electricity by a light-water-cooled nuclear power plant using uranium fuel, and reprocessing of spent uranium fuel to the extent that these activities directly support the production of electrical power for public use. Uranium fuel cycle does not include mining operations, operations at waste disposal sites, transportation of radioactive

material in support of these operations, and the reuse of recovered nonuranium special nuclear and byproduct materials from the cycle.

52. "Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

53. "Worker" means an individual engaged in work under a license or registration issued by the department and controlled by a licensee or registrant.

History: Effective January 1, 2019.
General Authority: NDCC 28-32-02, 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

33.1-10-01-05. Exemptions.

1. **General provision.** The department may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of this article as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

2. **United States department of energy contractors and United States nuclear regulatory commission contractors.** Any United States department of energy contractor or subcontractor and any United States nuclear regulatory commission contractor or subcontractor of the following categories operating within this state is exempt from this article to the extent that such contractor or subcontractor under the contractor's or subcontractor's contract receives, possesses, uses, transfers, or acquires sources of radiation:

    a. Prime contractors performing work for the United States department of energy at United States government-owned or government-controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation.

    b. Prime contractors of the United States department of energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof.

    c. Prime contractors of the United States department of energy using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel.

    d. Any other prime contractor or subcontractor of the United States department of energy or the nuclear regulatory commission when the state and the nuclear regulatory commission jointly determine (1) that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety and (2) that, the exemption of the prime contractor or subcontractor is authorized by law.

History: Effective January 1, 2019.
General Authority: NDCC 28-32-02, 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-04, 23.1-03-07, 23.1-03-08; S.L. 2017, ch. 199, § 18

33.1-10-01-06. Records.

Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in this article.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03; S.L. 2017, ch. 199, § 18

33.1-10-01-07. Inspections.

1. Each licensee and registrant shall afford the department at all reasonable times, opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

2. Each licensee and registrant shall make available to the department for inspection, upon reasonable notice, records maintained pursuant to this article.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

33.1-10-01-08. Tests.

Each licensee and registrant shall perform upon instructions from the department or shall permit the department to perform such reasonable tests as the department deems appropriate or necessary including, but not limited to, tests of:

1. Sources of radiation.

2. Facilities where sources of radiation are used or stored.

3. Radiation detection and monitoring instruments.

4. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

33.1-10-01-09. Additional requirements.

The department may, by rule or order, impose upon any licensee or registrant such requirements in addition to those established in this article as it deems appropriate or necessary to minimize danger to public health and safety or property.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-08; S.L. 2017, ch. 199, § 18

33.1-10-01-10. Violations.

An injunction or other court order may be obtained prohibiting any violation of any provision of North Dakota Century Code chapter 23.1-03 or any rules or order issued thereunder. Any person who violates any provision of North Dakota Century Code chapter 23.1-03 or any rule or order issued thereunder, and, upon conviction thereof, may be punished as provided by law.

History: Effective January 1, 2019.
General Authority: NDCC 28-32-02; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-12, 23.1-03-15; S.L. 2017, ch. 199, § 18

33.1-10-01-11. Impounding.

Sources of radiation shall be subject to impounding pursuant to North Dakota Century Code section 23.1-03-14.

History: Effective January 1, 2019.
General Authority: NDCC 28-32-02; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-14; S.L. 2017, ch. 199, § 18

33.1-10-01-12. Prohibited uses.

The following sources of ionizing radiation are prohibited:

1. A hand-held fluoroscopic screen shall not be used with x-ray equipment unless it has been listed in the registry of sealed source and devices or accepted for certification by the United States food and drug administration, center for devices and radiological health.

2. Shoe-fitting fluoroscopic devices shall not be used.

3. Those sources of ionizing radiation when found to be detrimental to health and safety or in violation of this article.

History: Effective January 1, 2019.
General Authority: NDCC 28-32-02; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-13; S.L. 2017, ch. 199, § 18

33.1-10-01-13. Communications.

All communications and reports concerning this article and applications filed thereunder shall be addressed to the department as follows:

Mailing and shipping address:
Department of Environmental Quality
Division of Waste Management~~Air Quality~~
~~918 East Divide Avenue~~4201 Normandy Street, Second Floor
Bismarck, ND 5850~~1~~3-1324~~1-1947~~

Telephone (701)328-5166~~88~~
Facsimile (Fax) (701)328-5200~~185~~
24-hour emergency in-state 800-472-2121; out-of-state (701)328-9921

History: Effective January 1, 2019.

General Authority: NDCC 23.1-03-04, 28-32-02; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-07; S.L. 2017, ch. 199, § 18

33.1-10-01-14. Units of exposure, dose, and activity.

1. As used in these rules, the unit of exposure is the coulomb per kilogram (C/kg) of air. One roentgen is equal to two hundred fifty-eight millionths coulomb per kilogram of air.

2. As used in these rules, the units of dose are:

   a. Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of one hundred erg per gram or one one-hundredths (1/100) joule per kilogram (0.01 Gy).

   b. Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram (100 rad).

   c. Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

   d. Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

3. As used in these rules, the quality factors for converting absorbed dose to dose equivalent are shown in table I.

Table I
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENTS

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent*
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments, and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

* Absorbed dose in rad equal to one rem or the absorbed dose in gray equal to one sievert.

4. If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rem per hour or sievert per hour, as provided in subsection 3, one one-hundredth sievert [1 rem] of neutron radiation of unknown energies may, for purposes of these rules, be assumed to result from a total fluence of twenty-five million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from table II to convert a measured tissue dose in gray or rad to dose equivalent in rem or sievert.

Table II
MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Fluence per Unit Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} rem^{-1})	Dose Equivalent[b] (neutrons cm^{-2} Sv^{-1})
(thermal)	2.5E-8	2	980E+6	980E+8
	1E-7	2	980E+6	980E+8
	1E-6	2	810E+6	810E+8
	1E-5	2	810E+6	810E+8
	1E-4	2	840E+6	840E+8
	1E-3	2	980E+6	980E+8
	1E-2	2.5	1010E+6	1010E+8
	1E-1	7.5	170E+6	170E+8
	5E-1	11	39E+6	39E+8
	1	11	27E+6	27E+8
	2.5	9	29E+6	29E+8
	5	8	23E+6	23E+8
	7	7	24E+6	24E+8
	10	6.5	24E+6	24E+8
	14	7.5	17E+6	17E+8
	20	8	16E+6	16E+8
	40	7	14E+6	14E+8
	60	5.5	16E+6	16E+8
	1E+2	4	20E+6	20E+8
	2E+2	3.5	19E+6	19E+8
	3E+2	3.5	16E+6	16E+8
	4E+2	3.5	14E+6	14E+8

[a] Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

[b] Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

5. For purposes of these rules, activity is expressed in the special unit of curie (Ci) or in the international system (SI) unit of becquerel (Bq), or their multiples, or disintegrations or transformations per unit of time.

   a. One curie (Ci) = 3.7E+10 disintegrations or transformations per second (dps or tps) = 3.7E+10 becquerel (Bq) = 2.22E+12 disintegrations or transformations per minute (dpm or tpm).

b. One becquerel (Bq) = one disintegration or transformation per second (dps or tps).

6. SI numerical prefix conversions. See table III for a listing of numerical prefixes to convert SI units or special units by appropriate multiples:

Table III
SI Numerical Prefix Conversion Table

Multiplication Factors	Prefix	Symbol
1 000 000 000 000 000 000 = 10^{18}	exa	E
1 000 000 000 000 000 = 10^{15}	peta	P
1 000 000 000 000 = 10^{12}	tera	T
1 000 000 000 = 10^{9}	giga	G
1 000 000 = 10^{6}	mega	M
1 000 = 10^{3}	kilo	k
100 = 10^{2}	hecto	h
10 = 10^{1}	deka	da
0.1 = 10^{-1}	deci	d
0.01 = 10^{-2}	centi	c
0.001 = 10^{-3}	milli	m
0.000 001 = 10^{-6}	micro	u
0.000 000 001 = 10^{-9}	nana	n
0.000 000 000 001 = 10^{-12}	pico	p
0.000 000 000 000 001 = 10^{-15}	femto	f
0.000 000 000 000 000 001 = 10^{-18}	atto	a

History: Effective January 1, 2019.
General Authority: NDCC 28-32-02; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03; S.L. 2017, ch. 199, § 18

CHAPTER 33.1-10-03.1
RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

Section
33.1-10-03.1-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 30

33.1-10-03.1-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 30.

10 Code of Federal Regulations 30.1, 30.2, 30.3, 30.4, 30.7, 30.9, 30.10, 30.11, 30.12, 30.13, 30.14, 30.15, 30.18, 30.19, 30.20, 30.21, 30.22, 30.31, 30.32, 30.33, 30.34, 30.35, 30.36, 30.37, 30.38, 30.39, 30.41, 30.50, 30.51, 30.52, 30.53, 30.61, 30.62, 30.70, 30.71, and 30.72 and appendix A through appendix E to part 30 are adopted by reference as they exist on May 9, 2022~~January 14, 2019~~, with the following exceptions:

1. Not adopted by reference is 10 Code of Federal Regulations 30.21(c), 30.3(b)(1), 30.3(b)(2), 30.3(b)(3), 30.34(d), 30.34(e)(1), 30.34(e)(3), 30.41(b)(6), paragraph (2) of the definition of "commencement of construction", and paragraph (9)(ii) of the definition of "construction".

2. Requirements in 10 Code of Federal Regulations part 30 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States nuclear regulatory commission", "NRC regional office", or "administrator of the appropriate regional office" appear in 10 Code of Federal Regulations part 30, substitute the words "department of environmental quality" except when used in 10 Code of Federal Regulations 30.12, 30.21(c) and ~~,~~ 30.34(h)(1)~~, and 30.50(c)(1)~~.

4. 10 Code of Federal Regulations 30.7 employee protection also applies to violations of North Dakota Century Code chapters 23.1-02 and 23.1-03.

5. "Act" includes North Dakota Century Code chapters 23.1-02 and 23.1-03.

6. North Dakota state form number 8418, "application for radioactive material license", must be used instead of NRC form 313 as specified in 10 Code of Federal Regulations part 30.

7. North Dakota state form number 8414, "notice to employees", must be posted instead of United States nuclear regulatory commission form 3 that is specified in 10 Code of Federal Regulations part 30.

8. The department of environmental quality radioactive material license replaces NRC form 374, "byproduct material license", as specified in 10 Code of Federal Regulations part 30.

9. North Dakota state form number 18941, "certificate: disposition of radioactive material", must be used instead of NRC form 314 as specified in 10 Code of Federal Regulations part 30.

10. For references to 10 Code of Federal Regulations part 170, see chapter 33.1-10-11 for applicable fee schedules.

History: Effective January 1, 2019; amended effective July 1, 2021.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

PART 30--RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

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30.62 Right to cause the withholding or recall of byproduct material.

30.63 Violations.

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30.70 Schedule A--Exempt concentrations.

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Appendix A to Part 30--Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

Appendix B to Part 30--Quantities of Licensed Material Requiring Labeling

Appendix C to Part 30--Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

Appendix D to Part 30--Criteria Relating To Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have no Outstanding Rated Bonds

Appendix E to Part 30--Criteria Relating to Use of Financial Tests and Self-Guarantee For Providing Reasonable Assurance of Funds For Decommissioning by Nonprofit Colleges, Universities, and Hospitals

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109–58, 119 Stat. 549 (2005). Section 30.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

[72 FR 55924, Oct. 1, 2007; 72 FR 58486, Oct. 16, 2007; 73 FR 63570, Oct. 24, 2008]

General Provisions

§ 30.1 Scope.

This part prescribes rules applicable to all persons in the United States governing domestic licensing of byproduct material under the Atomic Energy Act of 1954, as amended (68 Stat. 919), and under title II of the Energy Reorganization Act of 1974 (88 Stat. 1242), and exemptions from the domestic licensing requirements permitted by Section 81 of the Act. This part also gives notice to all persons who knowingly provide to any licensee, applicant, certificate of registration holder, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's, applicant's or certificate of registration holder's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 30.10.

[63 FR 1895, Jan. 13, 1998]

§ 30.2 Resolution of conflict.

The requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In any conflict between the requirements in this part and a specific requirement in another part of the regulations in this chapter, the specific requirement governs.

[30 FR 8185, June 26, 1965]

§ 30.3 Activities requiring license.

(a) Except as provided in paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section and for persons exempt as provided in this part and part 150 of this chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued in accordance with the regulations in this chapter.

(b)(1) The requirements, including provisions that are specific to licensees, in this part and parts 19, 20, 21, and 71 of this chapter, as well as the additional requirements for specific broad scope, industrial radiography, irradiator, or well logging uses in 10 CFR parts 33, 34, 36, or 39, respectively, shall apply to Government agencies or Federally recognized Indian Tribes on November 30, 2007, when conducting activities under the authority provided by paragraphs (b)(2) and (b)(3) of this section.

(2) A specifically licensed Government agency or Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a license amendment is required to authorize the activities in paragraph (a) of this section, may continue to use these materials for uses permitted under this part until the date of the NRC's final licensing determination, provided that the licensee submits an amendment application on or before June 2, 2008.

(3) A Government agency or Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific license is

required in paragraph (a) of this section, may continue to use such material for uses permitted under this part until the date of the NRC's final licensing determination provided that the agency or Indian Tribe submits an application for a license authorizing activities involving these materials on or before December 1, 2008.

(c)(1) The requirements, including provisions that are specific to licensees in this part and parts 19, 20, 21, and 71 of this chapter, as well as the additional requirements for specific broad scope, industrial radiography, irradiator, or well logging uses in 10 CFR parts 33, 34, 36, or 39, respectively, shall apply to all persons, other than those included in paragraph (b)(1) of this section, on August 8, 2009, or earlier as noticed by the NRC, when conducting activities under the authority provided by paragraphs (c)(2) and (c)(3) of this section.

(2) Except as provided in paragraph (b)(2) of this section, all other licensees, who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a license amendment is required to authorize the activities in paragraph (a) of this section, may continue to use these materials for uses permitted under this part until the date of the NRC's final licensing determination, provided that the person submits an amendment application within 6 months from the waiver expiration date of August 7, 2009 or within 6 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

(3) Except as provided in paragraph (b)(3) of this section, all other persons, who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific license is required in paragraph (a) of this section, may continue to use such material for uses permitted under this part until the date of the NRC's final licensing determination, provided that the person submits a license application within 12 months from the waiver expiration date of August 7, 2009 or within 12 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

(d) If a person or licensee is required to file an application for a license or amendment in accordance with paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section, but does not file for the license or amendment within the required time, the authority provided by paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section to receive or use the accelerator-produced radioactive material or discrete sources of radium-226 shall expire with respect to the person's or licensee's authority to receive and use such byproduct material. This authority shall not expire with respect to the responsibility of the person or licensee regarding the possession of such byproduct material, the decommissioning (including financial assurance) of facilities, or the disposal of such byproduct material.

[30 FR 8185, June 26, 1965, as amended at 43 FR 6921, Feb. 17, 1978; 72 FR 55924, Oct. 1, 2007]

§ 30.4 Definitions.

Accelerator-produced radioactive material means any material made radioactive by a particle accelerator.

Act means the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto;

Agreement State means any state with which the Atomic Energy Commission or the Nuclear Regulatory Commission has entered into an effective agreement under subsection 274b. of the Act. *Non-agreement State* means any other State;

Alert means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

Byproduct material means— (1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(3) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

Commencement of construction means any clearing of land, excavation, or other substantial action that would adversely affect the natural environment of a site but does not include changes desirable for the temporary use of the land for public recreational uses, necessary borings to determine site characteristics or other preconstruction monitoring to establish background information related to the suitability of a site or to the protection of environmental values.

Commission means the Nuclear Regulatory Commission and its duly authorized representatives;

Consortium means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

Curie means that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second;

Cyclotron means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits--

(1) Release of the property for unrestricted use and termination of the license; or

(2) Release of the property under restricted conditions and termination of the license.

Dentist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

Department and Department of Energy means the Department of Energy established by the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 et seq.) to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104 (b), (c) and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565 at 577-578, 42 U.S.C. 7151).

Discrete source means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

Effective dose equivalent means the sum of the products of the dose equivalent to the organ or tissue and the weighting factors applicable to each of the body organs or tissues that are irradiated. Weighting factors are: 0.25 for gonads, 0.15 for breast, 0.12 for red bone marrow, 0.12 for lungs, 0.03 for thyroid, 0.03 for bone surface, and 0.06 for each of the other five organs receiving the highest dose equivalent.

Government agency means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government;

License, except where otherwise specified means a license for by-product material issued pursuant to the regulations in this part and parts 31 through 36 and 39 of this chapter;

Medical use means the intentional internal or external administration of byproduct material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user as defined in 10 CFR Part 35.

Microcurie means that amount of radioactive material which disintegrates at the rate of 37 thousand atoms per second;

Millicurie means that amount of radioactive material which disintegrates at the rate of 37 million atoms per second;

Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, accelerator is an equivalent term.

Person means: (1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department, except that the Department shall be considered a person within the meaning of the regulations in this part to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (2) any legal successor, representative, agent, or agency of the foregoing;

Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine;

Podiatrist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

Principal activities, as used in this part, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

Production facility means production facility as defined in the regulations contained in part 50 of this chapter;

Quantities of Concern means the quantities of the radionuclides meeting or exceeding the threshold limits set forth in Table I–1 of Appendix I of part 73 of this chapter.

Research and development means: (1) Theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. "Research and development" as used in this part and parts 31 through 35 does not include the internal or external administration of byproduct material, or the radiation therefrom, to human beings;

Sealed source means any by product material that is encased in a capsule designed to prevent leakage or escape of the byproduct material;

Site area emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

Source material means source material as defined in the regulations contained in part 40 of this chapter;

Special nuclear material means special nuclear material as defined in the regulations contained in part 70 of this chapter;

United States, when used in a geographical sense, includes Puerto Rico and all territories and possessions of the United States;

Utilization facility means a utilization facility as defined in the regulations contained in part 50 of this chapter;

[30 FR 8185, June 26, 1965, as amended at 36 FR 1466, Jan. 30, 1971; 37 FR 5746, Mar. 21, 1972; 38 FR 29314, Oct. 24, 1973; 40 FR 8784, Mar. 3, 1975; 43 FR 6921, Feb. 17, 1978; 45 FR 14200, Mar. 5, 1980; 45 FR 18905, Mar. 24, 1980; 48 FR 39037, Aug. 29, 1983; 51 FR 36967, Oct. 16, 1986; 52 FR 8241, Mar. 17, 1987; 53 FR 24044, June 27, 1988; 54 FR 14059, Apr. 7, 1989; 58 FR 7736, Feb. 9, 1993; 59 FR 36034, July 15, 1994; 59 FR 61780, Dec. 2, 1994; 62 FR 28963, May 28, 1997; 62 FR 39089, July 21, 1997; 65 FR 54950, Sept. 12, 2000; 72 FR 55924, Oct. 1, 2007; 73 FR 63570, Oct. 24, 2008; 76 FR 56962, Sept. 15, 2011; 79 FR 58671, Sept. 30, 2014]

§ 30.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part and parts 31 through 36 and 39 by any officer or employee of the

Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

[30 FR 8185, June 26, 1965, as amended at 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993]

§ 30.6 Communications.

(a) Unless otherwise specified or covered under the regional licensing program as provided in paragraph (b) of this section, any communication or report concerning the regulations in parts 30 through 36 and 39 of this chapter and any application filed under these regulations may be submitted to the Commission as follows:

(1) By mail addressed: ATTN: Document Control Desk, Director, Office of Federal and State Materials and
Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

(2) By hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland.

(3) Where practicable, by electronic submission, for example, via Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html*, by calling (301) 415-0439, by e-mail to *EIE@nrc.gov*, or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information.

(b) The Commission has delegated to the four Regional Administrators licensing authority for selected parts of its decentralized licensing program for nuclear materials as described in paragraph (b)(1) of this section. Any communication, report, or application covered under this licensing program must be submitted to the appropriate Regional Administrator. The Administrators' jurisdictions and mailing addresses are listed in paragraph (b)(2) of this section.

(1) The delegated licensing program includes authority to issue, renew, amend, cancel, modify, suspend, or revoke licenses for nuclear materials issued pursuant to 10 CFR parts 30 through 36, 39, 40, and 70 to all persons for academic, medical, and industrial uses, with the following exceptions:

(i) Activities in the fuel cycle and special nuclear material in quantities sufficient to constitute a critical mass in any room or area. This exception does not apply to license modifications relating to termination of special nuclear material licenses that authorize possession of larger quantities when the case is referred for action from NRC's Headquarters to the Regional Administrators.

(ii) Health and safety design review of sealed sources and devices and approval, for licensing purposes, of sealed sources and devices.

(iii) Processing of source material for extracting of metallic compounds (including Zirconium, Hafnium, Tantalum, Titanium, Niobium, etc.).

(iv) Distribution of products containing radioactive material to persons exempt pursuant 10 CFR 32.11 through 32.26.

(v) New uses or techniques for use of byproducts, source, or special nuclear material.

(2) *Submissions*--(i) *Region I*. The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region I non-Agreement States and the District of Columbia: Connecticut, Delaware, Maine, Massachusetts, New Jersey, Pennsylvania, and Vermont. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, renewal, or termination request of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region I, Nuclear Material Section B, 475 Allendale Road, Suite 102, King of Prussia, Pennsylvania 19406-1415; where e-mail is appropriate it should be addressed to *RidsRgn1MailCenter@nrc.gov*.

(ii) *Region II*. The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region II non-Agreement States and territories: Virginia, West Virginia, Puerto Rico, and the Virgin Islands. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, renewal, or termination request of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region I, Nuclear Material Section B, 475 Allendale Road, Suite 102, King of Prussia, PA 19406-1415~~U.S. Nuclear Regulatory Commission, Region II, Material Licensing/Inspection Branch, Sam Nunn Atlanta Federal Center, Suite 23T85, 61 Forsyth Street, SW, Atlanta, GA 30303-8931~~; where e-mail is appropriate it should be addressed to *RidsRgn2MailCenter@nrc.gov*.

(iii) *Region III*. The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region III non-Agreement States: Indiana, Michigan, Minnesota, Missouri, Ohio, and Wisconsin. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, renewal, or termination, request of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region III, Material Licensing Section, 2443 Warrenville Road, Suite 210, Lisle, IL 60532- 4352; where e-mail is appropriate it should be addressed to *RidsRgn3MailCenter@nrc.gov*.

(iv) *Region IV*. The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region IV non-Agreement States and a territory: Alaska, Hawaii, Montana, Oklahoma, South Dakota, Wyoming, and Guam. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, renewal, or termination request

of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region IV, Material Radiation Protection Section, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011-4005; where e-mail is appropriate it should be addressed to *RidsRgn4MailCenter@nrc.gov*.

[48 FR 16031, Apr. 14, 1983, as amended at 49 FR 19630, May 9, 1984; 49 FR 47824, Dec. 7, 1984; 50 FR 14693, Apr. 11, 1985; 51 FR 36000, Oct. 8, 1986; 52 FR 8241, Mar. 17, 1987; 52 FR 38392, Oct. 16, 1987; 52 FR 48093, Dec. 18, 1987; 53 FR 3862, Feb. 10, 1988; 53 FR 43420, Oct. 27, 1988; 58 FR 7736, Feb. 9, 1993; 58 FR 64111, Dec. 6, 1993; 59 FR 17465, Apr. 13, 1994; 60 FR 24551, May 9, 1995; 62 FR 22880, Apr. 28, 1997; 68 FR 58803, Oct. 10, 2003; 70 FR 69421, Nov. 16, 2005; 71 FR 15007, Mar. 27, 2006; 72 FR 33386, Jun. 18, 2007; 73 FR 5717, Jan. 31, 2008; 74 FR 62681, Dec. 1, 2009; 75 FR 21980, Apr. 27, 2010; 75 FR 73942, Nov. 30, 2010; 76 FR 72085, Nov. 22, 2011; 77 FR 39905, Jul. 6, 2012; 77 FR 43689, Jul. 25, 2012; 78 FR 17006, Mar. 19, 2013; 78 FR 32338, May 29, 2013; 79 FR 75739, Dec. 19, 2014; 87 FR 20693, Apr. 8, 2022]

§ 30.7 Employee protection.

(a) Discrimination by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(1) The protected activities include but are not limited to:

(i) Providing the Commission or his or her employer information about alleged violations of either of the statutes named in paragraph (a) introductory text of this section or possible violations of requirements imposed under either of those statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) introductory text or under these requirements if the employee has identified the alleged illegality to the employer;

(iii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) introductory text.

(v) Assisting or participating in, or is about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraphs (a), (e), or (f) of this section by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant may be grounds for--

(1) Denial, revocation, or suspension of the license.

(2) Imposition of a civil penalty on the licensee, applicant, or a contractor or subcontractor of the licensee or applicant.

(3) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each specific licensee, each applicant for a specific license, and each general licensee subject to part 19 shall prominently post the revision of NRC Form 3, "Notice to Employees," referenced in 10 CFR 19.11(c).

(2) The posting of NRC Form 3 must be at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license termination.

(3) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of

this chapter, by calling (301) 415-5877, via e-mail to *forms@nrc.gov*, or by visiting the NRC's Web site at *http://www.nrc.gov* and selecting forms from the index found on the home page.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in paragraph (a)(1) of this section including, but not limited to, providing information to the NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

[58 FR 52408, Oct. 8, 1993, as amended at 60 FR 24551, May 9, 1995; 61 FR 6764, Feb. 22, 1996; 68 FR 58803, Oct. 10, 2003; 72 FR 63969, Nov. 14, 2007; 79 FR 66603, Nov. 10, 2014]

§ 30.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0017.

(b) The approved information collection requirements contained in this part appear in §§ 30.9, 30.11, 30.15, 30.19, 30.20, 30.32, 30.34, 30.35, 30.36, 30.37, 30.38, 30.41, 30.50, 30.51, 30.55, and appendices A, C, D, and E to this part.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In §§ 30.32, 30.37, and 30.38, NRC Form 313 is approved under control number 3150-0120.

(2) In § 30.36, NRC Form 314 is approved under control number 3150-0028.

(3) In § 30.34, DOC/NRC Forms AP–1, AP–A, and associated forms are approved under control number 0694–0135.

[49 FR 19625, May 9, 1984, as amended at 59 FR 61780, Dec. 2, 1994; 62 FR 52186, Oct. 6, 1997; 62 FR 63639, Dec. 2, 1997; 63 FR 29541, June 1, 1998; 67 FR 67099, Nov. 4, 2002; 73 FR 78604, Dec. 23, 2008; 77 FR 43689, Jul. 25, 2012]

§ 30.9 Completeness and accuracy of information.

(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

(b) Each applicant or licensee shall notify the Commission of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or common defense and security. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Commission of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification shall be provided to the Administrator of the appropriate Regional Office within two working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.

[52 FR 49371, Dec. 31, 1987]

§ 30.10 Deliberate misconduct.

(a) Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or

(2) Deliberately submit to the NRC, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

(c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy

of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

[63 FR 1896, Jan. 13, 1998]

Exemptions

§ 30.11 Specific exemptions.

(a) The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part and parts 31 through 36 and 39 of this chapter as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

(b) Any licensee's activities are exempt from the requirements of this part to the extent that its activities are licensed under the requirements of part 72 of this chapter.

(c) The Department of Energy is exempt from the requirements of this part to the extent that its activities are subject to the requirements of part 60 or 63 of this chapter.

(d) Except as specifically provided in part 61 of this chapter, any licensee is exempt from the requirements of this part to the extent that its activities are subject to the requirements of part 61 of this chapter.

[37 FR 5746, Mar. 21, 1972, as amended at 39 FR 26279, July 18, 1974; 40 FR 8784, Mar. 3, 1975; 43 FR 6921, Feb. 21, 1978; 45 FR 65530, Oct. 3, 1980; 46 FR 13979, Feb. 25, 1981; 47 FR 57480, Dec. 27, 1982; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 66 FR 51838, Oct. 11, 2001; 66 FR 55790, Nov. 2, 2001]

§ 30.12 Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts.

Except to the extent that Department facilities or activities of the types subject to licensing pursuant to section 202 of the Energy Reorganization Act of 1974 are involved, any prime contractor of the Department is exempt from the requirements for a license set forth in sections 81 and 82 of the Act and from the regulations in this part to the extent that such contractor, under his prime contract with the Department manufactures, produces, transfers, receives, acquires, owns, possesses, or uses byproduct material for:

(a) The performance of work for the Department at a United States Government-owned or controlled site, including the transportation of byproduct material to or from such site and the performance of contract services during temporary interruptions of such transportation;

(b) Research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or

(c) The use or operation of nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel.

In addition to the foregoing exemptions and subject to the requirement for licensing of Department facilities and activities pursuant to section 202 of the Energy Reorganization Act of 1974, any prime contractor or subcontractor of the Department or the Commission is exempt from the requirements for a license set forth in sections 81 and 82 of the Act and from the regulations in this part to the extent that such prime contractor or subcontractor manufacturers, produces, transfers, receives, acquires, owns, possesses, or uses byproduct material under his prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

[40 FR 8784, Mar. 3, 1975, as amended at 43 FR 6921, Feb. 17, 1978]

§ 30.13 Carriers.

Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the regulations in this part and parts 31 through 37 and 39 of this chapter and the requirements for a license set forth in section 81 of the Act to the extent that they transport or store byproduct material in the regular course of carriage for another or storage incident thereto.

[37 FR 3985, Feb. 25, 1972, as amended at 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 78 FR 17006, Mar. 19, 2013]

§ 30.14 Exempt concentrations.

(a) Except as provided in paragraphs (c) and (d) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and parts 31 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in concentrations not in excess of those listed in § 30.70.

(b) This section shall not be deemed to authorize the import of byproduct material or products containing byproduct material.

(c) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and parts 31 through 36 and 39 of this chapter to the extent that this person transfers byproduct material contained in a product or material in concentrations not in excess of those specified in § 30.70 and introduced into the product or material by a licensee holding a specific license issued by the Commission expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(d) No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.11 of this chapter.

[30 FR 8185, June 26, 1965, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 58486, Oct. 16, 2007]

§ 30.15 Certain items containing byproduct material.

(a) Except for persons who apply byproduct material to, or persons who incorporate byproduct material into, the following products, or persons who initially transfer for sale or distribution the following products containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 20 and 30 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires the following products:

(1) Timepieces or hands or dials containing not more than the following specified quantities of byproduct material and not exceeding the following specified levels of radiation:

(i) 25 millicuries of tritium per timepiece,

(ii) 5 millicuries of tritium per hand,

(iii) 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial),

(iv) 100 microcuries of promethium 147 per watch or 200 microcuries of promethium 147 per any other timepiece,

(v) 20 microcuries of promethium 147 per watch hand or 40 microcuries of promethium 147 per other timepiece hand,

(vi) 60 microcuries of promethium 147 per watch dial or 120 microcuries of promethium 147 per other timepiece dial (bezels when used shall be considered as part of the dial),

(vii) The levels of radiation from hands and dials containing promethium 147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(A) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface,

(B) For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface,

(C) For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.

(viii) 0.037 megabecquerel (1 microcurie) of radium-226 per timepiece in intact timepieces

manufactured prior to November 30, 2007.

(2)(i) Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 uCi) of polonium-210 per device.

(ii) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 uCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

(iii) Such devices authorized before October 23, 2012 for use under the general license then provided in § 31.3 and equivalent regulations of Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Commission.

(3) Balances of precision containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007.

(4) [Reserved]

(5) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007.

(6) [Reserved]

(7) Ionization chamber smoke detectors containing not more than 1 microcurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(8) Electron tubes: *Provided*, That each tube does not contain more than one of the following specified quantities of byproduct material:

(i) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

(ii) 1 microcurie of cobalt-60;

(iii) 5 microcuries of nickel-63;

(iv) 30 microcuries of krypton-85;

(v) 5 microcuries of cesium-137;

(vi) 30 microcuries of promethium-147;

And provided further, That the levels of radiation from each electron tube containing byproduct material do not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.[1]

(9) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of byproduct material: *Provided*, That;

(i) Each source contains no more than one exempt quantity set forth in § 30.71, Schedule B, and

(ii) Each instrument contains no more than 10 exempt quantities. For purposes of this paragraph (a)(9), an instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in § 30.71, Schedule B, provided that the sum of such fractions shall not exceed unity.

(iii) For purposes of this paragraph (a)(9), 0.05 microcurie of americium-241 is considered an exempt quantity under § 30.71, Schedule B.

(10) [Reserved]

(b) Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in paragraph (a) of this section, or who desires to initially transfer for sale or distribution such products containing byproduct material, should apply for a specific license pursuant to § 32.14 of this chapter, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section.

[31 FR 5316, Apr. 2, 1966, as amended at 31 FR 14349, Nov. 8, 1966; 32 FR 785, Jan. 24, 1967; 32 FR 6434, Apr. 26, 1967; 32 FR 13921, Oct. 6, 1967; 34 FR 6651, Apr. 18, 1969; 34 FR 19546, Dec. 11, 1969; 35 FR 6427, Apr. 22, 1970; 35 FR 8820, June 6, 1970; 43 FR 2387, Jan. 17, 1978; 43 FR 6921, Feb. 17, 1978; 46 FR 26471, May 13, 1981; 46 FR 46876, Sept. 23, 1981; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 55925, Oct. 1, 2007; 72 FR 58486, Oct. 16, 2007; 77 FR 43689, Jul. 25, 2012]

[1] For purposes of this paragraph "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

§ 30.16 [Removed].

[32 FR 4241, Mar. 18, 1967, as amended at 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 58486, Oct. 16, 2007]

§ 30.18 Exempt quantities.

(a) Except as provided in paragraphs (c) through (e) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 30 through 34, 36, and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in individual quantities, each of which does not exceed the applicable quantity set forth in § 30.71, Schedule B.

(b) Any person, who possesses byproduct material received or acquired before September 25, 1971, under the general license then provided in § 31.4 of this chapter or similar general license of a State, is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 30 through 34, 36 and 39 of this chapter to the extent that this person possesses, uses, transfers, or owns byproduct material.

(c) This section does not authorize for purposes of commercial distribution the production, packaging, repackaging, or transfer of byproduct material or the incorporation of byproduct material into products intended for commercial distribution.

(d) No person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in § 30.71 Schedule B, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.18 of this chapter, which license states that the byproduct material may be transferred by the licensee to persons exempt under this section or the equivalent regulations of an Agreement State.

(e) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in § 30.71, Schedule B, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this part.

[35 FR 6427, Apr. 22, 1970, as amended at 36 FR 16898, Aug. 26, 1971; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 55925, Oct. 1, 2007; 72 FR 58486, Oct. 16, 2007]

§ 30.19 Self-luminous products containing tritium, krypton-85, or promethium-147.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, and except as provided in paragraph (c) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 20 and 30 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to § 32.22 of this chapter, which license authorizes the initial transfer of the product for use under this section.

(b) Any person who desires to manufacture, process, or produce, or initially transfer for sale or

distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under paragraph (a) of this section, should apply for a license under § 32.22 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

(c) The exemption in paragraph (a) of this section does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

[34 FR 9026, June 6, 1969, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 77 FR 43689, Jul. 25, 2012]

§ 30.20 Gas and aerosol detectors containing byproduct material.

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(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, 21, and 30 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.26 of this chapter, which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by a State under comparable provisions to § 32.26 of this chapter authorizing distribution to persons exempt from regulatory requirements.

(b) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use under paragraph (a) of this section, should apply for a license under § 32.26 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

[34 FR 6653, Apr. 18, 1969, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 55925, Oct. 1, 2007; 77 FR 43689, Jul. 25, 2012]

§ 30.21 Radioactive drug: Capsules containing carbon-14 urea for "in vivo" diagnostic use for humans.

(a) Except as provided in paragraphs (b) and (c) of this section, any person is exempt from the requirements for a license set forth in Section 81 of the Act and from the regulations in this part and part 35 of this chapter provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

(b) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to part 35 of this chapter.

(c) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to § 32.21 of this chapter.

(d) Nothing in this section relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

[62 FR 63640, Dec. 2, 1997]

§ 30.22 Certain industrial devices.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, 21, 30 through 36, and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.30 of this chapter, which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(b) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under paragraph (a) of this section, should apply for a license under § 32.30 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

[77 FR 43689, Jul. 25, 2012]

Licenses

§ 30.31 Types of licenses.

Licenses for byproduct material are of two types: General and specific.

(a) The Commission issues a specific license to a named person who has filed an application for the license under the provisions of this part and parts 32 through 36, and 39.

(b) A general license is provided by regulation, grants authority to a person for certain activities

involving byproduct material, and is effective without the filing of an application with the Commission or the issuance of a licensing document to a particular person. However, registration with the Commission may be required by the particular general license.

[65 FR 79187, Dec. 18, 2000]

§ 30.32 Application for specific licenses.

(a) A person may file an application on NRC Form 313, "Application for Material License," in accordance with the instructions in § 30.6 of this chapter. Information contained in previous applications, statements or reports filed with the Commission or the Atomic Energy Commission may be incorporated by reference, provided that the reference is clear and specific.

(b) The Commission may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Commission to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(d) An application for license filed pursuant to the regulations in this part and parts 32 through 35 of this chapter will be considered also as an application for licenses authorizing other activities for which licenses are required by the Act, provided that the application specifies the additional activities for which licenses are requested and complies with regulations of the Commission as to applications for such licenses.

(e) Each application for a byproduct material license, other than a license exempted from part 170 of this chapter, shall be accompanied by the fee prescribed in § 170.31 of this chapter. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in § 170.31 of this chapter.

(f) An application for a license to receive and possess byproduct material for the conduct of any activity which the Commission has determined pursuant to subpart A of part 51 of this chapter will significantly affect the quality of the environment shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by any Environmental Report required pursuant to subpart A of part 51 of this chapter.

(g)(1) Except as provided in paragraphs (g)(2), (g)(3), and (g)(4) of this section, an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either--

(i) Identify the source or device by manufacturer and model number as registered with the

Commission under § 32.210 of this chapter, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to § 32.210 of this chapter; or

(ii) Contain the information identified in § 32.210(c) of this chapter.

(2) For sources or devices manufactured before October 23, 2012 that are not registered with the Commission under § 32.210 of this chapter or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in § 32.210(c) of this chapter, the application must include:

(i) All available information identified in § 32.210(c) of this chapter concerning the source, and, if applicable, the device; and

(ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with § 32.210(g)(1) of this chapter, the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

(h) As provided by § 30.35, certain applications for specific licenses filed under this part and parts 32 through 35 of this chapter must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. In the case of renewal applications submitted before July 27, 1990, this submittal may follow the renewal application but must be submitted on or before July 27, 1990.

(i)(1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in § 30.72, "Schedule C--Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:

(i) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

(ii) An emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation submitted under paragraph (i)(1)(i) of this section:

(i) The radioactive material is physically separated so that only a portion could be involved in an accident;

(ii) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(iii) The release fraction in the respirable size range would be lower than the release fraction shown § 30.72 due to the chemical or physical form of the material;

(iv) The solubility of the radioactive material would reduce the dose received;

(v) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in § 30.72;

(vi) Operating restrictions or procedures would prevent a release fraction as large as that shown in § 30.72; or

(vii) Other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under paragraph (i)(1)(ii) of this section must include the following information:

(i) *Facility description.* A brief description of the licensee's facility and area near the site.

(ii) *Types of accidents.* An identification of each type of radio-active materials accident for which protective actions may be needed.

(iii) *Classification of accidents.* A classification system for classifying accidents as alerts or site area emergencies.

(iv) *Detection of accidents.* Identification of the means of detecting each type of accident in a timely manner.

(v) *Mitigation of consequences.* A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(vi) *Assessment of releases.* A brief description of the methods and equipment to assess releases of radioactive materials.

(vii) *Responsibilities.* A brief description of the responsibilities of licensee personnel should an

accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the NRC; also responsibilities for developing, maintaining, and updating the plan.

(viii) *Notification and coordination.* A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the NRC operations center immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.[1]

(ix) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the NRC.

(x) *Training.* A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(xi) *Safe shutdown.* A brief description of the means of restoring the facility to a safe condition after an accident.

(xii) *Exercises.* Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(xiii) *Hazardous chemicals.* A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the byproduct material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to NRC. The licensee shall provide any comments received within the 60 days to the NRC with the emergency plan.

(j) An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under part 35 of this chapter or equivalent Agreement State requirements shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under part 30 of this chapter or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in § 32.72(a)(2) of this chapter.

(3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in § 32.72(b)(2) of this chapter.

(4) Information identified in § 32.72(a)(3) of this chapter on the PET drugs to be noncommercially transferred to members of its consortium.

[1] These reporting requirements do not superceed or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499 or other state or federal reporting requirements.

[30 FR 8185, June 26, 1965, as amended at 36 FR 145, Jan. 6, 1971; 37 FR 5747, Mar. 21, 1972; 43 FR 6922, Feb. 17, 1978; 49 FR 9403, Mar. 12, 1984; 49 FR 27924, July 9, 1984; 52 FR 27786, July 24, 1987; 53 FR 24044, June 27, 1988; 54 FR 14060, Apr. 7, 1989; 68 FR 58804, Oct. 10, 2003; 72 FR 55925, Oct. 1, 2007; 73 FR 63570, Oct. 24, 2008; 77 FR 43689, Jul. 25, 2012; 79 FR 58671, Sept. 30, 2014]

§ 30.33 General requirements for issuance of specific licenses.

(a) An application for a specific license will be approved if:

(1) The application is for a purpose authorized by the Act;

(2) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property;

(3) The applicant is qualified by training and experience to use the material for the purpose requested

in such manner as to protect health and minimize danger to life or property;

(4) The applicant satisfies any special requirements contained in parts 32 through 36 and 39; and

(5) In the case of an application for a license to receive and possess byproduct material for the conduct of any activity which the Commission determines will significantly affect the quality of the environment, the Director, Office of Federal and State Materials and Environmental Management Program or his designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to subpart A of part 51 of this chapter, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess byproduct material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

(b) Upon a determination that an application meets the requirements of the Act, and the regulations of the Commission, the Commission will issue a specific license authorizing the possession and use of byproduct material (Form NRC 374, "Byproduct Material License").

[30 FR 8185, June 26, 1965, as amended at 36 FR 12731, July 7, 1971; 37 FR 5747. Mar. 21, 1972; 39 FR 26279, July 18, 1974; 43 FR 6922, Feb. 17, 1978; 49 FR 9403, Mar. 12, 1984; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 73 FR 5717, Jan. 31, 2008; 76 FR 56962, Sep. 15, 2011; 78 FR 17006, Mar. 19, 2013; 79 FR 75739, Dec. 19, 2014]

§ 30.34 Terms and conditions of licenses.

(a) Each license issued pursuant to the regulations in this part and the regulations in parts 31 through 36 and 39 of this chapter shall be subject to all the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations and orders of the Commission.

(b)(1) No license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

(2) An application for transfer of license must include:

(i) The identity, technical and financial qualifications of the proposed transferee; and

(ii) Financial assurance for decommissioning information required by § 30.35.

(c) Each person licensed by the Commission pursuant to the regulations in this part and parts 31 through 36 and 39 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations in this part and parts 31 through 36 and 39 of this chapter shall carry with it the right to receive, acquire, own, and possess byproduct material. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of part 71 of this chapter.

(d) Each license issued pursuant to the regulations in this part and parts 31 through 36 and 39 shall be deemed to contain the provisions set forth in section 183b.- d., inclusive, of the Act, whether or not these provisions are expressly set forth in the license.

(e) The Commission may incorporate, in any license issued pursuant to the regulations in this part and parts 31 through 36 and 39, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of byproduct material as it deems appropriate or necessary in order to:

(1) Promote the common defense and security;

(2) Protect health or to minimize danger to life or property;

(3) Protect restricted data;

(4) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

(f) Licensees required to submit emergency plans by § 30.32(i) shall follow the emergency plan approved by the Commission. The licensee may change the approved without Commission approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the appropriate NRC Regional Office specified in § 30.6 and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Commission.

(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with § 35.204 of this chapter. The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in § 35.204(a) of this chapter at the time of generator elution, in accordance with § 35.3204 of this chapter.

(h)(1) Each general licensee that is required to register by § 31.5(c)(13) of this chapter and each specific licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code by or against:

(i) The licensee;

(ii) An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(iii) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(2) This notification must indicate:

(i) The bankruptcy court in which the petition for bankruptcy was filed; and

(ii) The date of the filing of the petition.

(i) Security requirements for portable gauges.

Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(j)(1) Authorization under § 30.32(j) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in § 32.72(a)(4) of this chapter for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for
noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in § 32.72(c) of this chapter.

(3) A licensee that is a pharmacy authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual

that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in § 32.72(b)(2) of this chapter, or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in § 35.27 of this chapter.

(4) A pharmacy, authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of § 32.72(b)(5) of this chapter.

(k) As required by the Additional Protocol, each specific licensee authorized to possess and use byproduct material shall file with the Commission location information described in § 75.11 of this chapter on DOC/NRC Forms AP–1 and associated forms. The licensee shall also permit verification of this information by the International Atomic Energy Agency (IAEA) and shall take other action as may be necessary to implement the US/IAEA Safeguards Agreement, as described in part 75 of this chapter.

(l) Each licensee shall ensure that Safeguards Information is protected against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.23 of this chapter, as applicable.

[30 FR 8185, June 26, 1965, as amended at 38 FR 33969, Dec. 10, 1973; 43 FR 6922, Feb. 17, 1978; 48 FR 32328, July 15, 1983; 52 FR 1295, Jan. 12, 1987; 52 FR 8241, Mar. 17, 1987; 53 FR 19245, May 27, 1988; 53 FR 23383, June 22, 1988; 54 FR 14061, Apr. 7, 1989; 58 FR 7736, Feb. 9, 1993; 59 FR 61780, Dec. 2, 1994; 65 FR 79187, Dec. 18, 2000; 70 FR 2009, Jan. 12, 2005; 72 FR 55926, Oct. 1, 2007; 73 FR 78604, Dec. 23, 2008; 74 FR 7785, Feb. 20, 2009; 76 FR 35564, Jun. 17, 2011; 77 FR 39905, Jul. 6, 2012; 79 FR 58671, Sept. 30, 2014; 83 FR 33046, Jul. 16, 2018]

§ 30.35 Financial assurance and recordkeeping for decommissioning.

(a)(1) Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in appendix B to part 30 shall submit a decommissioning funding plan as described in paragraph (e) of this section. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in appendix B to part 30.

(2) Each holder of, or applicant for, any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in appendix B to part 30 (or when a combination of isotopes is involved if R, as defined in § 30.35(a)(1), divided by 10^{12} is greater than 1), shall submit a decommissioning funding plan as described in paragraph (e) of this section. The decommissioning funding plan must be submitted to NRC by December 2, 2005.

(b) Each applicant for a specific license authorizing possession and use of byproduct material of half-life greater than 120 days and in quantities specified in paragraph (d) of this section shall either--

(1) Submit a decommissioning funding plan as described in paragraph (e) of this section; or

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by paragraph (d) of this section using one of the methods described in paragraph (f) of this section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section must be submitted to NRC before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to NRC, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section.

(c)(1) Each holder of a specific license issued on or after July 27, 1990, which is of a type described in paragraph (a) or (b) of this section, shall provide financial assurance for decommissioning in accordance with the criteria set forth in this section.

(2) Each holder of a specific license issued before July 27, 1990, and of a type described in paragraph (a) of this section shall submit a decommissioning funding plan as described in paragraph (e) of this section or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000 in accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.

(3) Each holder of a specific license issued before July 27, 1990, and of a type described in paragraph (b) of this section shall submit, on or before July 27, 1990, a decommissioning funding plan as described, in paragraph (e) of this section, or a certification of financial assurance for decommissioning in accordance with the criteria set forth in this section.

(4) Any licensee who has submitted an application before July 27, 1990, for renewal of license in accordance with § 30.37 shall provide financial assurance for decommissioning in accordance with paragraphs (a) and (b) of this section. This assurance must be submitted when this rule becomes effective November 24, 1995.

(5) Waste collectors and waste processors, as defined in 10 CFR part 20, Appendix G, must provide financial assurance in an amount based on a decommissioning funding plan as described in paragraph (e) of this section. The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license, and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of 10 CFR part 20. The decommissioning funding plan must be submitted by

December 2, 2005.

(d) Table of required amounts of financial assurance for decommissioning by quantity of material. Licensees required to submit the $1,125,000 amount must do so by December 2, 2004. Licensees required to submit the $113,000 or $225,000 amount must do so by June 2, 2005. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan.

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of appendix B to part 30 in unsealed form. (For a combination of isotopes, if R, as defined in § 30.35(a)(1), divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.)	$1,125,000
Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of appendix B to part 30 in unsealed form. (For a combination of isotopes, if R, as defined in § 30.35(a)(1), divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.)	225,000
Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of appendix B to part 30 in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in § 30.35(a)(1), divided by 10^{10} is greater than, 1, but R divided by 10^{12} is less than or equal to 1)	113,000

(e)(1) Each decommissioning funding plan must be submitted for review and approval and must contain –

(i) A detailed cost estimate for decommissioning, in the amount reflecting:

(A) The cost of an independent contractor to perform all decommissioning activities;

(B) The cost of meeting the 10 CFR 20.1402 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 10 CFR 20.1403, the cost estimate may be based on meeting the 10 CFR 20.1403 criteria;

(C) The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

(D) An adequate contingency factor.

(ii) Identification of and justification for using the key assumptions contained in the DCE;

(iii) A description of the method of assuring funds for decommissioning from paragraph (f) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(v) A signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

(i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(ii) Waste inventory increasing above the amount previously estimated;

(iii) Waste disposal costs increasing above the amount previously estimated;

(iv) Facility modifications;

(v) Changes in authorized possession limits;

(vi) Actual remediation costs that exceed the previous cost estimate;

(vii) Onsite disposal; and

(viii) Use of a settling pond.

(f) Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A to this part. A

parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix C to this part. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in appendix D to this part. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in appendix E to this part. A guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Commission, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Commission within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(iii) The surety method or insurance must remain in effect until the Commission has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in paragraph (f)(2) of this section.

(4) In the case of Federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in paragraph (d) of this section, and indicating that funds for decommissioning will be obtained when necessary.

(5) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(g) Each person licensed under this part or parts 32 through 36 and 39 of this chapter shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with § 30.34(b), licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Commission considers important to decommissioning consists of--

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:

(i) All areas designated and formerly designated restricted areas as defined in 10 CFR 20.1003 (For requirements prior to January 1, 1994, see 10 CFR 20.3 as contained in the CFR edition revised as of January 1, 1993.);

(ii) All areas outside of restricted areas that require documentation under § 30.35(g)(1).

(iii) All areas outside of restricted areas where current and previous wastes have been buried as documented under 10 CFR 20.2108; and

(iv) All areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 10 CFR part 20, subpart E, or apply for approval for disposal under 10 CFR 20.2002.

(4) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

[53 FR 24044, June 27, 1988, as amended at 56 FR 23471, May 21, 1991; 58 FR 39633, July 26,

1993; 58 FR 67659, Dec. 22, 1993; 58 FR 68730, Dec. 29, 1993; 59 FR 1618, Jan. 12, 1994; 60 FR 38238, July 26, 1995; 61 FR 24673, May 16, 1996; 62 FR 39090, July 21, 1997; 63 FR 29541, June 1, 1998; 68 FR 57335, Oct. 3, 2003; 76 FR 35564, Jun. 17, 2011; 79 FR 75739, Dec. 19, 2014]

§ 30.36 Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

(a) Each specific license expires at the end of the day on the expiration date stated in the license, unless the licensee has filed an application for renewal under § 30.37 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days before the expiration date stated in the existing license, the existing license expires at the end of the day on which the Commission makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(b) Each specific license revoked by the Commission expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Commission Order.

(c) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of byproduct material until the Commission notifies the licensee in writing that the license is terminated. During this time, the licensee shall--

(1) Limit actions involving byproduct material to those related to decommissioning; and

(2) Continue to control entry to restricted areas until they are suitable for release in accordance with NRC requirements.

(d) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in § 30.6, each licensee shall provide notification to the NRC in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with NRC requirements, or submit within 12 months of notification a decommissioning plan, if required by paragraph (g)(1) of this section, and begin decommissioning upon approval of that plan if--

(1) The license has expired pursuant to paragraph (a) or (b) of this section; or

(2) The licensee has decided to permanently cease principal activities, as defined in this part, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements; or

(3) No principal activities under the license have been conducted for a period of 24 months; or

(4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable

for release in accordance with NRC requirements.

(e) Coincident with the notification required by paragraph (d) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to § 30.35 in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph (g)(4)(v) of this section.

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective November 24, 1995.

(2) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Commission.

(f) The Commission may grant a request to extend the time periods established in paragraph (d) if the Commission determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to paragraph (d) of this section. The schedule for decommissioning set forth in paragraph (d) of this section may not commence until the Commission has made a determination on the request.

(g)(1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Commission and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The Commission may approve an alternate schedule for submittal of a decommissioning plan required pursuant to paragraph (d) of this section if the Commission determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue

risk from radiation to the public health and safety and is otherwise in the public interest.

(3) Procedures such as those listed in paragraph (g)(1) of this section with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(ii) A description of planned decommissioning activities;

(iii) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(iv) A description of the planned final radiation survey; and

(v) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(vi) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in paragraph (i) of this section.

(5) The proposed decommissioning plan will be approved by the Commission if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(h)(1) Except as provided in paragraph (i) of this section, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(2) Except as provided in paragraph (i) of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(i) The Commission may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Commission determines that the alternative is warranted by consideration of the following:

(1) Whether it is technically feasible to complete decommissioning within the allotted 24-month

period;

(2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(3) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(j) As the final step in decommissioning, the licensee shall--

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E. The licensee shall, as appropriate--

(i) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters--removable and fixed--for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(k) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Commission determines that:

(1) Byproduct material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3)(i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E.

(4) Records required by § 30.51 (d) and (f) have been received.

[59 FR 36034, July 15, 1994, as amended at 60 FR 38238, July 26, 1995; 61 FR 1114, Jan. 16, 1996; 61 FR 24673, May 16, 1996; 61 FR 29637, June 12, 1996; 62 FR 39090, July 21, 1997; 73 FR 42673, July 23, 2008]

§ 30.37 Application for renewal of licenses.

(a) Application for renewal of a specific license must be filed on NRC Form 313 and in accordance with § 30.32.

(b) If any licensee granted the extension described in 10 CFR 30.36(a)(2) has a currently pending renewal application for the extended license, that application will be considered withdrawn by the licensee and any renewal fees paid by the licensee for that application will be refunded.

[59 FR 36035, July 15, 1994, as amended at 61 FR 1114, Jan. 16, 1996; 66 FR 64738, Dec. 14, 2001; 75 FR 73942, Nov. 30, 2010]

§ 30.38 Application for amendment of licenses.

Applications for amendment of a license shall be filed on Form NRC-313 in accordance with § 30.32 and shall specify the respects in which the licensee desires its license to be amended and the grounds for the amendment.

[49 FR 19625, May 9, 1984; 77 FR 43690, Jul. 25, 2012]

§ 30.39 Commission action on applications to renew or amend.

In considering an application by a licensee to renew or amend his license the Commission will apply the applicable criteria set forth in § 30.33 and parts 32 through 36 and 39 of this chapter.

[30 FR 8185, June 26, 1965, as amended at 43 FR 6922, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 77 FR 43690, Jul. 25, 2012]

§ 30.41 Transfer of byproduct material.

(a) No licensee shall transfer byproduct material except as authorized pursuant to this section.

(b) Except as otherwise provided in his license and subject to the provisions of paragraphs (c) and (d) of this section, any licensee may transfer byproduct material:

(1) To the Department;

(2) To the agency in any Agreement State which regulates radioactive material pursuant to an agreement under section 274 of the Act;

(3) To any person exempt from the licensing requirements of the Act and regulations in this part, to the extent permitted under such exemption;

(4) To any person in an Agreement State, subject to the jurisdiction of that State, who has been exempted from the licensing requirements and regulations of that State, to the extent permitted under such exemption;

(5) To any person authorized to receive such byproduct material under terms of a specific license or a general license or their equivalents issued by the Atomic Energy Commission, the Commission, or an Agreement State;

(6) To a person abroad pursuant to an export license issued under part 110 of this chapter; or

(7) As otherwise authorized by the Commission in writing.

(c) Before transferring byproduct material to a specific licensee of the Commission or an Agreement State or to a general licensee who is required to register with the Commission or with an Agreement State prior to receipt of the byproduct material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred.

(d) The following methods for the verification required by paragraph (c) of this section are acceptable:

(1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

(2) The transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of byproduct material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date;

(3) For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of byproduct material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date: Provided, That the oral certification is confirmed in writing within 10 days;

(4) The transferor may obtain other sources of information compiled by a reporting service from official records of the Commission or the licensing agency of an Agreement State as to the identity of

licensees and the scope and expiration dates of licenses and registration; or

(5) When none of the methods of verification described in paragraphs (d)(1) to (4) of this section are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Commission or the licensing agency of an Agreement State that the transferee is licensed to receive the byproduct material.

[38 FR 33969, Dec. 10, 1973, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6922, Feb. 17, 1978]

Records, Inspections, Tests, and Reports

§ 30.50 Reporting requirements.

(a) *Immediate report*. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(b) *Twenty-four hour report*. Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material:

(1) An unplanned contamination event that:

(i) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified in appendix B of §§ 20.1001-20.2401 of 10 CFR part 20 for the material; and

(iii) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

(i) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(ii) The equipment is required to be available and operable when it is disabled or fails to function; and

(iii) No redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(i) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of §§ 20.1001-20.2401 of 10 CFR part 20 for the material; and

(ii) The damage affects the integrity of the licensed material or its container.

(c) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees shall make reports required by paragraphs (a) and (b) of this section by telephone to the ~~NRC Operations Center~~department of environmental quality.[1] To the extent that the information is available at the time of notification, the information provided in these reports must include:

(i) The caller's name and call back telephone number;

(ii) A description of the event, including date and time;

(iii) The exact location of the event;

(iv) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(v) Any personnel radiation exposure data available.

(2) Written report. Each licensee who makes a report required by paragraph (a) or (b) of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the NRC using an appropriate method listed in § 30.6(a); and a copy must be sent to the appropriate NRC Regional office listed in appendix D to part 20 of this chapter. The reports must include the following:

(i) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(ii) The exact location of the event;

(iii) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(iv) Date and time of the event;

(v) Corrective actions taken or planned and the results of any evaluations or assessments; and

(vi) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(3) The provisions of § 30.50 do not apply to licensees subject to the notification requirements in § 50.72. They do apply to those part 50 licensees possessing material licensed under part 30, who are not subject to the notification requirements in § 50.72.

[56 FR 40767, Aug. 16, 1991, as amended at 59 FR 14086, Mar. 25, 1994; 68 FR 58804, Oct. 10, 2003; 85 FR 65656, Oct. 16, 2020]

~~[1] The commercial telephone number for the NRC Operations Center is (301) 816-5100.~~

§ 30.51 Records.

(a) Each person who receives byproduct material pursuant to a license issued pursuant to the regulations in this part and parts 31 through 36 of this chapter shall keep records showing the receipt, transfer, and disposal of the byproduct material as follows:

(1) The licensee shall retain each record of receipt of byproduct material as long as the material is possessed and for three years following transfer or disposal of the material.

(2) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of the regulations in this chapter dictates otherwise.

(3) The licensee who disposed of the material shall retain each record of disposal of byproduct material until the Commission terminates each license that authorizes disposal of the material.

(b) The licensee shall retain each record that is required by the regulations in this part and parts 31 through 36 of this chapter or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Commission terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(c)(1) Records which must be maintained pursuant to this part and parts 31 through 36 of this chapter may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(2) If there is a conflict between the Commission's regulations in this part and parts 31 through 36 and 39 of this chapter, license condition, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this part and parts 31 through 36 and 39 of this chapter for such records shall apply unless the Commission, pursuant to § 30.11, has granted a specific exemption from the record retention requirements specified in the regulations in this part or parts 31 through 36 and 39 of this chapter.

(d) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the appropriate NRC Regional Office:

(1) Records of disposal of licensed material made under §§ 20.2002 (including burials authorized before January 28, 1981[1]), 20.2003, 20.2004, 20.2005; and

(2) Records required by § 20.2103(b)(4).

(e) If licensed activities are transferred or assigned in accordance with § 30.34(b), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under §§ 20.2002 (including burials authorized before January 28, 19811), 20.2003, 20.2004, 20.2005; and

(2) Records required by § 20.2103(b)(4).

(f) Prior to license termination, each licensee shall forward the records required by § 30.35(g) to the appropriate NRC Regional Office.

[41 FR 18301, May 5, 1976, as amended at 43 FR 6922, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 53 FR 19245, May 27, 1988; 58 FR 7736, Feb. 9, 1993; 61 FR 24673, May, 16, 1996]

[1] A previous § 20.304 permitted burial of small quantities of licensed materials in soil before January 28, 1981, without specific Commission authorization. See § 20.304 contained in the 10 CFR, parts 0 to 199, edition revised as of January 1, 1981.

§ 30.52 Inspections.

(a) Each licensee shall afford to the Commission at all reasonable times opportunity to inspect byproduct material and the premises and facilities wherein byproduct material is used or stored.

(b) Each licensee shall make available to the Commission for inspection, upon reasonable notice, records kept by him pursuant to the regulations in this chapter.

[30 FR 8185, June 26, 1965]

§ 30.53 Tests.

Each licensee shall perform, or permit the Commission to perform, such tests as the Commission deems appropriate or necessary for the administration of the regulations in this part and parts 31 through 36 and 39 of this chapter, including tests of:

(a) Byproduct material;

(b) Facilities wherein byproduct material is utilized or stored;

(c) Radiation detection and monitoring instruments; and

(d) Other equipment and devices used in connection with the utilization or storage of byproduct material.

[30 FR 8185, June 26, 1965, as amended by 43 FR 6922, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993]

§ 30.55 Tritium reports.

(a)-(b) [Reserved]

(c) Except as specified in paragraph (d) of this section, each licensee who is authorized to possess tritium shall report promptly to the appropriate NRC Regional Office listed in appendix D of part 20 of this chapter by telephone and telegraph, mailgram, or facsimile any incident in which an attempt has been made or is believed to have been made to commit a theft or unlawful diversion of more than 10 curies of such material at any one time or more than 100 curies of such material in any one calendar year. The initial report shall be followed within a period of fifteen (15) days by a written report submitted to the appropriate NRC Regional Office which sets forth the details of the incident and its consequences. Copies of such written report shall be sent to the Director, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in § 30.6(a). Subsequent to the submission of the written report required by this paragraph, the licensee shall promptly inform the Office of Nuclear Material Safety and Safeguards by means of a written report of any substantive additional information, which becomes available to the licensee, concerning an attempted or apparent theft or unlawful diversion of tritium.

(d) The reports described in this section are not required for tritium possessed pursuant to a general license provided in part 31 of this chapter or for tritium contained in spent fuel.

[37 FR 9208, May 6, 1972, as amended at 38 FR 1271, Jan. 11, 1973; 38 FR 2330, Jan. 24, 1973; 41 FR 16446, Apr. 19, 1976; 43 FR 6922, Feb. 17, 1978; 46 FR 55085, Nov. 6, 1981; 49 FR 24707, June 15, 1984; 52 FR 31611, Aug. 21, 1987; 68 FR 58804, Oct. 10, 2003; 73 FR 5718, Jan. 31, 2008; 79

FR 75739, Dec. 19, 2014]

Enforcement

§ 30.61 Modification and revocation of licenses.

(a) The terms and conditions of each license issued pursuant to the regulations in this part and parts 31 through 35 of this chapter shall be subject to amendment, revision or modification by reason of amendments to the Act, or by reason of rules, regulations and orders issued in accordance with the terms of the Act.

(b) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under section 182 of the Act, or because of conditions revealed by such application or statement of fact or any report, record or inspection or other means which would warrant the Commission to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and provisions of the Act or of any rule, regulation or order of the Commission.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

[30 FR 8185, June 26, 1965, as amended at 35 FR 11460, July 17, 1970; 43 FR 6922, Feb. 17, 1978; 77 FR 43690, Jul. 25, 2012]

§ 30.62 Right to cause the withholding or recall of byproduct material.

The Commission may cause the withholding or recall of byproduct material from any licensee who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Commission, or who uses such materials in violation of law or regulation of the Commission, or in a manner other than as disclosed in the application therefore or approved by the Commission.

[30 FR 8185, June 26, 1965, as amended at 40 FR 8785, Mar. 3, 1975]

§ 30.63 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55072, Nov. 24, 1992]

§ 30.64 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 30 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 30 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 30.1, 30.2, 30.4, 30.5, 30.6, 30.8, 30.11, 30.12, 30.13, 30.15, 30.31, 30.32, 30.33, 30.37, 30.38, 30.39, 30.61, 30.62, 30.63, 30.64, 30.70, 30.71, and 30.72.

[57 FR 55072, Nov. 24, 1992; 73 FR 42673, July 23, 2008]

Schedules

§ 30.70 Schedule A--Exempt concentrations.

[See footnotes at the end of this table]

Element (atomic number)	Isotope	Col. I	Col. II
		Gas Concentration µCi/ml[1]	Liquid and Solid Concentration µCi/ml[2]
Antimony (51)	Sb 122		3×10^{-4}
	Sb 124		2×10^{-4}
	Sb 125		1×10^{-3}
Argon (18)	A 37	1×10^{-3}	
	A 41	4×10^{-7}	
Arsenic (33)	As 73		5×10^{-3}
	As 74		5×10^{-4}
	As 76		2×10^{-4}
	As 77		8×10^{-4}
Barium (56)	Ba 131		2×10^{-3}
	Ba 140		3×10^{-4}
Beryllium (4)	Be 7		2×10^{-2}
Bismuth (83)	Bi 206		4×10^{-4}
Bromine (35)	Br 82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd 109		2×10^{-3}
	Cd 115M		3×10^{-4}
	Cd 115		3×10^{-4}
Calcium (20)	Ca 45		9×10^{-5}
	Ca 47		5×10^{-4}
Carbon (6)	C 14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce 141		9×10^{-4}
	Ce 143		4×10^{-4}
	Ce 144		1×10^{-4}
Cesium (55)	Cs 131		2×10^{-2}
	Cs 134m		6×10^{-2}
	Cs 134		9×10^{-5}
Chlorine (17)	Cl 38	9×10^{-7}	4×10^{-3}

Chromium (24)	Cr 51		2×10^{-2}
Cobalt (27)	Co 57		5×10^{-3}
	Co 58		1×10^{-3}
	Co 60		5×10^{-4}
Copper (29)	Cu 64		3×10^{-3}
Dysprosium (66)	Dy 165		4×10^{-3}
	Dy 166		4×10^{-4}
Erbium (68)	Er 169		9×10^{-4}
	Er 171		1×10^{-3}
Europium (63)	Eu 152 (T/2=9.2 hrs)		6×10^{-4}
	Eu 155		2×10^{-3}
Fluorine (9)	F 18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd 153		2×10^{-3}
	Gd 159		8 x `0^{-4}
Gallium (31)	Ga 72		4×10^{-4}
Germanium (32)	Ge 71		2×10^{-2}
Gold (79)	Au 196		2×10^{-3}
	Au 198		5×10^{-4}
	Au 199		2×10^{-3}
Hafnium (72)	Hf 181		7×10^{-4}
Hydrogen (1)	H 3	5×10^{-6}	3×10^{-2}
Indium (49)	In 113M		1×10^{-2}
	In 114M		2×10^{-4}
Iodine (53)	I 126	3×10^{-9}	2×10^{-5}
	I 131	3×10^{-9}	2×10^{-5}
	I 132	8×10^{-8}	6×10^{-4}
	I 133	1×10^{-8}	7×10^{-5}
	I 134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir 190		2×10^{-3}

	Ir 192		4×10^{-4}
	Ir 194		3×10^{-4}
Iron (26)	Fe 55		8×10^{-3}
	Fe 59		6×10^{-4}
Krypton (36)	Kr 85M	1×10^{-6}	
	Kr 85	3×10^{-6}	
Lanthanum (57)	La 140		2×10^{-4}
Lead (82)	Pb 203		4×10^{-3}
Lutetium (71)	Lu 177		1×10^{-3}
Manganese (25)	Mn 52		3×10^{-4}
	Mn 54		1×10^{-3}
	Mn 56		1×10^{-3}
Mercury (80)	Hg 197M		2×10^{-3}
	Hg 197		3×10^{-3}
	Hg 203		2×10^{-4}
Molybdenum (42)	Mo 99		2×10^{-3}
Neodymium (60)	Nd 147		6×10^{-4}
	Nd 149		3×10^{-3}
Nickel (28)	Ni 65		1×10^{-3}
Niobium (Columbium) (41)	Nb 95		1×10^{-3}
	Nb 97		9×10^{-3}
Osmium (76)	Os 185		7×10^{-4}
	Os 191M		3×10^{-2}
	Os 191		2×10^{-3}
	Os 193		6×10^{-4}
Palladium (46)	Pd 103		3×10^{-3}
	Pd 109		9×10^{-4}
Phosphorus (15)	P 32		2×10^{-4}
Platinum (78)	Pt 191		1×10^{-3}
	Pt 193M		1×10^{-2}
	Pt 197M		1×10^{-2}

	Pt 197		1×10^{-3}
Potassium (19)	K 42		3×10^{-3}
Praseodymium (59)	Pr 142		3×10^{-4}
	Pr 143		5×10^{-4}
Promethium (61)	Pm 147		2×10^{-3}
	Pm 149		4×10^{-4}
Rhenium (75)	Re 183		6×10^{-3}
	Re 186		9×10^{-4}
	Re 188		6×10^{-4}
Rhodium (45)	Rh 103M		1×10^{-1}
	Rh 105		1×10^{-3}
Rubidium (37)	Rb 86		7×10^{-4}
Ruthenium (44)	Ru 97		4×10^{-4}
	Ru 103		8×10^{-4}
	Ru 105		1×10^{-3}
	Ru 106		1×10^{-4}
Samarium (62)	Sm 153		8×10^{-4}
Scandium (21)	Sc 46		4×10^{-4}
	Sc 47		9×10^{-4}
	Sc 48		3×10^{-4}
Selenium (34)	Se 75		3×10^{-3}
Silicon (14)	Si 31		9×10^{-3}
Silver (47)	Ag 105		1×10^{-3}
	Ag 110M		3×10^{-4}
	Ag 111		4×10^{-4}
Sodium (11)	Na 24		2×10^{-3}
Strontium (38)	Sr 85		1×10^{-4}
	Sr 89		1×10^{-4}
	Sr 91		7×10^{-4}
	Sr 92		7×10^{-4}
Sulfur (16)	S 35	9 x 10 -8	6×10^{-4}

Tantalum (73)	Ta 182		4×10^{-4}
Technetium (43)	Tc 96M Tc 96		1×10^{-1} 1×10^{-3}
Tellurium (52)	Te 125M		2×10^{-3}
	Te 127M		6×10^{-4}
	Te 127		3×10^{-3}
	Te 129M		3×10^{-4}
	Te 131M		6×10^{-4}
	Te 132		3×10^{-4}
Terbium (65)	Tb 160		4×10^{-4}
Thallium (81)	Tl 200 Tl 201 Tl 202 Tl 204		4×10^{-3} 3×10^{-3} 1×10^{-3} 1×10^{-3}
Thulium (69)	Tm 170 Tm 171		5×10^{-4} 5×10^{-3}
Tin (50)	Sn 113 Sn 125		9×10^{-4} 2×10^{-4}
Tungsten (Wolfram) (74)	W 181 W 187		4×10^{-3} 7×10^{-4}
Vanadium (23)	V 48		3×10^{-4}
Xenon (54)	Xe 131M	4×10^{-6}	
	Xe 133	3×10^{-6}	
	Xe 135	1×10^{-6}	
Ytterbium (70)	Yb 175		1×10^{-3}
Yttrium (39)	Y 90		2×10^{-4}
	Y 91M		3×10^{-2}
	Y 91		3×10^{-4}
	Y 92		6×10^{-4}
	Y 93		3×10^{-4}
Zinc (30)	Zn 65		1×10^{-3}
	Zn 69M		7×10^{-4}
	Zn 69		2×10^{-2}

Zirconium (40)	Zr 95		6×10^{-4}
	Zr 97		2×10^{-4}
Beta and/or gamma emitting byproduct not listed above with half-life less than three years		1×10^{-10}	1×10^{-6}

Footnotes to Schedule A

1. Values are given only for those materials normally used as gases.
2. μCi/gm for solids.

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Schedule A, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of 30.14 where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

Example:

$$\frac{\text{Concentration of Isotope A in product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in product}}{\text{Exempt concentration of Isotope B}} \leq 1$$

[30 FR 8185, June 26, 1965, as amended at 35 FR 3982, Mar. 3, 1970; 38 FR 29314, Oct. 24, 1973; 59 FR 5520, Feb. 7, 1994]

§ 30.71 Schedule B.

Byproduct material	Microcuries
Antimony 122 (Sb 122)	100
Antimony 124 (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10
Arsenic 76 (As 76)	10
Arsenic 77 (as 77)	100

Barium 131 (Ba 131)	10
Barium 133 (Ba 133)	10
Barium 140 (Ba 140)	10
Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium 109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10
Cadmium 115 (Cd 115)	100
Calcium 45 (Ca 45)	10
Calcium 47 (Ca 47)	10
Carbon 14 (C 14)	100
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium 129 (Cs 129)	100
Cesium 131 (Cs 131)	1,000
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	10
Chromium 51 (Cr 51)	1,000
Cobalt 57 (Co 57)	100
Cobalt 58m (Co 58m)	10
Cobalt 58 (Co 58)	10
Cobalt 60 (Co 60)	1
Copper 64 (Cu 64)	100
Dysprosium 165 (Dy 165)	10
Dysprosium 166 (Dy 166)	100

Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 9.2 h (Eu 152 9.2 h)	100
Europium 152 13 yr (Eu 152 13 yr)	1
Europium 154 (Eu 154)	1
Europium 155 (Eu 155)	10
Fluorine 18 (F 18)	1,000
Gadolinium 153 (Gd 153)	10
Gadolinium 159 (Gd 159)	100
Gallium 67 (Ga 67)	100
Gallium 72 (Ga 72)	10
Germanium 68 (Ge 68)	10
Germanium 71 (Ge 71)	100
Gold 195 (Au 195)	10
Gold 198 (Au 198)	100
Gold 199 (Au 199)	100
Hafnium 181 (Hf 181)	10
Holmium 166 (Ho 166)	100
Hydrogen 3 (H3)	1,000
Indium 111 (In 111)	100
Indium 113m (In 113m)	100
Indium 114m (In 114m)	10
Indium 115m (In 115m)	100
Indium 115 (In 115)	10
Iodine 123 (I 123)	100
Iodine 125 (I 125)	1
Iodine 126 (I 126)	1
Iodine 129 (I 129)	0,1
Iodine 131 (I 131)	1
Iodine 132 (I 132)	10
Iodine 133 (I 133)	1

Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	10
Iridium 194 (Ir 194)	100
Iron 52 (Fe 52)	10
Iron 55 (Fe 55)	100
Iron 59 (Fe 59)	10
Krypton 85 (Kr 85)	100
Krypton 87 (Kr 87)	10
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10
Manganese 56 (Mn 56)	10
Mercury 197m (Hg 197m)	100
Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100
Neodymium 149 (Nd 149)	100
Nickel 59 (Ni 59)	100
Nickel 63 (Ni 63)	10
Nickel 65 (Ni 65)	100
Niobium 93m (Nb 93m)	10
Niobium 95 (Nb 95)`	10
Niobium 97 (Nb 97)	10
Osmium 185 (Os 185)	10
Osmium 191m (Os 191)	100
Osmium 191 (Os 191)	100
Osmium 193 (Os 193)	100
Palladium 103 (Pd 103)	100

Palladium 109 (Pd 109)	100
Phosphorus 32 (P 32)	10
Platinum 191 (Pt 191)	100
Platinum 193m (Pt 193m)	100
Platinum 193 (Pt 193)	100
Platinum 197m (Pt 197m)	100
Platinum 197 (Pt 197)	100
Polonium 210 (Po 210)	0.1
Potassium 42 (K 42)	10
Potassium 43 (K 43)	10
Praseodymium 142 (Pr 142)	100
Praseodymium 143 (Pr 143)	100
Promethium 147 (Pm 147)	10
Promethium 149 (Pm 149)	10
Rhenium 186 (Re 186)	100
Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100
Rhodium 105 (Rh 105)	100
Rubidium 81 (Rb 81)	10
Rubidium 86 (Rb 86)	10
Rubidium 87 (Rb 87)	10
Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105 (Ru 105)	10
Ruthenium 106 (Ru 106)	1
Samarium 151 (Sm 151)	10
Samarium 153 (Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Se 75)	10

Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 22 (Na 22)	10
Sodium 24 (Na 24)	10
Strontium 85 (Sr 85)	10
Strontium 89 (Sr 89)	1
Strontium 90 (Sr 90)	0.1
Strontium 91 (Sr 91)	10
Strontium 92 (Sr 92)	10
Sulphur 35 (S 35)	100
Tantalum 182 (Ta 182)	10
Technetium 96 (Tc 96)	10
Technetium 97m (Tc 97m)	100
Technetium 97 (Tc 97)	100
Technetium 99m (Tc 99m)	100
Technetium 99 (Tc 99)	10
Tellurium 125 m (Te 125 m)	10
Tellurium 127m (Te 127m)	10
Tellurium 127 (Te 127)	100
Tellurium 129m (Te 129m)	10
Tellurium 129 (Te 129)	100
Tellurium 131m (Te 131m)	10
Tellurium 132 (Te 132)	10
Terbium 160 (Tb 160)	10
Thallium 200 (Tl 200)	100
Thallium 201 (Tl 201)	100
Thallium 202 (Tl 202)	100
Thallium 204 (Tl 204)	10
Thulium 170 (Tm 170)	10

Thulium 171 (Tm 171)	10
Tin 113 (Sn 113)	10
Tin 125 (Sn 125)	10
Tungsten 181 (W 181)	10
Tungsten 185 (W 185)	10
Tungsten 187 (W 187)	100
Vanadium 48 (V 48)	10
Xenon 131m (Xe 131m)	1,000
Xenon 133 (Xe 133)	100
Xenon 135 (Xe 135)	100
Ytterbium 175 (Yb 175)	100
Yttrium 87 (Y 87)	10
Yttrium 88 (Y 88)	10
Yttrium 90 (Y 90)	10
Yttrium 91 (Y91)	10
Yttrium 92 (Y92)	100
Yttrium 93 (Y93)	100
Zinc 65 (Zn 65)	10
Zinc 69m (Zn 69m)	100
Zinc 69 (Zn 69)	1,000
Zirconium 93 (Zr 93)	10
Zirconium 95 (Zr 95)	10
Zirconium 97 (Zr 97)	10
Any byproduct material not listed above other than alpha emitting byproduct materials	0.1

[35 FR 6427, Apr. 22, 1970, as amended at 36 FR 16898, Aug. 26, 1971; 59 FR 5519, Feb. 7, 1994; 72 FR 55926, Oct. 1, 2007]

§ 30.72 Schedule C--Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release.

Radioactive material[1]	Release fraction	Quantity (curies)

Actinium-228	0.001	4,000
Americium 241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14 (non-carbon dioxide)	.01	50,000
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000

Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	.001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000

Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technitium-99	.01	10,000
Technitium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma[4]	.001	10,000
Any other alpha emitter	.001	2

Contaminated equipment, alpha	.0001	20
Packaged waste, alpha[4]	.0001	20
Combinations of radioactive materials listed above[1]		

[1] For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule C exceeds one.

[2] Waste packaged in Type B containers does not require an emergency plan.

[54 FR 14061, Apr. 7, 1989, as amended at 61 FR 9902, Mar. 12, 1996; 72 FR 55926, Oct. 1, 2007]

Appendix A to Part 30--Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. Financial Test

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this section:

1. The parent company must have:

(i) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and

(ii) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof (Tangible net worth shall be calculated to exclude the net book value of the nuclear unit(s)); and

(iii) Tangible net worth of at least $10 million; and

(iv) Assets located in the United States amounting to at least 90 percent of the total assets or at least

six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof.

2. The parent company must have:

(i) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or AAA, AA, A, or BAA as issued by Moody's; and

(ii) Tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof (Tangible net worth shall be calculated to exclude the net book value of the nuclear unit(s)); and

(iii) Tangible net worth of at least $10 million; and

(iv) Assets located in the United States amounting to at least 90 percent of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof.

B. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform NRC within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C. 1. After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

2. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the Commission of intent to establish alternate financial assurance as specified in the Commission's regulations. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Parent Company Guarantee

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Commission. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Commission, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in the Commission's regulations within 90 days after receipt by the licensee and Commission of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the Commission has terminated the license.

D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

[53 FR 24046, June 27, 1988 as amended at 63 FR 50479, Sept. 22, 1998; 76 FR 35565, Jun. 17, 2011]

Appendix B to Part 30--Quantities[1] of Licensed Material Requiring Labeling

Materials	Microcuries
Americium-241	.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10

Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 9.2h	100
Europium-152 13 yr	1
Europium-154	1
Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10

Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krpton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10

Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molbdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10

Radium-226	.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Seleium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.10
Strontium-91	10
Strontium-92	10
Sulphur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100

Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium127m	10
Tellurium-127	100
Tellurium129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)[1]	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)[2]	100
Uranium-233	.01
Uranium-234--Uranium-235	.01
Vandium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100

Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	.01
Any radionuclide other than alpha emitting radio-nuclides, not listed above or mixtures of beta emitters of unknown composition	.1

[1]Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.

[2]Based on alpha disintegration rate of U-238, U-234, and U-235.

Note: For purposes of § 20.303, where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" (i.e., "unity").

[35 FR 6425, Apr. 22, 1970, as amended at 36 FR 16898, Aug. 26, 1971; 38 FR 29314, Oct. 24, 1973; 39 FR 23991, June 28, 1974; 45 FR 71763, Oct. 30, 1980. Redesignated at 56 FR 23391, May 21, 1991, and further redesignated at 58 FR 67659, Dec. 22, 1993]

Appendix C to Part 30--Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self guarantee and establishes the terms for a

self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet all of the following criteria:

(1) Tangible net worth at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used), or, for a power reactor licensee, at least 10 times the amount of decommissioning funds being assured by a self guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all reactor units or parts thereof (Tangible net worth shall be calculated to exclude the net book value of the nuclear unit(s)).

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used), or, for a power reactor licensee, at least 10 times the amount of decommissioning funds being assured by a self guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all reactor units or parts thereof.

(3) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

B. To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform NRC within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the Commission of its intent to establish alternate financial assurance as specified in the Commission's regulations within 120 days of such notice.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Commission. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Commission, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in the Commission's regulations within 90 days following receipt by the Commission of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Commission has terminated the license or until another financial assurance method acceptable to the Commission has been put in effect by the licensee.

D. The licensee will promptly forward to the Commission and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Commission within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. The applicant or licensee must provide to the Commission a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Commission, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

[58 FR 68730, Dec. 29, 1993; 59 FR 1618, Jan. 12, 1994; 63 FR 50479, Sept. 22, 1998; 76 FR 35566, Jun. 17, 2011]

Appendix D to Part 30--Criteria Relating To Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have no Outstanding Rated Bonds

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a

self-guarantee.

II. Financial Test

A. To pass the financial test a company must meet the following criteria:

(1) Tangible net worth greater than $10 million, or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(3) A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following requirements:

(1) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited yearend financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform NRC within 90 days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(2) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of paragraph II.A of this appendix, the licensee must send notice to the NRC of intent to establish alternative financial assurance as specified in NRC regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the NRC. Cancellation may not occur until an alternative financial

assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the regulations within 90 days following receipt by the NRC of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Commission has terminated the license or until another financial assurance method acceptable to the Commission has been put in effect by the licensee.

D. The applicant or licensee must provide to the Commission a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Commission, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

[63 FR 29542, June 1, 1998; 76 FR 35567, Jun. 17, 2011]

Appendix E to Part 30--Criteria Relating to Use of Financial Tests and Self-Guarantee For Providing Reasonable Assurance of Funds For Decommissioning by Nonprofit Colleges, Universities, and Hospitals

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. For colleges and universities, to pass the financial test a college or university must meet either the criteria in Paragraph II.A.(1) or the criteria in Paragraph II.A.(2) of this appendix.

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P) or Aaa, Aa, or A as issued by Moodys.

(2) For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least $50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

B. For hospitals, to pass the financial test a hospital must meet either the criteria in Paragraph II.B.(1) or the criteria in Paragraph II.B.(2) of this appendix:

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P) or Aaa, Aa, or A as issued by Moodys.

(2) For applicants or licensees that do not issue bonds, all the following tests must be met:

(a) (Total Revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing license.

C. In addition, to pass the financial test, a licensee must meet all the following requirements:

(1) The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform NRC within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

(2) After the initial financial test, the licensee must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of Section I of this appendix, the licensee must send notice to the NRC of its intent to establish alternative financial assurance as specified in NRC regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that--

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, and/or return receipt requested, to the Commission. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the Commission's regulations within 90 days following receipt by the Commission of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Commission has terminated the license or until another financial assurance method acceptable to the Commission has been put in effect by the licensee.

D. The applicant or licensee must provide to the Commission a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Commission, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee shall provide notice in writing of such fact to the Commission within 20 days after publication of the change by the rating service.

[63 FR 29542, June 1, 1998; 76 FR 35568, Jun. 17, 2011]

CHAPTER 33.1-10-04.2
STANDARDS FOR PROTECTION AGAINST RADIATION

Section
33.1-10-04.2-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 20
33.1-10-04.2-02 Individuals Working With Medical Fluoroscopic Equipment
33.1-10-04.2-03 Location of Individual Monitoring Devices
33.1-10-04.2-04 Effective Dose Equivalent Determination During Medical Fluoroscopy
33.1-10-04.2-05 Radiation Machine Security and Prevention of Unauthorized Use
33.1-10-04.2-06 Radiation Machine Labels
33.1-10-04.2-07 Additional Requirements - Vacating Premises

33.1-10-04.2-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 20.

10 Code of Federal Regulations 20.1001, 20.1002, 20.1003, 20.1004, 20.1005, 20.1008, 20.1101, 20.1201, 20.1202, 20.1203, 20.1204, 20.1206, 20.1207, 20.1208, 20.1301, 20.1302, 20.1401, 20.1402, 20.1403, 20.1404, 20.1405, 20.1406, 20.1501, 20.1502, 20.1601, 20.1602, 20.1701, 20.1702, 20.1703, 20.1704, 20.1705, 20.1801, 20.1802, 20.1901, 20.1902, 20.1903, 20.1904, 20.1905, 20.1906, 20.2001, 20.2002, 20.2003, 20.2004, 20.2005, 20.2006, 20.2007, 20.2008, 20.2101, 20.2102, 20.2103, 20.2104, 20.2105, 20.2106, 20.2107, 20.2108, 20.2110, 20.2201, 20.2202, 20.2203, 20.2204, 20.2205, 20.2206, 20.2207, 20.2301, and 20.2302, appendix A through C to part 20, appendix E to part 20, and appendix G to part 20 are adopted by reference as they exist on May 9, 2022~~December 1, 2015~~, with the following exceptions:

1. Not adopted by reference are 10 Code of Federal Regulations (CFR) 20.1406(b), 20.1905(g), 20.2203(c), and 20.2206(a)(1), (a)(3), (a)(4), and (a)(5).

2. All of the requirements in chapter 33.1-10-04.2 apply to both licensees and registrants. A reference in 10 CFR part 20 to "license" includes "registration", a reference to "licensee" includes "registrant", a reference to "licensed" includes "registered", a reference to "licensed material(s)" includes "registered source of radiation", and a reference to "licensed radioactive material" includes "registered source of radiation". "Registrant" means any person who is registered with the department and is legally obligated to register with the department pursuant to article 33.1-10 and North Dakota Century Code chapter 23.1-03. "Registration" means the notification of the department of environmental quality of possession of a source of radiation and the furnishing of information with respect thereto, in accordance with North Dakota Century Code chapter 23.1-02.

3. Where the words "NRC", "commission", "administrator of the appropriate NRC regional office", "administrator of the nearest commission regional office", or "NRC regional office" appear in 10 CFR part 20, substitute the words "department of environmental quality".

4. Requirements in 10 CFR part 20 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

5. "Act" includes North Dakota Century Code chapters 23.1-02 and 23.1-03.

6. North Dakota state form number 19443, "occupational radiation exposure history", must be used instead of NRC form 4 as specified in 10 CFR part 20.

7. North Dakota state form number 8416, "current occupational radiation exposure", must be used instead of NRC form 5 as specified in 10 CFR part 20.

8. NRC form 748 shall not be used as described in 10 CFR part 20.

9. The words "in the Federal Register and" shall be omitted from 10 CFR 20.1405(b).

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

33.1-10-04.2-02. Individuals working with medical fluoroscopic equipment.

Each registrant shall provide dose monitoring and shall monitor occupational exposure to ensure compliance for:

1. Occupational dose limits to adults pursuant to 10 CFR 20.1201.

2. Occupational dose limits to minors pursuant to 10 CFR 20.1207.

3. The dose equivalent to an embryo/fetus pursuant to 10 CFR 20.1208.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

33.1-10-04.2-03. Location of individual monitoring devices.

Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with 10 CFR 20.1502 wear individual monitoring devices as follows:

1. An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar);

2. An individual monitoring device used for monitoring the dose to an embryo or fetus of a declared pregnant woman, pursuant to 10 CFR 20.1208, shall be located at the waist under any protective apron being worn by the woman;

3. An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with subparagraph a of 10 CFR 20.1201, shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye; and

4. An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with subparagraph a of 10 CFR 20.1201, shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

33.1-10-04.2-04. Effective dose equivalent determination during medical fluoroscopy.

When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in subdivision d, the effective dose equivalent for external radiation shall be determined as follows:

1. When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation.

2. When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, and the reported dose exceeds twenty-five percent of the limit specified in 10 CFR 20.1201, the reported deep dose equivalent value multiplied by three-tenths shall be the effective dose equivalent for external radiation.

3. When two individual monitoring devices are worn, one under the protective apron at the waist and the other outside the protective apron at the neck (collar), the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by one and five-tenths and the deep dose equivalent reported for the individual monitoring device located at the neck (collar) outside the protective apron multiplied by four-hundredths.

4. Subdivisions b and c only apply when all of the following conditions are met:

    a. The individual monitoring devices have not been exposed to radiation from radioactive material.

    b. Leaded glasses, a thyroid shield, and a wraparound protective apron have been worn whenever using the medical fluoroscopic equipment.

    c. The area around the medical fluoroscopic equipment has been equipped with lead shielding or transparent protective barriers for control of scattered radiation.

    d. The medical fluoroscopic procedures have been performed in a way that minimizes beam on time, such as utilizing last image hold.

    e. Users of the medical fluoroscopic equipment must have had formal training in radiation safety and operation of medical fluoroscopic equipment.

    f. Performance of the medical fluoroscopic equipment must be monitored and maintained via a quality assurance program.

    g. Patient and staff radiation exposures from medical fluoroscopic equipment must be monitored and actions taken to correct problems.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

33.1-10-04.2-05. Radiation machine security and prevention of unauthorized use.

1. The registrant shall secure registered radiation machines from unauthorized removal.

2. The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

33.1-10-04.2-06. Radiation machine labels.

Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

33.1-10-04.2-07. Additional requirements - Vacating premises.

Each specific licensee or registrant shall, no less than thirty days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of the licensee's or registrant's activities, notify the department in writing of intent to vacate. When deemed necessary by the department, the licensee shall decontaminate the premises in accordance with the following or in such other manner as the department may specify.

1. **Premises.** Each licensee before vacating any premise, or transferring the premise, shall permanently decontaminate such premises to meet the criteria for decommissioning in 10 CFR part 20, subpart E as adopted by this chapter. A survey shall be made after such decontamination and the department and the landlord or subsequent tenant or transferee shall be provided with a copy of such survey no less than thirty days before vacating or relinquishing possession or control of premises. No such premise may be vacated, sold, or transferred until the decontamination survey has been verified and accepted by the department. For naturally occurring radioactive materials (NORM) and technologically enhanced naturally occurring radioactive materials (TENORM), decontamination shall meet the standards found in table 4.2-07.1.

2. **Equipment.** No machinery, instruments, laboratory equipment, or any other property used in contact with, or close proximity to, NORM or TENORM, or both, at a licensed premise may be assigned, sold, leased, or transferred to an unlicensed person unless such property has been permanently decontaminated below or equal to the standards specified in 10 CFR part 20, subpart E as adopted by this chapter. A survey shall be made after such decontamination and the department and subsequent transferee or owner shall be provided with a copy of such survey. No such equipment may be assigned, sold, leased, or transferred until such documentation survey has been verified and accepted by the department.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04, 23.1-03-05; S.L. 2017, ch. 199, § 18

Table 4.2-07.1

Standards for Unrestricted Release for NORM and TENORM

(a) Surface contamination limits				
(1) Alpha emitters				
(i) Removable:	0.55Bq = 100cm^2	15.0 pCi = 100 cm^2	33 dpm 100 cm^2	average over any one surface
	1.665 Bq = 100 cm^2	45.0 pCi = 100 cm^2	100 dpm 100 cm^2	maximum
(ii) Total (fixed):	166.5 Bq = 100 cm^2	150.0 pCi = 100 cm^2	1,000 dpm 100 cm^2	average over any one surface
	832.5 Bq = 100 cm^2	2,250.0 pCi = 100 cm^2	5,000 dpm 100 cm^2	maximum
	2.5 µSv = hr	(0.25 mrem) = hr	maximum at 1 cm from surface	
(2) Beta-gamma emitters				
(i) Removable:	3.7 Bq = 100 cm^2	100.0 pCi = 100 cm^2	average over any one surface	
	18.5 Bq = 100 cm^2	500.0 pCi = 100 cm^2	maximum	
(ii) Total (fixed)	2.5 µSv = hr	(0.25 mrem) = hr	maximum at 1 cm from surface	

(b) Concentration in air and water: Appendix B, Table 2 of chapter 33.1-10-04.2.

(c) Concentrations in soil and other materials except water:

(1) Radium in soil: Concentration of radionuclides above background concentrations for total radium, averaged over areas of one hundred square meters, shall not exceed:

(i) Five (5.0) picocurries per gram of soil, averaged over layers of fifteen centimeters thickness more than fifteen centimeters below the surface.

(ii) Five (5.0) picocurries per gram of dry soil, averaged over layers of fifteen centimeters thickness more than fifteen centimeters below the surface.

(2) Radium in other materials: Concentration of radionuclides above background concentrations for total radium shall not exceed five (5.0) picocuries per gram.

(d) The level of gamma radiation measured at a distance of hundred centimeters from the surface shall not exceed background.

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Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948,

953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

[72 FR 55921, Oct. 1, 2007]

Subpart A--General Provisions

Source: 56 FR 23391, May 21, 1991, unless otherwise noted.

§ 20.1001 Purpose.

(a) The regulations in this part establish standards for protection against ionizing radiation resulting from activities conducted under licenses issued by the Nuclear Regulatory Commission. These regulations are issued under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

(b) It is the purpose of the regulations in this part to control the receipt, possession, use, transfer, and disposal of licensed material by any licensee in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in the regulations in this part. However, nothing in this part shall be construed as limiting actions that may be necessary to protect health and safety.

§ 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility under parts 30 through 36, 39, 40, 50, 52, 60, 61, 63, 70, or 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released under § 35.75, or to exposure from voluntary participation in medical research programs.

[67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002, as amended at 67 FR 77652, Dec. 19, 2002; 72 FR 49485, Aug. 28, 2007]

§ 20.1003 Definitions.

As used in this part:

Absorbed dose means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

Accelerator-produced radioactive material means any material made radioactive by a particle accelerator.

Act means the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.), as amended.

Activity is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

Adult means an individual 18 or more years of age.

Airborne radioactive material means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

Airborne radioactivity area means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations--

(1) In excess of the derived air concentrations (DACs) specified in appendix B, to §§ 20.1001-20.2401, or

(2) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

Air-purifying respirator means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

ALARA (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

Annual limit on intake (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. (ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Columns 1 and 2, of appendix B to §§ 20.1001-20.2401).

Assigned protection factor (APF) means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

Atmosphere-supplying respirator means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

Background radiation means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and

global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "*Background radiation*" does not include radiation from source, byproduct, or special nuclear materials regulated by the Commission.

Bioassay (radiobioassay) means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

Byproduct material means—

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(4) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

Class (or *lung class* or *inhalation class*) means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D (Days) of less than 10 days, for Class W (Weeks) from 10 to 100 days, and for Class Y (Years) of greater than 100 days.

Collective dose is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

Committed dose equivalent ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

Committed effective dose equivalent ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \Sigma W_T H_{T.50}$).

Constraint (dose constraint) means a value above which specified licensee actions are required.

Controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

Critical Group means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

Declared pregnant woman means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits--

(1) Release of the property for unrestricted use and termination of the license; or

(2) Release of the property under restricted conditions and termination of the license.

Deep-dose equivalent (H_d), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm (1000 mg/cm^2).

Demand respirator means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

Department means the Department of Energy established by the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 et seq.) to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers, and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104 (b), (c), and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat 565 at 577-578, 42 U.S.C. 7151).

Derived air concentration (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of one ALI. DAC values are given in Table 1, Column 3, of appendix B to §§ 20.1001-20.2401.

Derived air concentration-hour (DAC-hour) is the product of the concentration of radioactive material in air (expressed as a fraction or multiple of the derived air concentration for each radionuclide) and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 5 rems (0.05 Sv).

Discrete source means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

Disposable respirator means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

Distinguishable from background means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

Dose or *radiation dose* is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other paragraphs of this section.

Dose equivalent (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

Dosimetry processor means an individual or organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

Effective dose equivalent (H_E) is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma W_T H_T$).

Embryo/fetus means the developing human organism from conception until the time of birth.

Entrance or access point means any location through which an individual could gain access to radiation areas or to radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

Exposure means being exposed to ionizing radiation or to radioactive material.

External dose means that portion of the dose equivalent received from radiation sources outside the body.

Extremity means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

Filtering facepiece (dust mask) means a negative pressure particulate respirator with a filter as an

integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

Fit factor means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Fit test means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

Generally applicable environmental radiation standards means standards issued by the Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

Government agency means any executive department, commission, independent establishment, corporation wholly or partly owned by the United States of America, which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

Gray [See § 20.1004].

Helmet means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

High radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

Hood means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

Individual means any human being.

Individual monitoring means--

(1) The assessment of dose equivalent by the use of devices designed to be worn by an individual;

(2) The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or

(3) The assessment of dose equivalent by the use of survey data.

Individual monitoring devices (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air

sampling devices.

Internal dose means that portion of the dose equivalent received from radioactive material taken into the body.

Lens dose equivalent (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

License means a license issued under the regulations in parts 30 through 36, 39, 40, 50, 60, 61, 63, 70, or 72 of this chapter.

Licensed material means source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the Commission.

Licensee means the holder of a license.

Limits (dose limits) means the permissible upper bounds of radiation doses.

Loose-fitting facepiece means a respiratory inlet covering that is designed to form a partial seal with the face.

Lost or missing licensed material means licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

Member of the public means any individual except when that individual is receiving an occupational dose.

Minor means an individual less than 18 years of age.

Monitoring (radiation monitoring, radiation protection monitoring) means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

Nationally tracked source is a sealed source containing a quantity equal to or greater than Category 1 or Category 2
levels of any radioactive material listed in Appendix E of this part. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

Negative pressure respirator (tight fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Nonstochastic effect means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect).

NRC means the Nuclear Regulatory Commission or its duly authorized representatives.

Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, from voluntary participation in medical research programs, or as a member of the public.

Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.

Person means--

(1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department of Energy (except that the Department shall be considered a person within the meaning of the regulations in 10 CFR chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission under section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act of 1982 (96 Stat. 2201), and section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842)), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and

(2) Any legal successor, representative, agent, or agency of the foregoing.

Planned special exposure means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

Positive pressure respirator means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Pressure demand respirator means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Public dose means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of

a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, or from voluntary participation in medical research programs.

Qualitative fit test (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Quality Factor (Q) means the modifying factor (listed in tables 1004(b).1 and 1004(b).2 of § 20.1004) that is used to derive dose equivalent from absorbed dose.

Quantitative fit test (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Quarter means a period of time equal to one-fourth of the year observed by the licensee (approximately 13 consecutive weeks), providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

Rad (See § 20.1004).

Radiation (ionizing radiation) means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in this part, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.

Radiation area means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Reference man means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

Rem (See § 20.1004).

Residual radioactivity means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 10 CFR part 20.

Respiratory protective device means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

Restricted area means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials.

Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Sanitary sewerage means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

Self-contained breathing apparatus (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Shallow-dose equivalent (Hs), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

Sievert (See § 20.1004).

Site boundary means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

Source material means--

(1) Uranium or thorium or any combination of uranium and thorium in any physical or chemical form; or

(2) Ores that contain, by weight, one-twentieth of 1 percent (0.05 percent), or more, of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

Special nuclear material means--

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material, but does not include source material; or

(2) Any material artificially enriched by any of the foregoing but does not include source material.

Stochastic effects means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

Supplied-air respirator (SAR) or *airline respirator* means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

Tight-fitting facepiece means a respiratory inlet covering that forms a complete seal with the face.

Total Effective Dose Equivalent (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Uranium fuel cycle means the operations of milling of uranium ore, chemical conversion of uranium, isotopic enrichment of uranium, fabrication of uranium fuel, generation of electricity by a light-water-cooled nuclear power plant using uranium fuel, and reprocessing of spent uranium fuel to the extent that these activities directly support the production of electrical power for public use. Uranium fuel cycle does not include mining operations, operations at waste disposal sites, transportation of radioactive material in support of these operations, and the reuse of recovered non-uranium special nuclear and byproduct materials from the cycle.

User seal check (fit check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

Very high radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a radiation source or 1 meter from any surface that the radiation penetrates.

(Note: At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts)).

Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in this section.

Week means 7 consecutive days starting on Sunday.

Weighting factor W_T, for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of W_T are:

Organ Dose Weighting Factors

Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12

Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	[1]0.30
Whole Body	[2]1.00

[1] 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.
[2] For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, w_T=1.0, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

Whole body means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

Working level (WL) is any combination of short-lived radon daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in 1 liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy.

Working level month (WLM) means an exposure to 1 working level for 170 hours (2,000 working hours per year/12 months per year=approximately 170 hours per month).

Year means the period of time beginning in January used to determine compliance with the provisions of this part. The licensee may change the starting date of the year used to determine compliance by the licensee provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

[56 FR 23391, May 21, 1991, as amended at 57 FR 57878, Dec. 8, 1992; 58 FR 7736, Feb. 9, 1993; 60 FR 36043, July 13, 1995; 60 FR 48625, Sept. 20, 1995; 61 FR 65127, Dec. 10, 1996; 62 FR 4133, Jan. 29, 1997; 62 FR 39087, July 21, 1997; 63 FR 39481, July 23, 1998; 64 FR 54556, Oct. 7, 1999; 66 FR 55789, Nov. 2, 2001; 67 FR 16304, Apr. 5, 2002; 67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002; 72 FR 55921, Oct. 1, 2007; 72 FR 68058, Dec. 4, 2007]

§ 20.1004 Units of radiation dose.

(a) Definitions. As used in this part, the units of radiation dose are:

Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 Joule/kilogram (100 rads).

Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).

Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem=0.01 sievert).

Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv=100 rems).

(b) As used in this part, the quality factors for converting absorbed dose to dose equivalent are shown in table 1004(b).1.

Table 1004(b).1-Quality Factors and Absorbed Dose Equivalencies

Type of radiation	Quality factor (Q)	Absorbed dose equal to a unit dose equivalent[a]
X-, gamma, or beta radiation	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

[a] Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

(c) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, as provided in paragraph (b) of this section, 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the regulations in this part, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from table 1004(b).2 to convert a measured tissue dose in rads to dose equivalent in rems.

Table 1004(b).2.--Mean Quality Factors, Q, and Fluence Per Unit Dose Equivalent for Monoenergetic Neutrons

	Neutron energy (MeV)	Quality factor[a] (Q)	Fluence per unit dose equivalent[b] (neutrons cm^{-2} rem^{-1})
(thermal).....	2.5×10^{-8}	2	980×10^{6}
	1×10^{-7}	2	980×10^{6}
	1×10^{-6}	2	810×10^{6}
	1×10^{-5}	2	810×10^{6}
	1×10^{-4}	2	840×10^{6}
	1×10^{-3}	2	980×10^{6}
	1×10^{-2}	2.5	1010×10^{6}
	1×10^{-1}	7.5	170×10^{6}
	5×10^{-1}	11	39×10^{6}
	1	11	27×10^{6}
	2.5	9	29×10^{6}

	5	8	23×10^6
	7	7	24×10^6
	10	6.5	24×10^6
	14	7.5	17×10^6
	20	8	16×10^6
	40	7	14×10^6
	60	5.5	16×10^6
	1×10^2	4	20×10^6
	2×10^2	3.5	19×10^6
	3×10^2	3.5	16×10^6
	4×10^2	3.5	14×10^6

[a] Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-cm diameter cylinder tissue-equivalent phantom.
[b] Monoenergetic neutrons incident normally on a 30-cm diameter cylinder tissue-equivalent phantom.

§ 20.1005 Units of radioactivity.

For the purposes of this part, activity is expressed in the special unit of curies (Ci) or in the SI unit of becquerels (Bq), or their multiples, or disintegrations (transformations) per unit of time.

(a) One becquerel=1 disintegration per second (s^{-1}).

(b) One curie=3.7×10^{10} disintegrations per second=3.7×10^{10} becquerels=2.22×10^{12} disintegrations per minute.

[56 FR 23391, May 21, 1991; 56 FR 61352, Dec. 3, 1991]

§ 20.1006 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by an officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 20.1007 Communications.

Unless otherwise specified, communications or reports concerning the regulations in this part should be addressed to the Executive Director for Operations (EDO), and sent either by mail to the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at

http://www.nrc.gov/site-help/e-submittals.html, by calling (301) 415-0439, by e-mail to *EIE@nrc.gov*, or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information.

[68 FR 58801, Oct. 10, 2003 as amended at 70 FR 69421, Nov. 16, 2005; 72 FR 33386, Jun. 18, 2007]

§ 20.1008 Implementation.

(a) [Reserved]

(b) The applicable section of §§ 20.1001-20.2402 must be used in lieu of requirements in the standards for protection against radiation in effect prior to January 1, 1994[1] that are cited in license conditions or technical specifications, except as specified in paragraphs (c), (d), and (e) of this section. If the requirements of this part are more restrictive than the existing license condition, then the licensee shall comply with this part unless exempted by paragraph (d) of this section.

(c) Any existing license condition or technical specification that is more restrictive than a requirement in §§ 20.1001-20.2402 remains in force until there is a technical specification change, license amendment, or license renewal.

(d) If a license condition or technical specification exempted a licensee from a requirement in the standards for protection against radiation in effect prior to January 1, 1994,[1] it continues to exempt a licensee from the corresponding provision of §§ 20.1001-20.2402.

(e) If a license condition cites provisions in requirements in the standards for protection against radiation in effect prior to January 1, 1994[1] and there are no corresponding provisions in §§ 20.1001-20.2402, then the license condition remains in force until there is a technical specification change, license amendment, or license renewal that modifies or removes this condition.

[59 FR 41643, Aug. 15, 1994]

[1] See §§ 20.1-20.602 codified as of January 1, 1993.

§ 20.1009 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0014.

(b) The approved information collection requirements contained in this part appear in §§20.1003, 20.1101, 20.1202, 20.1203, 20.1204, 20.1206, 20.1208, 20.1301, 20.1302, 20.1403, 20.1404, 20.1406, 20.1501, 20.1601, 20.1703, 20.1901, 20.1904, 20.1905, 20.1906, 20.2002, 20.2004, 20.2005, 20.2006, 20.2008, 20.2102, 20.2103, 20.2104, 20.2105, 20.2106, 20.2107, 20.2108,

20.2110, 20.2201, 20.2202, 20.2203, 20.2204, 20.2205, 20.2206, 20.2207, 20.2301, and appendix G to this part.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 20.2104, NRC Form 4 is approved under control number 3150-0005.

(2) In §§ 20.2106 and 20.2206, NRC Form 5 is approved under control number 3150-0006.

(3) In § 20.2006 and appendix G to 10 CFR Part 20, NRC Form 540 and 540A is approved under control number 3150-0164.

(4) In § 20.2006 and appendix G to 10 CFR Part 20, NRC Form 541 and 541A is approved under control number 3150-0166.

(5) In § 20.2006 and appendix G to 10 CFR Part 20, NRC Form 542 and 542A is approved under control number 3150-0165.

(6) In § 20.2207, NRC Form 748 is approved under control number 3150– 0202.

[63 FR 50128, Sept. 21, 1998, as amended at 67 FR 67099, Nov. 4, 2002; 71 FR 65686, Nov. 8, 2006; 72 FR 55922, Oct. 1, 2007]

Subpart B--Radiation Protection Programs

Source: 56 FR 23396, May 21, 1991, unless otherwise noted.

§ 20.1101 Radiation protection programs.

(a) Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part. (See § 20.2102 for recordkeeping requirements relating to these programs.)

(b) The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

(c) The licensee shall periodically (at least annually) review the radiation protection program content and implementation.

(d) To implement the ALARA requirements of § 20.1101 (b), and notwithstanding the requirements in § 20.1301 of this part, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees other than those subject to § 50.34a, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose

constraint, the licensee shall report the exceedance as provided in § 20.2203 and promptly take appropriate corrective action to ensure against recurrence.

[56 FR 23396, May 21, 1991, as amended at 61 FR 65127, Dec. 10, 1996; 63 FR 39482, July 23, 1998]

Subpart C--Occupational Dose Limits

Source: 56 FR 23396, May 21, 1991, unless otherwise noted.

§ 20.1201 Occupational dose limits for adults.

(a) The licensee shall control the occupational dose to individual adults, except for planned special exposures under § 20.1206, to the following dose limits.

(1) An annual limit, which is the more limiting of--

(i) The total effective dose equivalent being equal to 5 rems (0.05 Sv); or

(ii) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

(2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

(i) A lens dose equivalent of 15 rems (0.15 Sv), and

(ii) A shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that the individual may receive during the current year (see § 20.1206(e)(1)) and during the individual's lifetime (see § 20.1206(e)(2)).

(c) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in table 1 of appendix B to part 20 and may be used to determine the individual's dose (see § 20.2106) and to demonstrate compliance with the occupational dose limits.

(e) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (see footnote 3 of appendix B to part 20).

(f) The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person (see § 20.2104(e)).

[56 FR 23396, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995; 63 FR 39482, July 23, 1998; 67 FR 16304, Apr. 5, 2002; 72 FR 68059, Dec. 4, 2007]

§ 20.1202 Compliance with requirements for summation of external and internal doses.

(a) If the licensee is required to monitor under both §§ 20.1502(a) and (b), the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only under § 20.1502(a) or only under § 20.1502(b), then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in paragraph (b) of this section and the conditions in paragraphs (c) and (d) of this section.

(Note: The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.)

(b) *Intake by inhalation*. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(1) The sum of the fractions of the inhalation ALI for each radionuclide, or

(2) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

(3) The sum of the calculated committed effective dose equivalents to all significantly irradiated[1] organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit.

(c) *Intake by oral ingestion*. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

(d) *Intake through wounds or absorption through skin*. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption.

Note: The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be further evaluated.

[56 FR 23396, May 21, 1991, as amended at 57 FR 57878, Dec. 8, 1992]

[1] An organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factor, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of $H_{T,50}$, (i.e., $w_T H_{T,50}$) per unit intake for any organ or tissue.

§ 20.1203 Determination of external dose from airborne radioactive material.

Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud (see appendix B to part 20, footnotes 1 and 2).

Note: Airborne radioactivity measurements and DAC values should not be used as the primary means to assess the deep-dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep-dose equivalent to an individual should be based upon measurements using instruments or individual monitoring devices.

[56 FR 23396, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995; 63 FR 39482, July 23, 1998]

§ 20.1204 Determination of internal exposure.

(a) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under § 20.1502, take suitable and timely measurements of--

(1) Concentrations of radioactive materials in air in work areas; or

(2) Quantities of radionuclides in the body; or

(3) Quantities of radionuclides excreted from the body; or

(4) Combinations of these measurements.

(b) Unless respiratory protective equipment is used, as provided in § 20.1703, or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(c) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior or the material in an individual is known, the licensee may--

(1) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and

(2) Upon prior approval of the Commission, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material (e.g., aerosol size distribution or density); and

(3) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a

given radionuclide (see appendix B to part 20) to the committed effective dose equivalent.

(d) If the licensee chooses to assess intakes of Class Y material using the measurements given in § 20.1204(a)(2) or (3), the licensee may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by §§ 20.2202 or 20.2203, in order to permit the licensee to make additional measurements basic to the assessments.

(e) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours must be either--

(1) The sum of the ratios of the concentration to the appropriate DAC value (e.g., D, W, Y) from appendix B to part 20 for each radionuclide in the mixture; or

(2) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(f) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture must be the most restrictive DAC of any radionuclide in the mixture.

(g) When a mixture of radionuclides in air exists, licensees may disregard certain radionuclides in the mixture if--

(1) The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in § 20.1201 and in complying with the monitoring requirements in § 20.1502(b), and

(2) The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and

(3) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

(h)(1) In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 5 rems (0.05 Sv) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(2) When the ALI (and the associated DAC) is determined by the nonstochastic organ dose limit of 50 rems (0.5 Sv), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) (the stochastic ALI) is listed in parentheses in table 1 of appendix B to part 20. In this case, the licensee may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALIs, the licensee must also demonstrate that the limit in § 20.1201(a)(1)(ii) is met.

[56 FR 23396, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995]

§ 20.1205 [Reserved]

§ 20.1206 Planned special exposures.

A licensee may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in § 20.1201 provided that each of the following conditions is satisfied--

(a) The licensee authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

(b) The licensee (and employer if the employer is not the licensee) specifically authorizes the planned special exposure, in writing, before the exposure occurs.

(c) Before a planned special exposure, the licensee ensures that the individuals involved are--

(1) Informed of the purpose of the planned operation;

(2) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(3) Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(d) Prior to permitting an individual to participate in a planned special exposure, the licensee ascertains prior doses as required by § 20.2104(b) during the lifetime of the individual for each individual involved.

(e) Subject to § 20.1201(b), the licensee does not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed--

(1) The numerical values of any of the dose limits in § 20.1201(a) in any year; and

(2) Five times the annual dose limits in § 20.1201(a) during the individual's lifetime.

(f) The licensee maintains records of the conduct of a planned special exposure in accordance with § 20.2105 and submits a written report in accordance with § 20.2204.

(g) The licensee records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures is not to be considered in controlling future occupational dose of the individual under § 20.1201(a) but is to be included in evaluations required by § 20.1206 (d) and (e).

[56 FR 23396, May 21, 1991, as amended at 63 FR 39482, July 23, 1998]

§ 20.1207 Occupational dose limits for minors.

The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers in § 20.1201.

§ 20.1208 Dose equivalent to an embryo/fetus.

(a) The licensee shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). (For recordkeeping requirements, see § 20.2106.)

(b) The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (a) of this section.

(c) The dose equivalent to the embryo/fetus is the sum of--

(1) The deep-dose equivalent to the declared pregnant woman; and

(2) The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

(d) If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee shall be deemed to be in compliance with paragraph (a) of this section if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

[56 FR 23396, May 21, 1991, as amended at 63 FR 39482, July 23, 1998]

Subpart D--Radiation Dose Limits for Individual Members of the Public

Source: 56 FR 23398, May 21, 1991, unless otherwise noted.

§ 20.1301 Dose limits for individual members of the public.

(a) Each licensee shall conduct operations so that —

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, from any administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, from voluntary participation in medical research programs, and from the licensee’s disposal of radioactive material into sanitary sewerage in accordance with § 20.2003, and

(2) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with § 35.75, does not exceed 0.002 rem (0.02 millisievert) in any one hour.

(b) If the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(c) Notwithstanding paragraph (a)(1) of this section, a licensee may permit visitors to an individual who cannot be released, under § 35.75, to receive a radiation dose greater than 0.1 rem (1 mSv)

if—

(1) The radiation dose received does not exceed 0.5 rem (5 mSv); and

(2) The authorized user, as defined in 10 CFR Part 35, has determined before the visit that it is appropriate.

(d) A licensee or license applicant may apply for prior NRC authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). The licensee or license applicant shall include the following information in this application:

(1) Demonstration of the need for and the expected duration of operations in excess of the limit in paragraph (a) of this section;

(2) The licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

(3) The procedures to be followed to maintain the dose as low as is reasonably achievable.

(e) In addition to the requirements of this part, a licensee subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR part 190 shall comply with those standards.

(f) The Commission may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

[56 FR 23398, May 21, 1991, as amended at 60 FR 48625, Sept. 20, 1995; 62 FR 4133, Jan. 29, 1997; 67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002]

§ 20.1302 Compliance with dose limits for individual members of the public.

(a) The licensee shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in § 20.1301.

(b) A licensee shall show compliance with the annual dose limit in § 20.1301 by--

(1) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual dose limit; or

(2) Demonstrating that--

(i) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in table 2 of appendix B to part 20; and

(ii) If an individual were continuously present in an unrestricted area, the dose from external

sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

(c) Upon approval from the Commission, the licensee may adjust the effluent concentration values in appendix B to part 20, table 2, for members of the public, to take into account the actual physical and chemical characteristics of the effluents (e.g., aerosol size distribution, solubility, density, radioactive decay equilibrium, chemical form).

[56 FR 23398, May 21, 1991; 56 FR 61352, Dec. 3, 1991, as amended at 57 FR 57878, Dec. 8, 1992; 60 FR 20185, Apr. 25, 1995]

Subpart E--Radiological Criteria for License Termination

Source: 62 FR 39088, July 21, 1987, unless otherwise noted.

§ 20.1401 General provisions and scope.

(a) The criteria in this subpart apply to the decommissioning of facilities licensed under parts 30, 40, 50, 52, 60, 61, 63, 70, and 72 of this chapter, and release of part of a facility or site for unrestricted use in accordance with § 50.83 of this chapter, as well as other facilities subject to the Commission's jurisdiction under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. For high-level and low-level waste disposal facilities (10 CFR parts 60, 61, and 63), the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities. The criteria do not apply to uranium and thorium recovery facilities already subject to appendix A to 10 CFR part 40 or the uranium solution extraction facilities.

(b) The criteria in this subpart do not apply to sites which:

(1) Have been decommissioned prior to the effective date of the rule in accordance with criteria identified in the Site Decommissioning Management Plan (SDMP) Action Plan of April 16, 1992 (57 FR 13389);

(2) Have previously submitted and received Commission approval on a license termination plan (LTP) or decommissioning plan that is compatible with the SDMP Action Plan criteria; or

(3) Submit a sufficient LTP or decommissioning plan before August 20, 1998 and such LTP or decommissioning plan is approved by the Commission before August 20, 1999 and in accordance with the criteria identified in the SDMP Action Plan, except that if an EIS is required in the submittal, there will be a provision for day-for-day extension.

(c) After a site has been decommissioned and the license terminated in accordance with the criteria in this subpart, or after part of a facility or site has been released for unrestricted use in accordance with § 50.83 of this chapter and in accordance with the criteria in this subpart, the Commission will require additional cleanup only, if based on new information, it determines that the criteria of this subpart were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(d) When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

[62 FR 39088, July 21, 1997, as amended at 66 FR 55789, Nov. 2, 2001; 72 FR 49485, Aug. 28, 2007]

§ 20.1402 Radiological criteria for unrestricted use.

A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

§ 20.1403 Criteria for license termination under restricted conditions.

A site will be considered acceptable for license termination under restricted conditions if:

(a) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of § 20.1402 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

(b) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year;

(c) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are--

(1) Funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual 1 percent real rate of return of investment;

(2) A statement of intent in the case of Federal, State, or local Government licensees, as described in § 30.35(f)(4) of this chapter; or

(3) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(d) The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Commission indicating the licensee's intent to decommission in accordance with §§ 30.36(d), 40.42(d), 50.82 (a) and (b), 70.38(d), or 72.54 of this chapter, and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

(1) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning--

(i) Whether provisions for institutional controls proposed by the licensee;

(A) Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) TEDE per year;

(B) Will be enforceable; and

(C) Will not impose undue burdens on the local community or other affected parties.

(ii) Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

(2) In seeking advice on the issues identified in § 20.1403(d)(1), the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

(e) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either--

(1) 100 mrem (1 mSv) per year; or

(2) 500 mrem (5 mSv) per year provided the licensee--

(i) Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem/y (1 mSv/y) value of paragraph (e)(1) of this section are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(ii) Makes provisions for durable institutional controls;

(iii) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every 5 years to assure that the institutional controls remain in place as necessary to meet the criteria of § 20.1403(b) and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial

assurance mechanisms are those in paragraph (c) of this section.

§ 20.1404 Alternate criteria for license termination.

a) The Commission may terminate a license using alternate criteria greater than the dose criterion of §§ 20.1402, 20.1403(b), and 20.1403(d)(1)(i)(A), if the licensee--

(1) Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 1 mSv/y (100 mrem/y) limit of subpart D, by submitting an analysis of possible sources of exposure;

(2) Has employed to the extent practical restrictions on site use according to the provisions of § 20.1403 in minimizing exposures at the site; and

(3) Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.

(4) Has submitted a decommissioning plan or License Termination Plan (LTP) to the Commission indicating the licensee's intent to decommission in accordance with §§ 30.36(d), 40.42(d), 50.82 (a) and (b), 70.38(d), or 72.54 of this chapter, and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

(5) Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

(b) The use of alternate criteria to terminate a license requires the approval of the Commission after consideration of the NRC staff's recommendations that will address any comments provided by the Environmental Protection Agency and any public comments submitted pursuant to § 20.1405.

§ 20.1405 Public notification and public participation.

Upon the receipt of an LTP or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to §§ 20.1403 or 20.1404, or whenever the Commission

deems such notice to be in the public interest, the Commission shall:

(a) Notify and solicit comments from:

(1) local and State governments in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(2) the Environmental Protection Agency for cases where the licensee proposes to release a site pursuant to § 20.1404.

(b) Publish a notice in the Federal Register and in a forum, such as local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

§ 20.1406 Minimization of contamination.

(a) Applicants for licenses, other than early site permits and manufacturing licenses under part 52 of this chapter and renewals, whose applications are submitted after August 20, 1997, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(b) Applicants for standard design certifications, standard design approvals, and manufacturing licenses under part 52 of this chapter, whose applications are submitted after August 20, 1997, shall describe in the application how facility design will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(c) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in Subpart B and radiological criteria for license termination in Subpart E of this part.

[72 FR 49485, Aug. 28, 2007]

Subpart F--Surveys and Monitoring

Source: 56 FR 23398, May 21, 1991, unless otherwise noted.

§ 20.1501 General.

(a) Each licensee shall make or cause to be made, surveys of areas, including the subsurface, that--

(1) May be necessary for the licensee to comply with the regulations in this part; and

(2) Are reasonable under the circumstances to evaluate--

(i) The magnitude and extent of radiation levels; and

(ii) Concentrations or quantities of residual radioactivity; and

(iii) The potential radiological hazards of the radiation levels and residual radioactivity detected.

(b) Nothwithstanding § 20.2103(a) of this part, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with §§ 30.35(g), 40.36(f), 50.75(g), 70.25(g), or 72.30(d), as applicable.

(c) The licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured.

(d) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees to comply with § 20.1201, with other applicable provisions of this chapter, or with conditions specified in a license must be processed and evaluated by a dosimetry processor--

(1) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(2) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

[56 FR 23398, May 21, 1991, as amended at 63 FR 39482, July 23, 1998]

§ 20.1502 Conditions requiring individual monitoring of external and internal occupational dose.

Each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum--

(a) Each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by--

(1) Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in § 20.1201(a),

(2) Minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);

(3) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv);[2] and

(4) Individuals entering a high or very high radiation area.

(b) Each licensee shall monitor (see § 20.1204) the occupational intake of radioactive material by and assess the committed effective dose equivalent to--

(1) Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in table 1, Columns 1 and 2, of appendix B to §§ 20.1001-20.2402;

(2) Minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv); and

(3) Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

[56 FR 23398, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995; 63 FR 39482, July 23, 1998]

[2] All of the occupational doses in § 20.1201 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

Subpart G--Control of Exposure From External Sources in Restricted Areas

Source: 56 FR 23398, May 21, 1991, unless otherwise noted.

§ 20.1601 Control of access to high radiation areas.

(a) The licensee shall ensure that each entrance or access point to a high radiation area has one or more of the following features--

(1) A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep-dose equivalent of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates;

(2) A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(3) Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(b) In place of the controls required by paragraph (a) of this section for a high radiation area, the licensee may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(c) A licensee may apply to the Commission for approval of alternative methods for controlling access to high radiation areas.

(d) The licensee shall establish the controls required by paragraphs (a) and (c) of this section in a way that does not prevent individuals from leaving a high radiation area.

(e) Control is not required for each entrance or access point to a room or other area that is a high

radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the Department of Transportation provided that--

(1) The packages do not remain in the area longer than 3 days; and

(2) The dose rate at 1 meter from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.

(f) Control of entrance or access to rooms or other areas in hospitals is not required solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this part and to operate within the ALARA provisions of the licensee's radiation protection program.

§ 20.1602 Control of access to very high radiation areas.

In addition to the requirements in § 20.1601, the licensee shall institute additional measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rads (5 grays) or more in 1 hour at 1 meter from a radiation source or any surface through which the radiation penetrates.

Subpart H--Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

Source: 56 FR 23400, May 21, 1991, unless otherwise noted.

§ 20.1701 Use of process or other engineering controls.

The licensee shall use, to the extent practical, process or other engineering controls (*e.g.,* containment, decontamination, or ventilation) to control the concentration of radioactive material in air.

[64 FR 54556, Oct. 7, 1999]

§ 20.1702 Use of other controls.

(a) When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in the air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means--

(1) Control of access;

(2) Limitation of exposure times;

(3) Use of respiratory protection equipment; or

(4) Other controls.

(b) If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

[64 FR 54556, Oct. 7, 1999]

§ 20.1703 Use of individual respiratory protection equipment.

If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material,

(a) The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH) except as otherwise noted in this part.

(b) If the licensee wishes to use equipment that has not been tested or certified by NIOSH, or for which there is no schedule for testing or certification, the licensee shall submit an application to the NRC for authorized use of this equipment except as provided in this part. The application must include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This must be demonstrated either by licensee testing or on the basis of reliable test information.

(c) The licensee shall implement and maintain a respiratory protection program that includes:

(1) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

(2) Surveys and bioassays, as necessary, to evaluate actual intakes;

(3) Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

(4) Written procedures regarding--

(i) Monitoring, including air sampling and bioassays;

(ii) Supervision and training of respirator users;

(iii) Fit testing;

(iv) Respirator selection;

(v) Breathing air quality;

(vi) Inventory and control;

(vii) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection

equipment;

(viii) Recordkeeping; and

(ix) Limitations on periods of respirator use and relief from respirator use;

(5) Determination by a physician that the individual user is medically fit to use respiratory protection equipment:

(i) Before the initial fitting of a face sealing respirator;

(ii) Before the first field use of non-face sealing respirators, and

(iii) Either every 12 months thereafter, or periodically at a frequency determined by a physician.

(6) Fit testing, with fit factor $\geq$ 10 times the APF for negative pressure devices, and a fit factor $\geq$ 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed 1 year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

(d) The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(e) The licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

(f) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

(g) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E). Grade D quality air criteria include--

(1) Oxygen content (v/v) of 19.5-23.5%;

(2) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

(3) Carbon monoxide (CO) content of 10 ppm or less;

(4) Carbon dioxide content of 1,000 ppm or less; and

(5) Lack of noticable odor.

(h) The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face--facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(i) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

[64 FR 54557, Oct. 7, 1999, as amended at 67 FR 77652, Dec. 19, 2002]

§ 20.1704 Further restrictions on the use of respiratory protection equipment.

The Commission may impose restrictions in addition to the provisions of §§ 20.1702, 20.1703, and Appendix A to Part 20, in order to:

(a) Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

(b) Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

[64 FR 54557, Oct. 7, 1999]

§ 20.1705 Application for use of higher assigned protection factors.

The licensee shall obtain authorization from the Commission before using assigned protection factors in excess of those specified in Appendix A to Part 20. The Commission may authorize a licensee to use higher assigned protection factors on receipt of an application that--

(a) Describes the situation for which a need exists for higher protection factors; and

(b) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

[64 FR 54557, Oct. 7, 1999]

Subpart I--Storage and Control of Licensed Material

Source: 56 FR 23401, May 21, 1991, unless otherwise noted.

§ 20.1801 Security of stored material.

The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

§ 20.1802 Control of material not in storage.

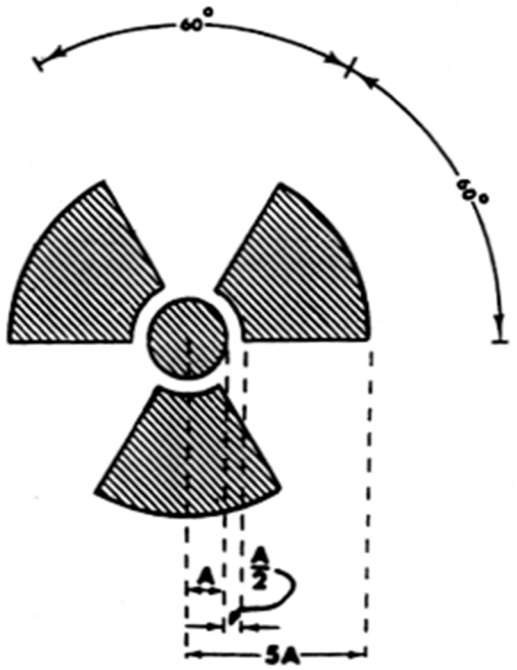
The licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Subpart J--Precautionary Procedures

Source: 56 FR 23401, May 21, 1991, unless otherwise noted.

§ 20.1901 Caution signs.

(a) *Standard radiation symbol*. Unless otherwise authorized by the Commission, the symbol prescribed by this part shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed by this part is the three-bladed design:



RADIATION SYMBOL

(1) Cross-hatched area is to be magenta, or purple, or black, and

(2) The background is to be yellow.

(b) *Exception to color requirements for standard radiation symbol*. Notwithstanding the requirements of paragraph (a) of this section, licensees are authorized to label sources, source holders, or device components containing sources of licensed materials that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(c) *Additional information on signs and labels*. In addition to the contents of signs and labels prescribed in this part, the licensee may provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

§ 20.1902 Posting requirements.

(a) *Posting of radiation areas*. The licensee shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

(b) *Posting of high radiation areas*. The licensee shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

(c) *Posting of very high radiation areas*. The licensee shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

(d) *Posting of airborne radioactivity areas*. The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

(e) *Posting of areas or rooms in which licensed material is used or stored*. The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in appendix C to part 20 with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

[56 FR 23401, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995]

§ 20.1903 Exceptions to posting requirements.

(a) A licensee is not required to post caution signs in areas or rooms containing radioactive materials for periods of less than 8 hours, if each of the following conditions is met:

(1) The materials are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to radiation or radioactive materials in excess of the limits established in this part; and

(2) The area or room is subject to the licensee's control.

(b) Rooms or other areas in hospitals that are occupied by patients are not required to be posted

with caution signs pursuant to § 20.1902 provided that the patient could be released from licensee control pursuant to § 35.75 of this chapter.

(c) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the source container or housing does not exceed 0.005 rem (0.05 mSv) per hour.

(d) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under § 20.1902 if--

(1) Access to the room is controlled pursuant to 10 CFR 35.615; and

(2) Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this part.

[56 FR 23401, May 21, 1991, as amended at 57 FR 39357, Aug. 31, 1992; 62 FR 4133, Jan. 29, 1997; 63 FR 39482, July 23, 1998]

§ 20.1904 Labeling containers.

(a) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(b) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

§ 20.1905 Exemptions to labeling requirements.

A licensee is not required to label--

(a) Containers holding licensed material in quantities less than the quantities listed in appendix C to part 20; or

(b) Containers holding licensed material in concentrations less than those specified in table 3 of appendix B to part 20; or

(c) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this part; or

(d) Containers when they are in transport and packaged and labeled in accordance with the regulations of the Department of Transportation,[3] or

(e) Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record (examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells). The record must be retained as long as the containers are in use for the purpose indicated on the record; or

(f) Installed manufacturing or process equipment, such as reactor components, piping, and tanks; or

(g) Containers holding licensed material (other than sealed sources that are either specifically or generally licensed) at a facility licensed under Parts 50 or 52 of this chapter, not including non-power reactors, that are within an area posted under the requirements in § 20.1902 if the containers are:

(1) Conspicuously marked (such as by providing a system of color coding of containers) commensurate with the radiological hazard;

(2) Accessible only to individuals who have sufficient instruction to minimize radiation exposure while handling or working in the vicinity of the containers; and

(3) Subject to plant procedures to ensure they are appropriately labeled, as specified at § 20.1904 before being removed from the posted area.

[56 FR 23401, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995; 72 FR 68059, Dec. 4, 2007]

[3] Labeling of packages containing radioactive materials is required by the Department of Transportation (DOT) if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by DOT regulations 49 CFR 173.403 (m) and (w) and 173.421-424.

§ 20.1906 Procedures for receiving and opening packages.

(a) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in § 71.4 and appendix A to part 71 of this chapter, shall make arrangements to receive--

(1) The package when the carrier offers it for delivery; or

(2) Notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

(b) Each licensee shall--

(1) Monitor the external surfaces of a labeled[3a] package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4;

(2) Monitor the external surfaces of a labeled[3a] package for radiation levels unless the package

contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in § 71.4 and appendix A to part 71 of this chapter; and

(3) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

(c) The licensee shall perform the monitoring required by paragraph (b) of this section as soon as practical after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

(d) The licensee shall immediately notify the final delivery carrier and the department of environmental quality~~NRC Operations Center (301-816-5100)~~, by telephone, when--

(1) Removable radioactive surface contamination exceeds the limits of § 71.87(i) of this chapter; or

(2) External radiation levels exceed the limits of § 71.47 of this chapter.

(e) Each licensee shall--

(1) Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(2) Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

(f) Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of paragraph (b) of this section, but are not exempt from the survey requirement in paragraph (b) of this section for measuring radiation levels that is required to ensure that the source is still properly lodged in its shield.

[56 FR 23401, May 21, 1991, as amended at 57 FR 39357, Aug. 31, 1992; 60 FR 20185, Apr. 25, 1995; 63 FR 39482, July 23, 1998; 85 FR 65656, Oct. 16, 2020]

[3a] Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 and 172.436-440.

Subpart K--Waste Disposal

Source: 56 FR 23403, May 21, 1991, unless otherwise noted.

§ 20.2001 General requirements.

(a) A licensee shall dispose of licensed material only--

(1) By transfer to an authorized recipient as provided in § 20.2006 or in the regulations in parts 30,

40, 60, 61, 63, 70, and 72 of this chapter;

(2) By decay in storage; or

(3) By release in effluents within the limits in § 20.1301; or

(4) As authorized under §§ 20.2002, 20.2003, 20.2004, 20.2005, or 20.2008.

(b) A person must be specifically licensed to receive waste containing licensed material from other persons for:

(1) Treatment prior to disposal; or

(2) Treatment or disposal by incineration; or

(3) Decay in storage; or

(4) Disposal at a land disposal facility licensed under part 61 of this chapter; or

(5) Disposal at a geologic repository under part 60 or part 63 of this chapter.

[56 FR 23403, May 21, 1991, as amended at 66 FR 55789, Nov. 2, 2001; 72 FR 55922, Oct. 1, 2007]

§ 20.2002 Method for obtaining approval of proposed disposal procedures.

A licensee or applicant for a license may apply to the Commission for approval of proposed procedures, not otherwise authorized in the regulations in this chapter, to dispose of licensed material generated in the licensee's activities. Each application shall include:

(a) A description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal; and

(b) An analysis and evaluation of pertinent information on the nature of the environment; and

(c) The nature and location of other potentially affected licensed and unlicensed facilities; and

(d) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this part.

§ 20.2003 Disposal by release into sanitary sewerage.

(a) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

(1) The material is readily soluble (or is readily dispersible biological material) in water; and

(2) The quantity of licensed or other radioactive material that the licensee releases into the sewer in

1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in table 3 of appendix B to part 20; and

(3) If more than one radionuclide is released, the following conditions must also be satisfied:

(i) The licensee shall determine the fraction of the limit in table 3 of appendix B to part 20 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in table 3 of appendix B to part 20; and

(ii) The sum of the fractions for each radionuclide required by paragraph (a)(3)(i) of this section does not exceed unity; and

(4) The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed 5 curies (185 GBq) of hydrogen-3, 1 curie (37 GBq) of carbon-14, and 1 curie (37 GBq) of all other radioactive materials combined.

(b) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in paragraph (a) of this section.

[56 FR 23403, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995]

§ 20.2004 Treatment or disposal by incineration.

(a) A licensee may treat or dispose of licensed material by incineration only:

(1) As authorized by paragraph (b) of this section; or

(2) If the material is in a form and concentration specified in § 20.2005; or

(3) As specifically approved by the Commission pursuant to § 20.2002.

(b) (1) Waste oils (petroleum derived or synthetic oils used principally as lubricants, coolants, hydraulic or insulating fluids, or metalworking oils) that have been radioactively contaminated in the course of the operation or maintenance of a nuclear power reactor licensed under part 50 of this chapter may be incinerated on the site where generated provided that the total radioactive effluents from the facility, including the effluents from such incineration, conform to the requirements of appendix I to part 50 of this chapter and the effluent release limits contained in applicable license conditions other than effluent limits specifically related to incineration of waste oil. The licensee shall report any changes or additions to the information supplied under §§ 50.34 and 50.34a of this chapter associated with this incineration pursuant to § 50.71 of this chapter, as appropriate. The licensee shall also follow the procedures of § 50.59 of this chapter with respect to such changes to the facility or procedures.

(2) Solid residues produced in the process of incinerating waste oils must be disposed of as provided by § 20.2001.

(3) The provisions of this section authorize onsite waste oil incineration under the terms of this section and supersede any provision in an individual plant license or technical specification that

may be inconsistent.

[57 FR 57656, Dec. 7, 1992]

§ 20.2005 Disposal of specific wastes.

(a) A licensee may dispose of the following licensed material as if it were not radioactive:

(1) 0.05 microcurie (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

(2) 0.05 microcurie (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

(b) A licensee may not dispose of tissue under paragraph (a)(2) of this section in a manner that would permit its use either as food for humans or as animal feed.

(c) The licensee shall maintain records in accordance with § 20.2108.

§ 20.2006 Transfer for disposal and manifests.

(a) The requirements of this section and appendix G to 10 CFR Part 20 are designed to--

(1) Control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in this part, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility (as defined in Part 61 of this chapter);

(2) Establish a manifest tracking system; and

(3) Supplement existing requirements concerning transfers and recordkeeping for those wastes.

(b) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to 10 CFR Part 20.

(c) Each shipment manifest must include a certification by the waste generator as specified in section II of appendix G to 10 CFR Part 20.

(d) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in section III of appendix G to 10 CFR Part 20.

(e) Any licensee shipping byproduct material as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in § 20.1003 intended for ultimate disposal at a land disposal facility licensed under part 61 of this
chapter must document the information required on the NRC’s Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in

accordance with appendix G to this part.

[63 FR 50128, Sept. 21, 1998; 72 FR 55922, Oct. 1, 2007]

§ 20.2007 Compliance with environmental and health protection regulations.

Nothing in this subpart relieves the licensee from complying with other applicable Federal, State, and local regulations governing any other toxic or hazardous properties of materials that may be disposed of under this subpart.

§ 20.2008 Disposal of certain byproduct material.

(a) Licensed material as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in §20.1003 may be disposed of in accordance with part 61 of this chapter, even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under part 61 of this chapter, must meet the requirements of § 20.2006.

(b) A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in § 20.1003, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

[72 FR 55922, Oct. 1, 2007]

Subpart L--Records

Source: 56 FR 23404, May 21, 1991, unless otherwise noted.

§ 20.2101 General provisions.

(a) Each licensee shall use the units: curie, rad, rem, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this part.

(b) In the records required by this part, the licensee may record quantities in SI units in parentheses following each of the units specified in paragraph (a) of this section. However, all quantities must be recorded as stated in paragraph (a) of this section.

(c) Not withstanding the requirements of paragraph (a) of this section, when recording information on shipment manifests, as required in § 20.2006(b), information must be recorded in the International System of Units (SI) or in SI and units as specified in paragraph (a) of this section.

(d) The licensee shall make a clear distinction among the quantities entered on the records required by this part (e.g., total effective dose equivalent, shallow-dose equivalent, lens dose equivalent, deep-dose equivalent, committed effective dose equivalent).

[56 FR 23404, May 21, 1991, as amended at 60 FR 15663, Mar. 27, 1995; 63 FR 39483, July 23, 1998]

§ 20.2102 Records of radiation protection programs.

(a) Each licensee shall maintain records of the radiation protection program, including:

(1) The provisions of the program; and

(2) Audits and other reviews of program content and implementation.

(b) The licensee shall retain the records required by paragraph (a)(1) of this section until the Commission terminates each pertinent license requiring the record. The licensee shall retain the records required by paragraph (a)(2) of this section for 3 years after the record is made.

§ 20.2103 Records of surveys.

(a) Each licensee shall maintain records showing the results of surveys and calibrations required by §§ 20.1501 and 20.1906(b). The licensee shall retain these records for 3 years after the record is made.

(b) The licensee shall retain each of the following records until the Commission terminates each pertinent license requiring the record:

(1) Records of the results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents. This includes those records of results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents required under the standards for protection against radiation in effect prior to January 1, 1994; and

(2) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose. This includes those records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose required under the standards for protection against radiation in effect prior to January 1, 1994; and

(3) Records showing the results of air sampling, surveys, and bioassays required pursuant to § 20.1703(c)(1) and (2). This includes those records showing the results of air sampling, surveys, and bioassays required under the standards for protection against radiation in effect prior to January 1, 1994; and

(4) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment. This includes those records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment required under the standards for protection against radiation in effect prior to January 1, 1994.

[56 FR 23404, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995; 66 FR 64737, Dec. 14, 2001]

§ 20.2104 Determination of prior occupational dose.

(a) For each individual who is likely to receive an annual occupational dose requiring monitoring under § 20.1502, the licensee shall determine the occupational radiation dose received during the current year.

(b) Prior to permitting an individual to participate in a planned special exposure, the licensee shall determine--

(1) The internal and external doses from all previous planned special exposures; and

(2) All doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual.

(c) In complying with the requirements of paragraphs (a) or (b) of this section, a licensee may—

(1) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year;

(2) Accept, as the record of cumulative radiation dose, an up-to-date NRC Form 4, or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee); and

(3) Obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee) by telephone, telegram, electronic media, or letter. The licensee shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(d) The licensee shall record the exposure history of each individual, as required by paragraphs (a) or (b) of this section, on NRC Form 4, or other clear and legible record, including all of the information required by NRC Form 4.[4] The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee obtains reports, the licensee shall use the dose shown in the report in preparing the NRC Form 4. For any period in which the licensee does not obtain a report, the licensee shall place a notation on the NRC Form 4 indicating the periods of time for which data are not available.

(e) If the licensee is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee shall assume--

(1) In establishing administrative controls under § 20.1201(f) for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(2) That the individual is not available for planned special exposures.

(f) The licensee shall retain the records on NRC Form 4 or equivalent until the Commission terminates each pertinent license requiring this record. The licensee shall retain records used in preparing NRC Form 4 for 3 years after the record is made. This includes records required under the standards for protection against radiation in effect prior to January 1, 1994.

[56 FR 23404, May 21, 1991, as amended at 57 FR 57878, Dec. 8, 1992; 60 FR 20186, Apr. 25, 1995; 60 FR 36043, July 13, 1995; 72 FR 68059, Dec. 4, 2007]

[4] Licensees are not required to partition historical dose between external dose equivalent(s) and internal committed dose equivalent(s). Further, occupational exposure histories obtained and recorded on NRC Form 4 before January 1, 1994, might not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

§ 20.2105 Records of planned special exposures.

(a) For each use of the provisions of § 20.1206 for planned special exposures, the licensee shall maintain records that describe--

(1) The exceptional circumstances requiring the use of a planned special exposure; and

(2) The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

(3) What actions were necessary; and

(4) Why the actions were necessary; and

(5) How doses were maintained ALARA; and

(6) What individual and collective doses were expected to result, and the doses actually received in the planned special exposure.

(b) The licensee shall retain the records until the Commission terminates each pertinent license requiring these records.

§ 20.2106 Records of individual monitoring results.

(a) *Recordkeeping requirement*. Each licensee shall maintain records of doses received by all individuals for whom monitoring was required pursuant to § 20.1502, and records of doses received during planned special exposures, accidents, and emergency conditions. These records[5] must include, when applicable--

(1) The deep-dose equivalent to the whole body, lens dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;

(2) The estimated intake of radionuclides (see § 20.1202);

(3) The committed effective dose equivalent assigned to the intake of radionuclides;

(4) The specific information used to assess the committed effective dose equivalent pursuant to § 20.1204(a) and (c), and when required by § 20.1502;

(5) The total effective dose equivalent when required by § 20.1202; and

(6) The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.

(b) *Recordkeeping frequency*. The licensee shall make entries of the records specified in paragraph (a) of this section at least annually.

(c) *Recordkeeping format*. The licensee shall maintain the records specified in paragraph (a) of this section on NRC Form 5, in accordance with the instructions for NRC Form 5, or in clear and legible records containing all the information required by NRC Form 5.

(d) *Privacy protection*. The records required under this section should be protected from public disclosure because of their personal privacy nature. These records are protected by most State privacy laws and, when transferred to the NRC, are protected by the Privacy Act of 1974, Public Law 93-579, 5 U.S.C. 552a, and the Commission's regulations in 10 CFR part 9.

(e) The licensee shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy shall also be kept on file, but may be maintained separately from the dose records.

(f) The licensee shall retain the required form or record until the Commission terminates each pertinent license requiring this record. This includes records required under the standards for protection against radiation in effect prior to January 1, 1994.

[56 FR 23404, May 21, 1991, as amended at 60 FR 20186, Apr. 25, 1995; 63 FR 39483, July 23, 1998]

[5] Assessments of dose equivalent and records made using units in effect before the licensee's adoption of this part need not be changed.

§ 20.2107 Records of dose to individual members of the public.

(a) Each licensee shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (see § 20.1301).

(b) The licensee shall retain the records required by paragraph (a) of this section until the Commission terminates each pertinent license requiring the record.

§ 20.2108 Records of waste disposal.

(a) Each licensee shall maintain records of the disposal of licensed materials made under §§ 20.2002, 20.2003, 20.2004, 20.2005, 10 CFR part 61 and disposal by burial in soil, including burials authorized before January 28, 1981.[6]

(b) The licensee shall retain the records required by paragraph (a) of this section until the

Commission terminates each pertinent license requiring the record. Requirements for disposition of these records, prior to license termination, are located in §§ 30.51, 40.61, 70.51, and 72.80 for activities licensed under these parts.

[56 FR 23404, May 21, 1991, as amended at 60 FR 20186, Apr. 25, 1995; 61 FR 24673, May 16, 1996]

[6] A previous § 20.304 permitted burial of small quantities of licensed materials in soil before January 28, 1981, without specific Commission authorization.

§ 20.2109 [Reserved]

§ 20.2110 Form of records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

Subpart M--Reports

Source: 56 FR 23406, May 21, 1991, unless otherwise noted.

§ 20.2201 Reports of theft or loss of licensed material.

(a) *Telephone reports.* (1) Each licensee shall report by telephone as follows:

(i) Immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in appendix C to part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas; or

(ii) Within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in appendix C to part 20 that is still missing at this time.

(2) Reports must be made as follows:

(i) Licensees having an installed Emergency Notification System shall make the reports to the NRC Operations Center in accordance with § 50.72 of this chapter, and

(ii) All other licensees shall make reports by telephone to the department of environmental quality~~NRC Operations Center (301) 816-5100~~.

(b) *Written reports*. (1) Each licensee required to make a report under paragraph (a) of this section

shall, within 30 days after making the telephone report, make a written report setting forth the following information:

(i) A description of the licensed material involved, including kind, quantity, and chemical and physical form; and

(ii) A description of the circumstances under which the loss or theft occurred; and

(iii) A statement of disposition, or probable disposition, of the licensed material involved; and

(iv) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

(v) Actions that have been taken, or will be taken, to recover the material; and

(vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

(2) Reports must be made as follows:

(i) For holders of an operating license for a nuclear power plant, the events included in paragraph (b) of this section must be reported in accordance with the procedures described in § 50.73(b), (c), (d), (e), and (g) of this chapter and must include the information required in paragraph (b)(1) of this section, and

(ii) All other licensees shall make reports to the Administrator of the appropriate NRC Regional Office listed in appendix D to part 20.

(c) A duplicate report is not required under paragraph (b) of this section if the licensee is also required to submit a report pursuant to §§ 30.55(c), 40.64(c), 50.72, 50.73, 70.52, 73.27(b), 73.67(e)(3)(vii), 73.67(g)(3)(iii), 73.71, or § 150.19(c) of this chapter.

(d) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

(e) The licensee shall prepare any report filed with the Commission pursuant to this section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

[56 FR 23406, May 21, 1991, as amended at 58 FR 69220, Dec. 30, 1993; 60 FR 20186, Apr. 25, 1995; 66 FR 64738, Dec. 14, 2001; 67 FR 3585, Jan. 25, 2002; 85 FR 65656, Oct. 16, 2020]

§ 20.2202 Notification of incidents.

(a) Immediate notification. Notwithstanding any other requirements for notification, each licensee shall immediately report any event involving byproduct, source, or special nuclear material possessed by the licensee that may have caused or threatens to cause any of the following conditions--

(1) An individual to receive--

(i) A total effective dose equivalent of 25 rems (0.25 Sv) or more; or

(ii) A lens dose equivalent of 75 rems (0.75 Sv) or more; or

(iii) A shallow-dose equivalent to the skin or extremities of 250 rads (2.5 Gy) or more; or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the annual limit on intake (the provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

(b) Twenty-four hour notification. Each licensee shall, within 24 hours of discovery of the event, report any event involving loss of control of licensed material possessed by the licensee that may have caused, or threatens to cause, any of the following conditions:

(1) An individual to receive, in a period of 24 hours--

(i) A total effective dose equivalent exceeding 5 rems (0.05 Sv); or

(ii) A lens dose equivalent exceeding 15 rems (0.15 Sv); or

(iii) A shallow-dose equivalent to the skin or extremities exceeding 50 rems (0.5 Sv); or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake (the provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

(c) The licensee shall prepare any report filed with the Commission pursuant to this section so that names of individuals who have received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.

(d) Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees having an installed Emergency Notification System shall make the reports required by paragraphs (a) and (b) of this section to the NRC Operations Center in accordance with 10 CFR 50.72; and

(2) All other licensees shall make the reports required by paragraphs (a) and (b) of this section by telephone to the department of environmental quality~~NRC Operations Center (301) 816-5100~~.

(e) The provisions of this section do not include doses that result from planned special exposures, that are within the limits for planned special exposures, and that are reported under § 20.2204.

[56 FR 23406, May 21, 1991, as amended at 56 FR 40766, Aug. 16, 1991; 57 FR 57879, Dec. 8,

1992; 59 FR 14086, Mar. 25, 1994; 63 FR 39483, July 23, 1998; 85 FR 65656, Oct. 16, 2020]

§ 20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

(a) *Reportable events*. In addition to the notification required by § 20.2202, each licensee shall submit a written report within 30 days after learning of any of the following occurrences:

(1) Any incident for which notification is required by § 20.2202; or

(2) Doses in excess of any of the following:

(i) The occupational dose limits for adults in § 20.1201; or

(ii) The occupational dose limits for a minor in § 20.1207; or

(iii) The limits for an embryo/fetus of a declared pregnant woman in § 20.1208; or

(iv) The limits for an individual member of the public in § 20.1301; or

(v) Any applicable limit in the license; or

(vi) The ALARA constraints for air emissions established under § 20.1101(d); or

(3) Levels of radiation or concentrations of radioactive material in--

(i) A restricted area in excess of any applicable limit in the license; or

(ii) An unrestricted area in excess of 10 times any applicable limit set forth in this part or in the license (whether or not involving exposure of any individual in excess of the limits in § 20.1301); or

(4) For licensees subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR part 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(b) *Contents of reports*. (1) Each report required by paragraph (a) of this section must describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(i) Estimates of each individual's dose; and

(ii) The levels of radiation and concentrations of radioactive material involved; and

(iii) The cause of the elevated exposures, dose rates, or concentrations; and

(iv) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

(2) Each report filed pursuant to paragraph (a) of this section must include for each occupationally overexposed[1] individual: the name, Social Security account number, and date of birth. The report must be prepared so that this information is stated in a separate and detachable part of the report and must be clearly labeled "Privacy Act Information: Not for Public Disclosure."

(c) For holders of an operating license or a combined license for a nuclear power plant, the occurrences included in paragraph (a) of this section must be reported in accordance with the procedures described in §§ 50.73(b), (c), (d), (e), and (g) of this chapter, and must include the information required by paragraph (b) of this section. Occurrences reported in accordance with § 50.73 of this chapter need not be reported by a duplicate report under paragraph (a) of this section.

(d) All licensees, other than those holding an operating license or a combined license for a nuclear power plant, who make reports under paragraph (a) of this section shall submit the report in writing either by mail addressed to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555–0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, Electronic Information Exchange, or CD–ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/esubmittals.html*, by calling (301) 415–0439, by e-mail to *EIE@nrc.gov*, or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. A copy should be sent to the appropriate NRC Regional Office listed in appendix D to this part.

[56 FR 23406, May 21, 1991, as amended at 60 FR 20186, Apr. 25, 1995; 61 FR 65127, Dec. 10, 1996; 68 FR 14309, Mar. 25, 2003; 68 FR 58802, Oct. 10, 2003; 70 FR 69421, Nov. 16, 2005; 72 FR 33386, Jun. 18, 2007; 72 FR 49486, Aug. 28, 2007]

[1] With respect to the limit for the embryo-fetus (§ 20.1208), the identifiers should be those of the declared pregnant woman.

§ 20.2204 Reports of planned special exposures.

The licensee shall submit a written report to the Administrator of the appropriate NRC Regional Office listed in appendix D to part 20 within 30 days following any planned special exposure conducted in accordance with § 20.1206, informing the Commission that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by § 20.2105.

[56 FR 23406, May 21, 1991, as amended at 60 FR 20186, Apr. 25, 1995]

440.250 [Amended]

§ 20.2205 Reports to individuals of exceeding dose limits.

When a licensee is required by §§ 20.2203 or 20.2204 to report to the Commission any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide the individual a report on his or her exposure

data included in the report to Commission. This report must be transmitted no later than the transmittal to the Commission.

[60 FR 36043, July 13, 1995; 72 FR 68059, Dec. 4, 2007]

§ 20.2206 Reports of individual monitoring.

(a) This section applies to each person licensed by the Commission to--

(1) Operate a nuclear reactor designed to produce electrical or heat energy pursuant to § 50.21(b) or § 50.22 of this chapter or a testing facility as defined in § 50.2 of this chapter; or

(2) Possess or use byproduct material for purposes of radiography pursuant to Parts 30 and 34 of this chapter; or

(3) Possess or use at any one time, for purposes of fuel processing, fabricating, or reprocessing, special nuclear material in a quantity exceeding 5,000 grams of contained uranium-235, uranium-233, or plutonium, or any combination thereof pursuant to part 70 of this chapter; or

(4) Possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter; or

(5) Possess spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to part 72 of this chapter; or

(6) Receive radioactive waste from other persons for disposal under part 61 of this chapter; or

(7) Possess or use at any time, for processing or manufacturing for distribution pursuant to parts 30, 32, 33 or 35 of this chapter, byproduct material in quantities exceeding any one of the following quantities:

Radionuclide	Quantity of radionuclide[1] in curies
Cesium-137	1
Cobalt-60	1
Gold-198	100
Iodine-131	1
Iridium-192	10
Krypton-85	1,000
Promethium-147	10
Techetium-99m	1,000

[1] The Commission may require as a license condition, or by rule, regulation, or order pursuant to § 20.2302, reports from licensees who are licensed to use radionuclides not on this list, in quantities

sufficient to cause comparable radiation levels.

(b) Each licensee in a category listed in paragraph (a) of this section shall submit an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by § 20.1502 during that year. The licensee may include additional data for individuals for whom monitoring was provided but not required. The licensee shall use Form NRC 5 or electronic media containing all the information required by Form NRC 5.

(c) The licensee shall file the report required by § 20.2206(b), covering the preceding year, on or before April 30 of each year. The licensee shall submit the report to the REIRS Project Manager by an appropriate method listed in § 20.1007 or via the REIRS Web site at *http://www.reirs.com*.

[56 FR 23406, May 21, 1991, as amended at 56 FR 32072, July 15, 1991; 66 FR 5578, Nov. 2, 2001; 68 FR 58802, Oct. 10, 2003]

§ 20.2207 Reports of transactions involving nationally tracked sources.

Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in paragraphs (a) through (e) of
this section for each type of transaction.

(a) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking
Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source;

(4) The radioactive material in the source;

(5) The initial source strength in becquerels (curies) at the time of manufacture; and

(6) The manufacture date of the source.

(b) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The name and license number of the recipient facility and the shipping address;

(4) The manufacturer, model, and serial number of the source or, if not available, other information

to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The shipping date;

(9) The estimated arrival date; and

(10) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

(c) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The name, address, and license number of the person that provided the source;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The date of receipt; and

(9) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

(d) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(4) The radioactive material in the source;

(5) The initial or current source strength in becquerels (curies);

(6) The date for which the source strength is reported;

(7) The disassemble date of the source.

(e) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The waste manifest number;

(4) The container identification with the nationally tracked source.

(5) The date of disposal; and

(6) The method of disposal.

(f) The reports discussed in paragraphs (a) through (e) of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

(1) The on-line National Source Tracking System;

(2) Electronically using a computer readable format;

(3) By facsimile;

(4) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

(5) By telephone with follow-up by facsimile or mail.

(g) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs (a) through (e) of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking

System is correct.

~~(h) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified by paragraph (f)(1) through (f)(4) of this section. The initial inventory report must include the following information:~~

~~(1) The name, address, and license number of the reporting licensee;~~

~~(2) The name of the individual preparing the report;~~

~~(3) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;~~

~~(4) The radioactive material in the sealed source;~~

~~(5) The initial or current source strength in becquerels (curies); and~~

~~(6) The date for which the source strength is reported.~~

[72 FR 59163, Oct. 19, 2007; 86 FR 43397, Aug. 9, 2021; 86 FR 47209, Aug. 24, 2021 (corrected version)]

Subpart N--Exemptions and Additional Requirements

Source: 56 FR 23408, May 21, 1991, unless otherwise noted.

§ 20.2301 Applications for exemptions.

The Commission may, upon application by a licensee or upon its own initiative, grant an exemption from the requirements of the regulations in this part if it determines the exemption is authorized by law and would not result in undue hazard to life or property.

§ 20.2302 Additional requirements.

The Commission may, by rule, regulation, or order, impose requirements on a licensee, in addition to those established in the regulations in this part, as it deems appropriate or necessary to protect health or to minimize danger to life or property.

Subpart O--Enforcement

§ 20.2401 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107 or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section; and

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

[56 FR 23408, May 21, 1991; 56 FR 61352, Dec. 3, 1991, as amended at 57 FR 55071, Nov. 24, 1992]

§ 20.2402 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in §§ 20.1001 through 20.2402 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) this section.

(b) The regulations in §§ 20.1001 through 20.2402 that are not issued under Sections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 20.1001, 20.1002, 20.1003, 20.1004, 20.1005, 20.1006, 20.1007, 20.1008, 20.1009, 20.1405, 20.1704, 20.1903, 20.1905, 20.2002, 20.2007, 20.2301, 20.2302, 20.2401, and 20.2402.

[57 FR 55071, Nov. 24, 1992]

Appendix A to Part 20--Assigned Protection Factors for Respirators[a]

	Operating mode	Assigned Protection Factors
I. Air Purifying Respirators [Particulate[b]		

only][c]:		
Filtering facepiece disposable[d]	Negative Pressure	([d])
Facepiece, half [e]	Negative Pressure	10
Facepiece, full	Negative Pressure	100
Facepiece, half	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirators	1000
Helmet/hood	Powered air-purifying respirators	1000
Facepiece, loose-fitting	Powered air-purifying respirators	25
II. Atmosphere supplying respirators [particulate, gases and vapors[f]]:		
1. Air-line respirator:		
Facepiece, half	Demand	10
Facepiece, half	Continuous Flow	50
Facepiece, half	Pressure Demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous Flow	1000
Facepiece, full	Pressure Demand	1000
Helmet/hood	Continuous Flow	1000
Facepiece, loose-fitting	Continuous Flow	25
Suit	Continuous Flow	([g])
2. Self-contained breathing Apparatus (SCBA):		
Facepiece, full	Demand	[h]100
Facepiece, full	Pressure Demand	[i]10,000
Facepiece, full	Demand, Recirculating	[h]100
Facepiece, full	Positive Pressure Recirculating	[i]10,000
III. Combination Respirators:		
Any combination of air-purifying and atmosphere-supplying respirators	Assigned protection factor for type and mode of operation as listed above.	

[a] These assigned protection factors apply only in a respiratory protection program that meets the requirements of this Part. They are applicable only to airborne radiological hazards and may not be

appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table 1, Column 3 of Appendix B to Part 20 are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

[b] Air purifying respirators with APF <100 must be equipped with particulate filters that are at least 95 percent efficient. Air purifying respirators with APF = 100 must be equipped with particulate filters that are at least 99 percent efficient. Air purifying respirators with APFs >100 must be equipped with particulate filters that are at least 99.97 percent efficient.

[c] The licensee may apply to the Commission for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

[d] Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in § 20.1703 apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

[e] Under-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient and all other requirements of this Part are met.

[f] The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

[g] No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met (i.e., § 20.1703).

[h] The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).

[i] This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted

exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

[64 FR 54558, Oct. 7, 1999; 64 FR 55524, Oct. 13, 1999]

Appendix B to Part 20--Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage

Introduction

For each radionuclide Table 1 indicates the chemical form which is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 μm and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times of less than 10 days for D, for W from 10 to 100 days, and for Y greater than 100 days. The class (D, W, or Y) given in the column headed "Class" applies only to the inhalation ALIs and DACs given in Table 1, columns 2 and 3. Table 2 provides concentration limits for airborne and liquid effluents released to the general environment. Table 3 provides concentration limits for discharges to sanitary sewer systems.

Notation

The values in Tables 1, 2, and 3 are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of $6x10^{-2}$ or 0.06, 6E+2 represents $6x10^{2}$ or 600, and 6E+0 represents $6x10^{0}$ or 6.

Table 1 "Occupational"

Note that the columns in Table 1, of this appendix captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in this appendix are the annual intakes of a given radionuclide by "Reference Man" which would result in either (1) a committed effective dose equivalent of 5 rems (stochastic ALI) or (2) a committed dose equivalent of 50 rems to an organ or tissue (non-stochastic ALI). The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of 5 rems. The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, w_T. This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of w_T are listed under the definition of weighting factor in § 20.1003. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of w_T=0.06 is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following parts of the GI tract--stomach, small intestine, upper large intestine,

and lower large intestine--are to be treated as four separate organs.

Note that the dose equivalents for extremities (hands and forearms, feet and lower legs), skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

When an ALI is defined by the stochastic dose limit, this value alone, is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. (Abbreviated organ or tissue designations are used: LLI wall = lower large intestine wall; St. wall = stomach wall; Blad wall = bladder wall; and Bone surf = bone surface.)

The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 50-rem dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose to that organ (not the effective dose). For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic ALIs (ALI_{ns}) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity (i.e., (intake (in μCi) of each radionuclide/ALI_{ns}) < 1.0). If there is an external deep dose equivalent contribution of H_d then this sum must be less than 1 - (H_d/50) instead of being < 1.0.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by: DAC=ALI(in μCi)/(2000 hours per working year x 60 minutes/hour x 2 x 10^4 ml per minute)=[ALI/2.4x10^9] μCi/ml, where 2x10^4 ml is the volume of air breathed per minute at work by "Reference Man" under working conditions of "light work."

The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. Derived air concentrations based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values relate to exposure to the single radionuclide named, but also include contributions from the in-growth of any daughter radionuclide produced in the body by the decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

The value of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external radiation (see § 20.1202). When an individual is exposed to radioactive materials which fall under several of the translocation classifications (i.e., Class D, Class W, or Class Y) of the same radionuclide, the exposure may be evaluated as if it were a mixture of different radionuclides.

It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radioisotopes. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

Table 2

The columns in Table 2 of this appendix captioned "Effluents," "Air," and "Water," are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of § 20.1302. The concentration values given in Columns 1 and 2 of Table 2 are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.05 rem (50 millirem or 0.5 millisieverts).

Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table 2. For this reason, the DAC and airborne effluent limits are not always proportional as was the case in appendix B to §§ 20.1-20.601.

The air concentration values listed in Table 2, Column 1, were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4×10^9ml, relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 5-rem annual occupational dose limit to the 0.1-rem limit for members of the public, a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of 2 to adjust the occupational values (derived for adults) so that they are applicable to other age groups.

For those radionuclides for which submersion (external dose) is limiting, the occupational DAC in Table 1, Column 3, was divided by 219. The factor of 219 is composed of a factor of 50, as described above, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age considerations is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^7. The factor of 7.3×10^7 (ml) includes the following components: the factors of 50 and 2 described above and a factor of 7.3×10^5 (ml) which is the annual water intake of "Reference Man."

Note 2 of this appendix provides groupings of radionuclides which are applicable to unknown mixtures of radionuclides. These groupings (including occupational inhalation ALIs and DACs, air and water effluent concentrations and sewerage) require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded either from knowledge of the radionuclide composition of the source or from actual measurements.

Table 3 "Sewer Disposal"

The monthly average concentrations for release to sanitary sewers are applicable to the provisions in § 20.2003. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^6(ml). The factor of 7.3×10^6(ml) is composed of a factor of 7.3×10^5(ml), the annual water intake by "Reference Man," and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a reference man during a year, would result in a committed effective dose equivalent of 0.5 rem.

List of Elements

Name	Atomic	
	Symbol	No.
Actinium	Ac	89
Aluminum	Al	13
Americium	Am	95
Antimony	Sb	51
Argon	Ar	18
Arsenic	As	33
Astatine	At	85
Barium	Ba	56
Berkelium	Bk	97
Beryllium	Be	4
Bismuth	Bi	83
Bromine	Br	35
Cadmium	Cd	48
Calcium	Ca	20
Californium	Cf	98
Carbon	C	6
Cerium	Ce	58
Cesium	Cs	55
Chlorine	Cl	17
Chromium	Cr	24
Cobalt	Co	27
Copper	Cu	29
Curium	Cm	96
Dysprosium	Dy	66
Einsteinium	Es	99

Erbium	Er	68
Europium	Eu	63
Femium	Fm	100
Fluorine	F	9
Francium	Fr	87
Gadolinium	Gd	64
Gallium	Ga	31
Germanium	Ge	32
Gold	Au	79
Hafniim	Hf	72
Holmium	Ho	67
Hydrogen	H	1
Indium	In	49
Iodine	I	53
Iridium	Ir	77
Iron	Fe	26
Krypton	Kr	36
Lanthanum	La	57
Lead	Pb	82
Lutetium	Lu	71
Magnesium	Mg	12
Manganese	Mn	25
Mendelevium	Md	101
Mercury	Hg	80
Molybdenum	Mo	42
Neodymium	Nd	60
Neptunium	Np	93
Nickel	Ni	28
Niobium	Nb	41
Nitrogen	N	7
Osmium	Os	76
Oxygen	O	8
Palladium	Pd	46
Phosphorus	P	15

Platinum	Pt	78
Plutonium	Pu	94
Polonium	Po	84
Potassium	K	19
Praseodymium	Pr	59
Promethium	Pm	61
Protactinium	Pa	91
Radium	Ra	88
Radon	Rn	86
Rhenium	Re	75
Rhodium	Rh	45
Rubidium	Rb	37
Ruthenium	Ru	44
Samarium	Sm	62
Scandium	Sc	21
Selenium	Se	34
Silicon	Si	14
Silver	Ag	47
Sodium	Na	11
Strontium	Sr	38
Sulfur	S	16
Tantaium	Ta	73
Technetium	Tc	43
Tellurium	Te	52
Terbium	Tb	65
Thallium	Tl	81
Thorium	Th	90
Thulium	Tm	69
Tin	Sn	50
Titanium	Ti	22
Tungsten	W	74
Uranium	U	92
Vanadium	V	23
Xenon	Xe	54

Yterbium	Yb	70
Yttrium	Y	39
Zinc	Zn	30
Zirconium	Zr	40

[56 FR 23409, May 21, 1991; 56 FR 61352, Dec. 3, 1991, as amended at 57 FR 57879, Dec. 8, 1992. Redesignated at 58 FR 67659, Dec. 22, 1993; 71 FR 15007, Mar. 27, 2006; 72 FR 55922, Oct. 1, 2007]

Appendix C to Part 20--Quantities[1] of Licensed Material Requiring Labeling

Radionuclide	Abbreviation	Quantity (μCi)
Hydrogen-3	H-3	1,000
Beryllium-7	Be-7	1,000
Beryllium-10	Be-10	1
Carbon-11	C-11	1,000
Carbon-14	C-14	100
Fluorine-18	F-18	1,000
Sodium-22	Na-22	10
Sodium-24	Na-24	100
Magnesium-28	Mg-28	100
Aluminum-26	Al-26	10
Silicon-31	Si-31	1,000
Silicon-32	Si-32	1
Phosphorus-32	P-32	10
Phosphorus-33	P-33	100
Sulfur-35	S-35	100
Chlorine-36	Cl-36	10
Chlorine-38	Cl-38	1,000
Chlorine-39	Cl-39	1,000
Argon-39	Ar-39	1,000
Argon-41	Ar-41	1,000
Potassium-40	K-40	100
Potassium-42	K-42	1,000
Potassium-43	K-43	1,000
Potassium-44	K-44	1,000

Potassium-45	K-45	1,000
Calcium-41	Ca-41	100
Calcium-45	Ca-45	100
Calcium-47	Ca-47	100
Scandium-43	Sc-43	1,000
Scandium-44m	Sc-44m	100
Scandium-44	Sc-44	100
Scandium-46	Sc-46	10
Scandium-47	Sc-47	100
Scandium-48	Sc-48	100
Scandium-49	Sc-49	1,000
Titanium-44	Ti-44	1
Titanium-45	Ti-45	1,000
Vanadium-47	V-47	1,000
Vanadium-48	V-48	100
Vanadium-49	V-49	1,000
Chromium-48	Cr-48	1,000
Chromium-49	Cr-49	1,000
Chromium-51	Cr-51	1,000
Manganese-51	Mn-51	1,000
Manganese-52m	Mn-52m	1,000
Manganese-52	Mn-52	100
Manganese-53	Mn-53	1,000
Manganese-54	Mn-54	100
Manganese-56	Mn-56	1,000
Iron-52	Fe-52	100
Iron-55	Fe-55	100
Iron-59	Fe-59	10
Iron-60	Fe-60	1
Cobalt-55	Co-55	100
Cobalt-56	Co-56	10
Cobalt-57	Co-57	100
Cobalt-58m	Co-58m	1,000
Cobalt-58	Co-58	100

Cobalt-60m	Co-60m	1,000
Cobalt-60	Co-60	1
Cobalt-61	Co-61	1,000
Cobalt-62m	Co-62m	1,000
Nickel-56	Ni-56	100
Nickel-57	Ni-57	100
Nickel-59	Ni-59	100
Nickel-63	Ni-63	100
Nickel-65	Ni-65	1,000
Nickel-66	Ni-66	10
Copper-60	Cu-60	1,000
Copper-61	Cu-61	1,000
Copper-64	Cu-64	1,000
Copper-67	Cu-67	1,000
Zinc-62	Zn-62	100
Zinc-63	Zn-63	1,000
Zinc-65	Zn-65	10
Zinc-69m	Zn-69m	100
Zinc-69	Zn-69	1,000
Zinc-71m	Zn-71m	1,000
Zinc-72	Zn-72	100
Gallium-65	Ga-65	1,000
Gallium-66	Ga-66	100
Gallium-67	Ga-67	1,000
Gallium-68	Ga-68	1,000
Gallium-70	Ga-70	1,000
Gallium-72	Ga-72	100
Gallium-73	Ga-73	1,000
Germanium-66	Ge-66	1,000
Germanium-67	Ge-67	1,000
Germanium-68	Ge-68	10
Germanium-69	Ge-69	1,000
Germanium-71	Ge-71	1,000
Germanium-75	Ge-75	1,000

Germanium-77	Ge-77	1,000
Germanium-78	Ge-78	1,000
Arsenic-69	As-69	1,000
Arsenic-70	As-70	1,000
Arsenic-71	As-71	100
Arsenic-72	As-72	100
Arsenic-73	As-73	100
Arsenic-74	As-74	100
Arsenic-76	As-76	100
Arsenic-77	As-77	100
Arsenic-78	As-78	1,000
Selenium-70	Se-70	1,000
Selenium-73m	Se-73m	1,000
Selenium-73	Se-73	100
Selenium-75	Se-75	100
Selenium-79	Se-79	100
Selenium-81m	Se-81m	1,000
Selenium-81	Se-81	1,000
Selenium-83	Se-83	1,000
Bromine-74m	Br-74m	1,000
Bromine-74	Br-74	1,000
Bromine-75	Br-75	1,000
Bromine-76	Br-76	100
Bromine-77	Br-77	1,000
Bromine-80m	Br-80m	1,000
Bromine-80	Br-80	1,000
Bromine-82	Br-82	100
Bromine-83	Br-83	1,000
Bromine-84	Br-84	1,000
Krypton-74	Kr-74	1,000
Krypton-76	Kr-76	1,000
Krypton-77	Kr-77	1,000
Krypton-79	Kr-79	1,000
Krypton-81	Kr-81	1,000

Krypton-83m	Kr-83m	1,000
Krypton-85m	Kr-85m	1,000
Krypton-85	Kr-85	1,000
Krypton-87	Kr-87	1,000
Krypton-88	Kr-88	1,000
Rubidium-79	Rb-79	1,000
Rubidium-81m	Rb-81m	1,000
Rubidium-81	Rb-81	1,000
Rubidium-82m	Rb-82m	1,000
Rubidium-83	Rb-83	100
Rubidium-84	Rb-84	100
Rubidium-86	Rb-86	100
Rubidium-87	Rb-87	100
Rubidium-88	Rb-88	1,000
Rubidium-89	Rb-89	1,000
Strontium-80	Sr-80	100
Strontium-81	Sr-81	1,000
Strontium-83	Sr-83	100
Strontium-85m	Sr-85m	1,000
Strontium-85	Sr-85	100
Strontium-87m	Sr-87m	1,000
Strontium-89	Sr-89	10
Strontium-90	Sr-90	0.1
Strontium-91	Sr-91	100
Strontium-92	Sr-92	100
Yttrium-86m	Y-86m	1,000
Yttrium-86	Y-86	100
Yttrium-87	Y-87	100
Yttrium-88	Y-88	10
Yttrium-90m	Y-90m	1,000
Yttrium-90	Y-90	10
Yttrium-91m	Y-91m	1,000
Yttrium-91	Y-91	10
Yttrium-92	Y-92	100

Yttrium-93	Y-93	100
Yttrium-94	Y-94	1,000
Yttrium-95	Y-95	1,000
Zirconium-86	Zr-86	100
Zirconium-88	Zr-88	10
Zirconium-89	Zr-89	100
Zirconium-93	Zr-93	1
Zirconium-95	Zr-95	10
Zirconium-97	Zr-97	100
Niobium-88	Nb-88	1,000
Niobium-89m (66 min)	Nb-89m	1,000
Niobium-89 (122 min)	Nb-89	1,000
Niobium-89	Nb-89	1,000
Niobium-90	Nb-90	100
Niobium-93m	Nb-93m	10
Niobium-94	Nb-94	1
Niobium-95m	Nb-95m	100
Niobium-95	Nb-95	100
Niobium-96	Nb-96	100
Niobium-97	Nb-97	1,000
Niobium-98	Nb-98	1,000
Molybdenum-90	Mo-90	100
Molybdenum-93m	Mo-93m	100
Molybdenum-93	Mo-93	10
Molybdenum-99	Mo-99	100
Molybdenum-101	Mo-101	1,000
Technetium-93m	Tc-93m	1,000
Technetium-93	Tc-93	1,000
Technetium-94m	Tc-94m	1,000
Technetium-94	Tc-94	1,000
Technetium-96m	Tc-96	1,000
Technetium-96	Tc-96	100
Technetium-97m	Tc-97m	100
Technetium-97	Tc-97	1,000

Technetium-98	Tc-98	10
Technetium-99m	Tc-99m	1,000
Technetium-99	Tc-99	100
Technetium-101	Tc-101	1,000
Technetium-104	Tc-104	1,000
Ruthenium-94	Ru-94	1,000
Ruthenium-97	Ru-97	1,000
Ruthenium-103	Ru-103	100
Ruthenium-105	Ru-105	1,000
Ruthenium-106	Ru-106	1
Rhodium-99m	Rh-99m	1,000
Rhodium-99	Rh-99	100
Rhodium-100	Rh-100	100
Rhodium-101m	Rh-101m	1,000
Rhodium-101	Rh-101	10
Rhodium-102m	Rh-102m	10
Rhodium-102	Rh-102	10
Rhodium-103m	Rh-103m	1,000
Rhodium-105	Rh-105	100
Rhodium-106m	Rh-106m	1,000
Rhodium-107	Rh-107	1,000
Palladium-100	Pd-100	100
Palladium-101	Pd-101	1,000
Palladium-103	Pd-103	100
Palladium-107	Pd-107	10
Palladium-109	Pd-109	100
Silver-102	Ag-102	1,000
Silver-103	Ag-103	1,000
Silver-104m	Ag-104m	1,000
Silver-104	Ag-104	1,000
Silver-105	Ag-105	100
Silver-106m	Ag-106m	100
Silver-106	Ag-106	1,000
Silver-108m	Ag-108m	1

Silver-110m	Ag-110m	10
Silver-111	Ag-111	100
Silver-112	Ag-112	100
Silver-115	Ag-115	1,000
Cadmium-104	Cd-104	1,000
Cadmium-107	Cd-107	1,000
Cadmium-109	Cd-109	1
Cadmium-113m	Cd-113m	0.1
Cadmium-113	Cd-113	100
Cadmium-115m	Cd-115m	10
Cadmium-115	Cd-115	100
Cadmium-117m	Cd-117m	1,000
Cadmium-117	Cd-117	1,000
Indium-109	In-109	1,000
Indium-110 (69.1 min.)	In-110	1,000
Indium-110 (4.9h)	In-110	1,000
Indium-111	In-111	100
Indium-112	In-112	1,000
Indium-113m	In-113m	1,000
Indium-114m	In-114m	10
Indium-115m	In-115m	1,000
Indium-115	In-115	100
Indium-116m	In-116m	1,000
Indium-117m	In-117m	1,000
Indium-117	In-117	1,000
Indium-119m	In-119m	1,000
Tin-110	Sn-110	100
Tin-111	Sn-111	1,000
Tin-113	Sn-113	100
Tin-117m	Sn-117m	100
Tin-119m	Sn-119m	100
Tin-121m	Sn-121m	100
Tin-121	Sn-121	1,000
Tin-123m	Sn-123m	1,000

Tin-123	Sn-123	10
Tin-125	Sn-125	10
Tin-126	Sn-126	10
Tin-127	Sn-127	1,000
Tin-128	Sn-128	1,000
Antimony-115	Sb-115	1,000
Antimony-116m	Sb-116m	1,000
Antimony-116	Sb-116	1,000
Antimony-117	Sb-117	1,000
Antimony-118m	Sb-118m	1,000
Antimony-119	Sb-119	1,000
Antimony-120 (16 min.)	Sb-120	1,000
Antimony-120 (5.76d)	Sb-120	100
Antimony-122	Sb-122	100
Antimony-124m	Sb-124m	1,000
Antimony-124	Sb-124	10
Antimony-125	Sb-125	100
Antimony-126m	Sb-126m	1,000
Antimony-126	Sb-126	100
Antimony-127	Sb-127	100
Antimony-128 (10.4 min.)	Sb-128	1,000
Antimony-128 (9.01h)	Sb-128	100
Antimony-129	Sb-129	100
Antimony-130	Sb-130	1,000
Antimony-131	Sb-131	1,000
Tellurium-116	Te-116	1,000
Tellurium-121m	Te-121m	10
Tellurium-121	Te-121	100
Tellurium-123m	Te-123m	10
Tellurium-123	Te-123	100
Tellurium-125m	Te-125m	10
Tellurium-127m	Te-127m	10
Tellurium-127	Te-127	1,000
Tellurium-129m	Te-129m	10

Tellurium-129	Te-129	1,000
Tellurium-131m	Te-131m	10
Tellurium-131	Te-131	100
Tellurium-132	Te-132	10
Tellurium-133m	Te-133m	100
Tellurium-133	Te-133	1,000
Tellurium-134	Te-134	1,000
Iodine-120m	I-120m	1,000
Iodine-120	I-120	100
Iodine-121	I-121	1,000
Iodine-123	I-123	100
Iodine-124	I-124	10
Iodine-125	I-125	1
Iodine-126	I-126	1
Iodine-128	I-128	1,000
Iodine-129	I-129	1
Iodine-130	I-130	10
Iodine-131	I-131	1
Iodine-132m	I-132m	100
Iodine-132	I-132	100
Iodine-133	I-133	10
Iodine-134	I-134	1,000
Iodine-135	I-135	100
Xenon-120	Xe-120	1,000
Xenon-121	Xe-121	1,000
Xenon-122	Xe-122	1,000
Xenon-123	Xe-123	1,000
Xenon-125	Xe-125	1,000
Xenon-127	Xe-127	1,000
Xenon-129m	Xe-129m	1,000
Xenon-131m	Xe-131m	1,000
Xenon-133m	Xe-133m	1,000
Xenon-133	Xe-133	1,000
Xenon-135m	Xe-135m	1,000

Xenon-135	Xe-135	1,000
Xenon-138	Xe-138	1,000
Cesium-125	Cs-125	1,000
Cesium-127	Cs-127	1,000
Cesium-129	Cs-129	1,000
Cesium-130	Cs-130	1,000
Cesium-131	Cs-131	1,000
Cesium-132	Cs-132	100
Cesium-134m	Cs-134m	1,000
Cesium-134	Cs-134	10
Cesium-135m	Cs-135m	1,000
Cesium-135	Cs-135	100
Cesium-136	Cs-136	10
Cesium-137	Cs-137	10
Cesium-138	Cs-138	1,000
Barium-126	Ba-126	1,000
Barium-128	B-128	100
Barium-131m	Ba-131m	1,000
Barium-131	Ba-131	100
Barium-133m	Ba-133m	100
Barium-133	Ba-133	100
Barium-135m	Ba-135m	100
Barium-139	Ba-139	1,000
Barium-140	Ba-140	100
Barium-141	Ba-141	1,000
Barium-142	Ba-142	1,000
Lanthanum-131	La-131	1,000
Lanthanum-132	La-132	100
Lanthanum-135	La-135	1,000
Lanthanum-137	La-137	10
Lanthanum-138	La-138	100
Lanthanum-140	La-140	100
Lanthanum-141	La-141	100
Lanthanum-142	La-142	1,000

Lanthanum-143	La-143	1,000
Cerium-134	Ce-134	100
Cerium-135	Ce-135	100
Cerium-137m	Ce-137m	100
Cerium-137	Ce-137	1,000
Cerium-139	Ce-139	100
Cerium-141	Ce-141	100
Cerium-143	Ce-143	100
Cerium-144	Ce-144	1
Praseodymium-136	Pr-136	1,000
Praseodymium-137	Pr-137	1,000
Praseodymium-138m	Pe-138m	1,000
Praseodymium-139	Pe-139	1,000
Praseodymium-142m	Pe-142m	1,000
Praseodymium-142	Pe-142	100
Praseodymium-143	Pe-143	100
Praseodymium-144	Pe-144	1,000
Praseodymium-145	Pe-145	100
Praseodymium-147	Pe-147	1,000
Neodymium-136	Nd-136	1,000
Neodymium-138	Nd-138	100
Neodymium-139m	Nd-139m	1,000
Neodymium-139	Nd-139	1,000
Neodymium-141	Nd-141	1,000
Neodymium-147	Nd-147	100
Neodymium-149	Nd-149	1,000
Neodymium-151	Nd-151	1,000
Promethium-141	Pm-141	1,000
Promethium-143	Pm-143	100
Promethium-144	Pm-144	10
Promethium-145	Pm-145	10
Promethium-146	Pm-146	1
Promethium-147	Pm-147	10
Promethium-148m	Pm-148m	10

Promethium-148	Pm-148	10
Promethium-149	Pm-149	100
Promethium-150	Pm-150	1,000
Promethium-151	Pm-151	100
Samarium-141m	Sm-141m	1,000
Samarium-141	Sm-141	1,000
Samarium-142	Sm-142	1,000
Samarium-145	Sm-145	100
Samarium-146	Sm-146	1
Samarium-147	Sm-147	100
Samarium-151	Sm-151	10
Samarium-153	Sm-153	100
Samarium-155	Sm-155	1,000
Samarium-156	Sm-156	1,000
Europium-145	Eu-145	100
Europium-146	Eu-146	100
Europium-147	Eu-147	100
Europium-148	Eu-148	10
Europium-149	Eu-149	100
Europium-150 (12.62h)	Eu-150	100
Europium-150 (34.2y)	Eu-150	1
Europium-152m	Eu-152m	100
Europium-152	Eu-152	1
Europium-154	Eu-154	1
Europium-155	Eu-155	10
Europium-156	Eu-156	100
Europium-157	Eu-157	100
Europium-158	Eu-158	1,000
Gadolinium-145	Gd-145	1,000
Gadolinium-146	Gd-146	10
Gadolinium-147	Gd-147	100
Gadolinium-148	Gd-148	0.001
Gadolinium-149	Gd-149	100
Gadolinium-151	Gd-151	10

Gadolinium-152	Gd-152	100
Gadolinium-153	Gd-153	10
Gadolinium-159	Gd-159	100
Terbium-147	Tb-147	1,000
Terbium-149	Tb-149	100
Terbium-150	Tb-150	1,000
Terbium-151	Tb-151	100
Terbium-153	Tb-153	1,000
Terbium-154	Tb-154	100
Terbium-155	Tb-155	1,000
Terbium-156m (5.0h)	Tb-156m	1,000
Terbium-156m (24.4h)	Tb-156m	1,000
Terbium-156	Tb-156	100
Terbium-157	Tb-157	10
Terbium-158	Tb-158	1
Terbium-160	Tb-160	10
Terbium-161	Tb-161	100
Dysprosium-155	Dy-155	1,000
Dysprosium-157	Dy-157	1,000
Dysprosium-159	Dy-159	100
Dysprosium-165	Dy-165	1,000
Dysprosium-166	Dy-166	100
Holmium-155	Ho-155	1,000
Holmium-157	Ho-157	1,000
Holmium-159	Ho-159	1,000
Holmium-161	Ho-161	1,000
Holmium-162m	Ho-162m	1,000
Holmium-162	Ho-162	1,000
Holmium-164m	Hp-164m	1,000
Holmium-164	Ho-164	1,000
Holmium-166m	Ho-166m	1
Holmium-166	Ho-166	100
Holmium-167	Ho-167	1,000
Erbium-161	Er-161	1,000

Erbium-165	Er-165	1,000
Erbium-169	Er-169	100
Erbium-171	Er-171	100
Erbium-172	Er-172	100
Thulium-162	Tm-162	1,000
Thulium-166	Tm-166	100
Thulium-167	Tm-167	100
Thulium-170	Tm-170	10
Thulium-171	Tm-171	10
Thulium-172	Tm-172	100
Thulium-173	Tm-173	100
Thulium-175	Tm-175	1,000
Ytterbium-162	Yb-162	1,000
Ytterbium-166	Yb-166	100
Ytterbium-167	Yb-167	1,000
Ytterbium-169	Yb-169	100
Ytterbium-175	Yb-175	100
Ytterbium-177	Yb-177	1,000
Ytterbium-178	Yb-178	1,000
Lutetium-169	Lu-169	100
Lutetium-170	Lu-170	100
Lutetium-171	Lu-171	100
Lutetium-172	Lu-172	100
Lutetium-173	Lu-173	10
Lutetium-174m	Lu-174m	10
Lutetium-174	Lu-174	10
Lutetium-176m	Lu-176m	1,000
Lutetium-176	Lu-176	100
Lutetium-177m	Lu-177m	10
Lutetium-177	Lu-177	100
Lutetium-178m	Lu-178m	1,000
Lutetium-178	Lu-178	1,000
Lutetium-179	Lu-179	1,000
Hafnium-170	Hf-170	100

Hafnium-172	Hf-172	1
Hafnium-173	Hf-173	1,000
Hafnium-175	Hf-175	100
Hafnium-177m	Hf-177m	1,000
Hafnium-178m	Hf-178m	0.1
Hafnium-179m	Hf-179m	10
Hafnium-180m	Hf-180m	1,000
Hafnium-181	Hf-181	10
Hafnium-182m	Hf-182m	1,000
Hafnium-182	Hf-182	0.1
Hafnium-183	Hf-183	1,000
Hafnium-184	Hf-184	100
Tantalum-172	Ta-172	1,000
Tantalum-173	Ta-173	1,000
Tantalum-174	Ta-174	1,000
Tantalum-175	Ta-175	1,000
Tantalum-176	Ta-176	100
Tantalum-177	Ta-177	1,000
Tantalum-178	Ta-178	1,000
Tantalum-179	Ta-179	100
Tantalum-180m	Ta-180m	1,000
Tantalum-180	Ta-180	100
Tantalum-182m	Ta-182m	1,000
Tantalum-182	Ta-182	10
Tantalum-183	Ta-183	100
Tantalum-184	Ta-184	100
Tantalum-185	Ta-185	1,000
Tantalum-186	Ta-186	1,000
Tungsten-176	W-176	1,000
Tungsten-177	W-177	1,000
Tungsten-178	W-178	1,000
Tungsten-179	W-179	1,000
Tungsten-181	W-181	1,000
Tungsten-185	W-185	100

Tungsten-187	W-187	100
Tungsten-188	W-188	10
Rhenium-177	Re-177	1,000
Rhenium-178	Re-178	1,000
Rhenium-181	Re-181	1,000
Rhenium-182 (12.7h)	Re-182	1,000
Rhenium-182 (64.0h)	Re-182	100
Rhenium-184m	Re-184m	10
Rhenium-184	Re-184	100
Rhenium-186m	Re-186m	10
Rhenium-186	Re-186	100
Rhenium-187	Re-187	1,000
Rhenium-188m	Re-188m	1,000
Rhenium-188	Re-188	100
Rhenium-189	Re-189	100
Osmium-180	Os-180	1,000
Osmium-181	Os-181	1,000
Osmium-182	Os-182	100
Osmium-185	Os-185	100
Osmium-189m	Os-189m	1,000
Osmium-191m	Os-191m	1,000
Osmium-191	Os-191	100
Osmium-193	Os-193	100
Osmium-194	Os-194	1
Iridium-182	Ir-182	1,000
Iridium-184	Ir-184	1,000
Iridium-185	Ir-185	1,000
Iridium-186	Ir-186	100
Iridium-187	Ir-187	1,000
Iridium-188	Ir-188	100
Iridium-189	Ir-189	100
Iridium-190m	Ir-190m	1,000
Iridium-190	Ir-190	100
Iridium-192 (73.8d)	Ir-192	1

Iridium-192m (1.4 min.)	Ir-192m	10
Iridium-194m	Ir-194m	10
Iridium-194	Ir-194	100
Iridium-195m	Ir-195m	1,000
Iridium-195	Ir-95	1,000
Platinum-186	Pt-186	1,000
Platinum-188	Pt-188	100
Platinum-189	Pt-189	1,000
Platinum-191	Pt-191	100
Platinum-193m	Pt-193m	100
Platinum-193	Pt-193	1,000
Platinum-195m	Pt-195m	100
Platinum-197m	Pt-197m	1,000
Platinum-197	Pt-197	100
Platinum-199	Pt-199	1,000
Platinum-200	Pt-200	100
Gold-193	Au-193	1,000
Gold-194	Au-194	100
Gold-195	Au-195	10
Gold-198m	Au-198m	100
Gold-198	Au-198	100
Gold-199	Au-199	100
Gold-200m	Au-200m	100
Gold-200	Au-200	1,000
Gold-201	Au-201	1,000
Mercury-193m	Hg-193m	100
Mercury-193	Hg-193	1,000
Mercury-194	Hg-194	1
Mercury-195m	Hg-195m	100
Mercury-195	Hg-195	1,000
Mercury-197m	Hg-197m	100
Mercury-197	Hg-197	1,000
Mercury-199m	Hg-199m	1,000
Mercury-203	Hg-203	100

Thallium-194m	Tl-194m	1,000
Thallium-194	Tl-194	1,000
Thallium-195	Tl-195	1,000
Thallium-197	Tl-197	1,000
Thallium-198m	Tl-198m	1,000
Thallium-198	Tl-198	1,000
Thallium-199	Tl-199	1,000
Thallium-200	Tl-200	1,000
Thallium-201	Tl-201	1,000
Thallium-202	Tl-202	100
Thallium-204	Tl-204	100
Lead-195m	Pb-195m	1,000
Lead-198	Pb-198	1,000
Lead-199	Pb-199	1,000
Lead-200	Pb-200	100
Lead-201	Pb-201	1,000
Lead-202m	Pb-202m	1,000
Lead-202	Pb-202	10
Lead-203	Pb-2023	1,000
Lead-205	Pb-205	100
Lead-209	Pb-209	1,000
Lead-210	Pb-210	0.01
Lead-211	Pb-211	100
Lead-212	Pb-212	1
Lead-214	Pb-214	100
Bismuth-200	Bi-200	1,000
Bismuth-201	Bi-201	1,000
Bismuth-202	Bi-202	1,000
Bismuth-203	Bi-203	100
Bismuth-205	Bi-205	100
Bismuth-206	Bi-206	100
Bismuth-207	Bi-207	10
Bismuth-210m	Bi-210m	0.1
Bismuth-210	Bi-210	1

Bismuth-212	Bi-212	10
Bismuth-213	Bi-213	10
Bismuth-214	Bi-214	100
Polonium-203	Po-203	1,000
Polonium-205	Po-205	1,000
Polonium-207	Po-207	1,000
Polonium-210	Po-210	0.1
Astatine-207	At-207	100
Astatine-211	At-211	10
Radon-220	Rn-220	1
Radon-222	Rn-222	1
Francium-222	Fr-222	100
Francium-223	Fr-223	100
Radium-223	Ra-223	0.1
Radium-224	Ra-224	0.1
Radium-225	Ra-225	0.1
Radium-226	Ra-226	0.1
Radium-227	Ra-227	1,000
Radium-228	Ra-228	0.1
Actinium-224	Ac-224	1
Actinium-225	Ac-225	0.01
Actinium-226	Ac-226	0.1
Actinium-227	Ac-227	0.001
Actinium-228	Ac-228	1
Thorium-226	Th-226	10
Thorium-227	Th-227	0.01
Thorium-228	Th-228	0.001
Thorium-229	Th-229	0.001
Thorium-230	Th-230	0.001
Thorium-231	Th-231	100
Thorium-232	Th-232	100
Thorium-234	Th-234	10
Thorium-natural		100
Protactinium-227	Pa-227	10

Protactinium-228	Pa-228	1
Protactinium-230	Pa-230	0.01
Protactinium-231	Pa-231	0.001
Protactinium-232	Pa-232	1
Protactinium-233	Pa-233	100
Protactinium-234	Pa-234	100
Uranium-230	U-230	0.01
Uranium-231	U-231	100
Uranium-232	U-232	0.001
Uranium-233	U-233	0.001
Uranium-234	U-234	0.001
Uranium-235	U-235	0.001
Uranium-236	U-236	0.001
Uranium-237	U-237	100
Uranium-238	U-238	100
Uranium-239	U-239	1,000
Uranium-240	U-240	100
Uranium-natural		100
Neptunium-232	Np-232	100
Neptunium-233	Np-233	1,000
Neptunium-234	Np-234	100
Neptunium-235	Np-235	100
Neptunium-236 ($1.15x10^5$y)	Np-236	0.001
Neptunium-236 (22.5h)	Np-236	1
Neptunium-237	Np-237	0.001
Neptunium-238	Np-238	10
Neptunium-239	Np-239	100
Neptunium-240	Np-240	1,000
Plutonium-234	Pu-234	10
Plutonium-235	Pu-235	1,000
Plutonium-236	Pu-236	0.001
Plutonium-237	Pu-237	100
Plutonium-238	Pu-238	0.001
Plutonium-239	Pu-239	0.001

Plutonium-240	Pu-240	0.001
Plutonium-241	Pu-241	0.01
Plutonium-242	Pu-242	0.001
Plutonium-243	Pu-243	1,000
Plutonium-244	Pu-244	0.001
Plutonium-245	Pu-245	100
Americium-237	Am-237	1,000
Americium-238	Am-238	100
Americium-239	Am-239	1,000
Americium-240	Am-240	100
Americium-241	Am-241	0.001
Americium-242m	Am-242m	0.001
Americium-242	Am-242	10
Americium-243	Am-243	0.001
Americium-244m	Am-244m	100
Americium-244	Am-244	10
Americium-245	Am-245	1,000
Americium-246m	Am-246	1,000
Americium-246	Am-246	1,000
Curium-238	Cm-238	100
Curium-240	Cm-240	0.1
Curium-241	Cm-241	1
Curium-242	Cm-242	0.01
Curium-243	Cm-243	0.001
Curium-244	Cm-244	0.001
Curium-245	Cm-245	0.001
Curium-246	Cm-246	0.001
Curium-247	Cm-247	0.001
Curium-248	Cm-248	0.001
Curium-249	Cm-249	1,000
Berkelium-245	Bk-245	100
Berkelium-246	Bk-246	100
Berkelium-247	Bk-247	0.001
Berkelium-249	Bk-249	0.1

Berkelium-250	Bk-250	10
Californium-244	Cf-244	100
Californium-246	Cf-246	1
Californium-248	Cf-248	0.01
Californium-249	Cf-249	0.001
Californium-250	Cf-250	0.001
Californium-251	Cf-251	0.001
Californium-252	Cf-252	0.001
Californium-253	Cf-253	0.1
Californium-254	Cf-254	0.001
Any alpha emitting radionuclide not listed above or mixtures or alpha emitters of unknown composition		0.001
Einsteinium-250	Es-250	100
Einsteinium-251	Es-251	100
Einsteinium-253	Es-253	0.1
Einsteinium-254m	Es-254m	1
Einsteinium-254	Es-254	0.01
Fermium-252	Fm-252	1
Fermium-253	Fm-253	1
Fermium-254	Fm-254	10
Fermium-255	Fm-255	1
Fermium-257	Fm-257	0.01
Mendelevium-257	Md-257	10
Mendelevium-258	Md-258	0.01
Any radionuclide other than alpha emitter radionuclides not listed above, or mixtures of beta emitters of unknown composition		0.01

[1] The quantities listed above were derived by taking $^{1}/_{10}$th of the most restrictive ALI listed in table 1, columns 1 and 2, of appendix B to §§ 20.1001-20.2401 of this part, rounding to the nearest factor of 10, and arbitrarily constraining the values listed between 0.001 and 1,000 μCi. Values of 100 μCi have been assigned for radionuclides having a radioactive half-life in excess of 10^9 years (except rhenium, 1000 μCi) to take into account their low specific activity.

NOTE: For purposes of §§ 20.1902(e), 20.1905(a), and 20.2201(a) where there is involved a combination of radionuclides in known amounts, the limit for the combination should be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity

present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" (i.e., "unity").

[56 FR 23465, May 21, 1991; 56 FR 61352, Dec. 3, 1991. Redesignated and amended at 58 FR 67659, Dec. 22, 1993; 60 FR 20186, Apr. 25, 1995]

APPENDIX D TO PART 20--UNITED STATES NUCLEAR REGULATORY COMMISSION REGIONAL OFFICES

Region	Address	Telephone (24 hour)	E-Mail
NRC Headquarters Operations Center	USNRC, Division of ~~Incident Response Operations~~Preparedness and Response, Washington, DC 20555-0001.	(301) 816-5100 (301) 951-0550 (301) 816-5151 (fax)	*~~H001~~Hoo.Hoc@nrc.gov*
Region I: Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.	USNRC, Region I, 475 Allendale Road, Suite 102, King of Prussia, PA 19406-1415.	(610) 337-5000, (800) 432-1156 TDD: (301) 415-5575	*RidsRgn1MailCenter@nrc.gov*
Region II: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virginia, Virgin Islands, and West Virginia.	USNRC, Region II, Sam Nunn Atlanta Federal Center, Suite 23T85, 61 Forsyth Street, SW, Atlanta, GA 30303-8931.	(404) 562-4400, (800) 877-8510 TDD: (301) 415-5575	*RidsRgn2MailCenter@nrc.gov*
Region III: Illinois, Indiana,	USNRC, Region III, 2443 Warrenville Road,	(630) 829-9500 (800) 522-3025	*RidsRgn3MailCenter@nrc.gov*

Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin.	Suite 210, Lisle, IL 60532-4352.	TDD: (301) 415-5575	
Region IV: Alaska, Arizona, Arkansas, California, Colorado, Hawaii, Idaho, Kansas, Louisiana, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, Wyoming, and the U.S. territories and possessions in the Pacific.	USNRC, Region IV, Texas Health Resources Tower, 612 E. Lamar Blvd., Arlington, TX 76011-4005.	(817) 860-8100 (800) 952-9677 TDD: (301) 415-5575	*RidsRgn4MailCenter@nrc.gov*

[56 FR 23468, May 21, 1991, as amended at 56 FR 41449, Aug. 21, 1991; 58 FR 64111, Dec. 6, 1993; 59 FR 17465, Apr. 13, 1994; 60 FR 24551, May 9, 1995; 62 FR 22880, Apr. 28, 1997; 67 FR 67099, Nov. 4, 2002; 67 FR 77652, Dec. 19, 2002; 68 FR 58802, Oct. 10, 2003; 71 FR 15007, Mar. 27, 2006; 85 FR 65656, Oct. 16, 2020; 87 FR 20693, Apr. 8, 2022]

Appendix E to Part 20--Nationally Tracked Source Thresholds

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4

Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

[71 FR 65686, November 8, 2006]

Appendix F to Part 20--[Reserved]

Appendix G to Part 20--Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests

I. Manifest

A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a Manifest (OMB Control Numbers 3150-0164,-0165, and-0166) reflecting information requested on applicable NRC Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable NRC Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). NRC Forms 540 and 540A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, NRC Forms 541 and 541A and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by NRC to comply with the manifesting requirements of this part when they ship:

(a) LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

(b) LLW that is being returned to the licensee who is the "waste generator" or "generator," as defined in this part; or

(c) Radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste."

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

NRC Forms 540, 540A, 541, 541A, 542 and 542A, and the accompanying instructions, in hard copy, may be obtained by writing or calling the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-5877, or by visiting the NRC's Web site at *http://www.nrc.gov* and selecting forms from the index found on the home page.

This appendix includes information requirements of the Department of Transportation, as codified in 49 CFR part 172. Information on hazardous, medical, or other waste, required to meet Environmental Protection Agency regulations, as codified in 40 CFR parts 259, 261 or elsewhere, is not addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this chapter.

As used in this appendix, the following definitions apply:

Chelating agent has the same meaning as that given in § 61.2 of this chapter.

Chemical description means a description of the principal chemical characteristics of a low-level radioactive waste.

Computer-readable medium means that the regulatory agency's computer can transfer the information from the medium into its memory.

Consignee means the designated receiver of the shipment of low-level radioactive waste.

Decontamination facility means a facility operating under a Commission or Agreement State license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this part, is not considered to be a consignee for LLW shipments.

Disposal container means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

EPA identification number means the number received by a transporter following application to the Administrator of EPA as required by 40 CFR part 263.

Generator means a licensee operating under a Commission or Agreement State license who (1) is a waste generator as defined in this part, or (2) is the licensee to whom waste can be attributed

within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

High integrity container (HIC) means a container commonly designed to meet the structural stability requirements of § 61.56 of this chapter, and to meet Department of Transportation requirements for a Type A package.

Land disposal facility has the same meaning as that given in § 61.2 of this chapter.

NRC Forms 540, 540A, 541, 541A, 542, and 542A are official NRC Forms referenced in this appendix. Licensees need not use originals of these NRC Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

Package means the assembly of components necessary to ensure compliance with the packaging requirements of DOT regulations, together with its radioactive contents, as presented for transport.

Physical description means the items called for on NRC Form 541 to describe a low-level radioactive waste.

Residual waste means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

Shipper means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

Shipping paper means NRC Form 540 and, if required, NRC Form 540A which includes the information required by DOT in 49 CFR part 172.

Source material has the same meaning as that given in § 40.4 of this chapter.

Special nuclear material has the same meaning as that given in § 70.4 of this chapter.

Uniform Low-Level Radioactive Waste Manifest or *uniform manifest* means the combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

Waste collector means an entity, operating under a Commission or Agreement State license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

Waste description means the physical, chemical and radiological description of a low-level radioactive waste as called for on NRC Form 541.

Waste generator means an entity, operating under a Commission or Agreement State license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

Waste processor means an entity, operating under a Commission or Agreement State license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

Waste type means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

Information Requirements

A. General Information

The shipper of the radioactive waste, shall provide the following information on the uniform manifest:

1. The name, facility address, and telephone number of the licensee shipping the waste;

2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

3. The name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

B. Shipment Information

The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;

2. The total number of packages/disposal containers;

3. The total disposal volume and disposal weight in the shipment;

4. The total radionuclide activity in the shipment;

5. The activity of each of the radionuclides H-3, C-14, Tc-99, and I-129 contained in the shipment; and

6. The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass

of uranium and thorium in source material.

C. Disposal Container and Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;

3. The volume displaced by the disposal container;

4. The gross weight of the disposal container, including the waste;

5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

6. A physical and chemical description of the waste;

7. The total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

8. The approximate volume of waste within a container;

9. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

10. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container shall be reported;

11. The total radioactivity within each container; and

12. For wastes consigned to a disposal facility, the classification of the waste pursuant to § 61.55 of this chapter. Waste not meeting the structural stability requirements of § 61.56(b) of this chapter must be identified.

D. Uncontainerized Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;

2. A physical and chemical description of the waste;

3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight, plus the identity of the principal chelating agent;

4. For waste consigned to a disposal facility, the classification of the waste pursuant to § 61.55 of this chapter. Waste not meeting the structural stability requirements of § 61.56(b) of this chapter must be identified;

5. The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multi-Generator Disposal Container Information

This section applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLW resulting from a processor's activities may be attributable to one or more "generators" (including "waste generators") as defined in this part). It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

2. For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:

(a) The volume of waste within the disposal container;

(b) A physical and chemical description of the waste, including the solidification agent, if any;

(c) The total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(d) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in 10 CFR 61.56(b); and

(e) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

II. Certification

An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and the Commission. A collector in signing the certification is certifying that nothing has been done to the collected waste which would invalidate the waste generator's certification.

III. Control and Tracking

A. Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs A.1 through 9 of this section. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of paragraphs A.4 through 9 of this section. A licensee shall:

1. Prepare all wastes so that the waste is classified according to § 61.55 and meets the waste characteristics requirements in § 61.56 of this chapter;

2. Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater then Class C waste, in accordance with § 61.55 of this chapter;

3. Conduct a quality assurance program to assure compliance with §§ 61.55 and 61.56 of this chapter (the program must include management evaluation of audits);

4. Prepare the NRC Uniform Low-Level Radioactive Waste Manifest as required by this appendix;

5. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either (i) receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

6. Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph A.5 of this section;

7. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of NRC Form 540;

8. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by 10 CFR Parts 30, 40, and 70 of this chapter; and

9. For any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix.

B. Any waste collector licensee who handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

3. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (i) Receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

4. Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph B.3 of this section;

5. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of NRC Form 540;

6. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by 10 CFR parts 30, 40, and 70 of this chapter;

7. For any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

8. Notify the shipper and the Administrator of the nearest Commission Regional Office listed in appendix D of this part when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

C. Any licensed waste processor who treats or repackages waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

2. Prepare a new manifest that meets the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in paragraph I.E. of this appendix;

3. Prepare all wastes so that the waste is classified according to § 61.55 of this chapter and meets the waste characteristics requirements in § 61.56 of this chapter;

4. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with §§ 61.55 and 61.57 of this chapter;

5. Conduct a quality assurance program to assure compliance with §§ 61.55 and 61.56 of this chapter (the program shall include management evaluation of audits);

6. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest

to the intended consignee so that either: (i) Receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

7. Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph C.6 of this section;

8. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of NRC Form 540;

9. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by 10 CFR parts 30, 40, and 70 of this chapter;

10. For any shipment or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

11. Notify the shipper and the Administrator of the nearest Commission Regional Office listed in appendix D of this part when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

D. The land disposal facility operator shall:

1. Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of NRC Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

2. Maintain copies of all completed manifests and electronically store the information required by 10 CFR 61.80(l) until the Commission terminates the license; and

3. Notify the shipper and the Administrator of the nearest Commission Regional Office listed in appendix D of this part when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

E. Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in this section must:

1. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with the nearest Commission Regional Office listed in Appendix D to this part. Each licensee who conducts a trace investigation shall file a written report with the appropriate NRC Regional Office within 2 weeks of completion of the investigation.

[60 FR 15664, Mar. 27, 1995, as amended at 60 FR 25983, May 16, 1995; 68 FR 58802, Oct. 10, 2003; 70 FR 69421, Nov. 16, 2005]

CHAPTER 33.1-10-05.1
RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Section
33.1-10-05.1-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 34

33.1-10-05.1-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 34.

10 Code of Federal Regulations 34.1, 34.3, 34.11, 34.13, 34.20, 34.21, 34.23, 34.25, 34.27, 34.29, 34.31, 34.33, 34.35, 34.41, 34.42, 34.43, 34.45, 34.46, 34.47, 34.49, 34.51, 34.53, 34.61, 34.63, 34.65, 34.67, 34.69, 34.71, 34.73, 34.75, 34.79, 34.81, 34.83, 34.85, 34.87, 34.89, 34.101, and 34.111 and appendix A to part 34 are adopted by reference as they exist on November 16, 2020~~July 30, 2018~~, with the following exceptions:

1. All of the requirements in chapter 33.1-10-05.1 apply to both licensees and registrants. A reference in 10 Code of Federal Regulations part 34 to "license" includes "registration", a reference to "licensee" includes "registrant", a reference to "licensed" includes "registered", and a reference to "licensed material" includes "registered source of radiation". "Registrant" means any person who is registered with the department and is legally obligated to register with the department pursuant to article 33.1-10 and North Dakota Century Code chapter 23.1-03. "Registration" means the notification of the department of environmental quality of possession of a source of radiation and the furnishing of information with respect thereto, in accordance with North Dakota Century Code chapter 23.1-02.

2. Where the words "NRC", "commission", "nuclear regulatory commission", "United States nuclear regulatory commission", "NRC regional administrator", "NRC regional office", "administrator of the appropriate nuclear regulatory commission's regional office", or "NRC's office of nuclear material safety and safeguards, division of industrial and medical nuclear safety" appear in 10 Code of Federal Regulations part 34, substitute the words "department of environmental quality".

3. Requirements in 10 Code of Federal Regulations part 34 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

4. North Dakota state form number 8418, "application for radioactive material license", must be used instead of NRC form 313 as specified in 10 Code of Federal Regulations part 34.

5. For references to 10 Code of Federal Regulations parts 170 and 171, see chapter 33.1-10-11 for applicable fee schedules.

History: Effective January 1, 2019; amended effective July 1, 2021.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

PART 34--LICENSES FOR INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

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Subpart F--Notifications

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Subpart H--Violations

34.121 Violations.

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Appendix A to 10 CFR Part 34--Radiographer Certification.

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note). Section 34.45 also issued under sec. 206, 88 Stat. 1246 (42 U.S.C. 5846).

Source: 62 FR 28963, May 28, 1997, unless otherwise noted.

Subpart A--General Provisions

§ 34.1 Purpose and scope.

This part prescribes requirements for the issuance of licenses for the use of sealed sources containing byproduct material and radiation safety requirements for persons using these sealed sources in industrial radiography. The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the requirements and provisions of 10 Parts 19, 20, 21, 30, 71, 150, 170, and 171 of this chapter apply to applications and licenses subject to this part. This rule does not apply to medical uses of byproduct material.

§ 34.3 Definitions.

ALARA (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits specified in 10 CFR Part 20 as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of

technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

Annual refresher safety training means a review conducted or provided by the licensee for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

Associated equipment means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, (e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head.

Becquerel (Bq) means one disintegration per second.

Certifying Entity means an independent certifying organization meeting the requirements in appendix A of this part or an Agreement State meeting the requirements in appendix A, Parts II and III of this part.

Collimator means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

Control (drive) cable means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

Control drive mechanism means a device that enables the source assembly to be moved to and from the exposure device.

Control tube means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

Exposure head means a device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a source stop.)

Field station means a facility where licensed material may be stored or used and from which equipment is dispatched.

Gray means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 Joule/kilogram. It is also equal to 100 rads.

Guide tube (Projection sheath) means a flexible or rigid tube (i.e., "J" tube) for guiding the

source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

Hands-on experience means experience in all of those areas considered to be directly involved in the radiography process.

Independent certifying organization means an independent organization that meets all of the criteria of Appendix A to this part.

Industrial radiography (radiography) means an examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images.

Lay-barge radiography means industrial radiography performed on any water vessel used for laying pipe.

Offshore platform radiography means industrial radiography conducted from a platform over a body of water.

Permanent radiographic installation means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

Practical Examination means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

Radiation Safety Officer for industrial radiography means an individual with the responsibility for the overall radiation safety program on behalf of the licensee and who meets the requirements of § 34.42.

Radiographer means any individual who performs or who, in attendance at the site where the sealed source or sources are being used, personally supervises industrial radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of the Commission's regulations and the conditions of the license.

Radiographer certification means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

Radiographer's assistant means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in industrial radiography.

Radiographic exposure device (also called a camera, or a projector) means any instrument

containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

Radiographic operations means all activities associated with the presence of radioactive sources in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

S-tube means a tube through which the radioactive source travels when inside a radiographic exposure device.

Sealed source means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Shielded position means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

Sievert means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).

Source assembly means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

Source changer means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources.

Storage area means any location, facility, or vehicle which is used to store or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

Storage container means a container in which sealed sources are secured and stored.

Temporary jobsite means a location where radiographic operations are conducted and where licensed material may be stored other than those location(s) of use authorized on the license.

Underwater radiography means industrial radiography performed when the radiographic exposure device and/or related equipment are beneath the surface of the water.

§ 34.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission, other than a written interpretation by the General Counsel, will be recognized to be binding upon the Commission.

§ 34.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0007.

(b) The approved information collection requirements contained in this part appear in §§ 34.13, 34.20, 34.25, 34.27, 34.29, 34.31, 34.33, 34.35, 34.41, 34.42, 34.43, 34.45, 34.47, 34.49, 34.53, 34.61, 34.63, 34.65, 34.67, 34.69, 34.71, 34.73, 34.75, 34.79, 34.81, 34.83, 34.85, 34.87, 34.89, 34.101, 34.111 and appendix A.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 34.11, NRC Form 313 is approved under control number 3150-0120.

(2) [Reserved]

[62 FR 52186, Oct. 6, 1997; 85 FR 65656, Oct. 16, 2020]

Subpart B--Specific Licensing Provisions

§ 34.11 Application for a specific license.

A person may file an application for specific license for use of sealed sources in industrial radiography on NRC Form 313, "Application for Material License," in accordance with the provisions of § 30.32 of this chapter.

[68 FR 58805, Oct. 10, 2003]

§ 34.13 Specific license for industrial radiography.

An application for a specific license for the use of licensed material in industrial radiography will be approved if the applicant meets the following requirements:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter for

byproduct material, as appropriate, and any special requirements contained in this part.

(b) The applicant submits an adequate program for training radiographers and radiographers' assistants that meets the requirements of § 34.43.

(1) After May 28, 1999, a license applicant need not describe its initial training and examination program for radiographers in the subjects outlined in § 34.43(g).

(2) From June 27, 1997 to May 28, 1999 a license applicant may affirm that all individuals acting as industrial radiographers will be certified in radiation safety by a certifying entity before commencing duty as radiographers. This affirmation substitutes for a description of its initial training and examination program for radiographers in the subjects outlined in § 34.43(g).

(c) The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

(d) The applicant submits written operating and emergency procedures as described in § 34.45.

(e) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographers' assistant at intervals not to exceed 6 months as described in § 34.43(e).

(f) The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility.

(g) The applicant identifies and lists the qualifications of the individual(s) designated as the RSO (§ 34.42) and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

(h) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the--

(1) Instruments to be used;

(2) Methods of performing the analysis; and

(3) Pertinent experience of the person who will analyze the wipe samples.

(i) If the applicant intends to perform "in-house" calibrations of survey instruments the applicant

must describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in § 34.25.

(j) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

(k) The applicant identifies the locations where all records required by this part and other parts of this chapter will be maintained.

Subpart C--Equipment

§ 34.20 Performance requirements for industrial radiography equipment.

Equipment used in industrial radiographic operations must meet the following minimum criteria:

(a)(1) Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standards Institute, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981). This publication has been approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a)and 1 CFR part 51. This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street , New York, New York 10036; Telephone (212) 642-4900. Copies of the document are available for inspection at the Nuclear Regulatory Commission Library, 11545 Rockville Pike, Rockville, Maryland 20852. A copy of the document is also on file at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(2) Engineering analysis may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the Commission may find this an acceptable alternative to actual testing of the component pursuant to the above referenced standard.

(b) In addition to the requirements specified in paragraph (a) of this section, the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources.

(1) The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the--

(i) Chemical symbol and mass number of the radionuclide in the device;

(ii) Activity and the date on which this activity was last measured;

(iii) Model (or product code) and serial number of the sealed source;

(iv) Manufacturer's identity of the sealed source; and

(v) Licensee's name, address, and telephone number.

(2) Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 10 CFR part 71.

(3) Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless the design of any replacement component,including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

(c) In addition to the requirements specified in paragraphs (a) and (b) of this section, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers.

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(2) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

(3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

(4)(i) Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words: "DANGER--RADIOACTIVE."

(ii) The label may not interfere with the safe operation of the exposure device or associated equipment.

(5) The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

(6) Guide tubes must be used when moving the source out of the device.

(7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiography operations.

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.

(9) Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(d) All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of this section.

(e) Notwithstanding paragraph (a)(1) of this section, equipment used in industrial radiographic operations need not comply with § 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

[62 FR 28963, May 28, 1997, as amended at 69 FR 18803, Apr. 9, 2004]

§ 34.21 Limits on external radiation levels from storage containers and source changers.

The maximum exposure rate limits for storage containers and source changers are 2 millisieverts (200 millirem) per hour at any exterior surface, and 0.1 millisieverts (10 millirem) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

§ 34.23 Locking of radiographic exposure devices, storage containers and source changers.

(a) Each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked (and if a keyed-lock, with the key removed at all times) when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in § 34.51. In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

(b) Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked (and if a keyed-lock, with the key removed at all times) when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

§ 34.25 Radiation survey instruments.

(a) The licensee shall keep sufficient calibrated and operable radiation survey instruments at each location where radioactive material is present to make the radiation surveys required by this part and by 10 CFR part 20 of this chapter. Instrumentation required by this section must be capable of measuring a range from 0.02 millisieverts (2 millirems) per hour through 0.01 sievert (1 rem) per hour.

(b) The licensee shall have each radiation survey instrument required under paragraph (a) of this section calibrated--

(1) At intervals not to exceed 6 months and after instrument servicing, except for battery changes;

(2) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 millirems) per hour; and

(3) So that an accuracy within plus or minus 20 percent of the calibration source can be demonstrated at each point checked.

(c) The licensee shall maintain records of the results of the instrument calibrations in accordance with § 34.65.

§ 34.27 Leak testing and replacement of sealed sources.

(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed by persons authorized to do so by the NRC or an Agreement State.

(b) The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the Commission or an Agreement State.

(c) Testing and recordkeeping requirements.

(1) Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed 6 months. The leak testing of the source must be performed using a method approved by the Commission or by an Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 Bq (0.005 microcurie) of radioactive material on the test sample and must be performed by a person specifically authorized by the Commission or an Agreement State to perform the analysis.

(2) The licensee shall maintain records of the leak tests in accordance with § 34.67.

(3) Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds 6 months.

(d) Any test conducted pursuant to paragraph (c) of this section which reveals the presence of 185 Bq (0.005 microcurie) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall have it decontaminated and repaired or disposed of in accordance with Commission regulations. A report must be filed with the Director, Office of Federal and State Materials and Environmental Management Programs, by an appropriate method listed in § 30.6(a) of this chapter, the report to be filed within 5 days of any test with results that exceed the threshold in this paragraph (d), and to describe the equipment involved, the test results, and the corrective action taken. A copy of the report must be sent to the Administrator of the appropriate Nuclear Regulatory Commission's Regional Office listed in appendix D of 10 CFR part 20 of this chapter "Standards for Protection Against Radiation."

(e) Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 185 Bq (0.005 microcuries) of radioactive material on the test sample and must be performed by a person specifically authorized by the Commission or an Agreement State to perform the analysis. Should such testing reveal the presence of 185 Bq (0.005 microcuries) or more of removable DU contamination, the exposure device must be removed from use until an evaluation of the wear on the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device however, the device must be tested for DU contamination if the interval of storage exceeded 12 months. A record of the DU leak-test must be made in accordance with § 34.67. Licensees will have until June 27, 1998, to comply with the DU leak-testing requirements of this paragraph.

[62 FR 28963, May 28, 1997, as amended at 63 FR 37061, July 9, 1998; 67 FR 77652, Dec. 19, 2002; 68 FR 58805, Oct. 10, 2003; 73 FR 5719, Jan. 31, 2008]

§ 34.29 Quarterly inventory.

(a) Each licensee shall conduct a quarterly physical inventory to account for all sealed sources and for devices containing depleted uranium received and possessed under this license.

(b) The licensee shall maintain records of the quarterly inventory in accordance with § 34.69.

§ 34.31 Inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments.

(a) The licensee shall perform visual and operability checks on survey meters, radiographic exposure devices, transport and storage containers, associated equipment and source changers before use on each day the equipment is to be used to ensure that the equipment is in good working condition, that the sources are adequately shielded, and that required labeling is present. Survey instrument operability must be performed using check sources or other appropriate means. If equipment problems are found, the equipment must be removed from service until repaired.

(b) Each licensee shall have written procedures for:

(1) Inspection and routine maintenance of radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed 3 months or before the first use thereafter to ensure the proper functioning of components important to safety. Replacement components shall meet design specifications. If equipment problems are found, the equipment must be removed from service until repaired.

(2) Inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

(c) Records of equipment problems and of any maintenance performed under paragraphs (a) and (b) of this section must be made in accordance with § 34.73.

§ 34.33 Permanent radiographic installations.

(a) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

(1) An entrance control of the type described in § 20.1601(a)(1) of this chapter that reduces the radiation level upon entry into the area, or

(2) Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed.

(b) The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry (designated in paragraph (a)(1) of this section) must be tested monthly. If an entrance control

device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within 7 calendar days. The facility may continue to be used during this 7-day period, provided the licensee implements the continuous surveillance requirements of § 34.51 and uses an alarming ratemeter. Test records for entrance controls and audible and visual alarm must be maintained in accordance with § 34.75.

§ 34.35 Labeling, storage, and transportation.

(a) The licensee may not use a source changer or a container to store licensed material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording

CAUTION*
RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES (or "NAME OF COMPANY")
*_____ or "DANGER"

(b) The licensee may not transport licensed material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in 10 CFR part 71.

(c) Locked radiographic exposure devices and storage containers must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.

(d) The licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.

Subpart D--Radiation Safety Requirements

§ 34.41 Conducting industrial radiographic operations.

(a) Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of § 34.43(c). The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

(b) All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation, unless specifically authorized by the

Commission.

(c) A licensee may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Commission or by an Agreement State.

(d) Licensees will have until June 27, 1998, to meet the requirements for having two qualified individuals present at locations other than a permanent radiographic installation as specified in paragraph (a) of this section.

[62 FR 28963, May 28, 1997, as amended at 63 FR 37061, July 9, 1998]

§ 34.42 Radiation Safety Officer for industrial radiography.

The RSO shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's program.

(a) The minimum qualifications, training, and experience for RSOs for industrial radiography are as follows:

(1) Completion of the training and testing requirements of § 34.43(a);

(2) 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

(3) Formal training in the establishment and maintenance of a radiation protection program.

(b) The Commission will consider alternatives when the RSO has appropriate training and/or experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

(c) The specific duties and authorities of the RSO include, but are not limited to:

(1) Establishing and overseeing all operating, emergency, and ALARA procedures as required by 10 CFR part 20 of this chapter, and reviewing them regularly to ensure that the procedures in use conform to current 10 CFR part 20 procedures, conform to other NRC regulations and to the license conditions.

(2) Overseeing and approving all phases of the training program for radiographic personnel, ensuring that appropriate and effective radiation protection practices are taught;

(3) Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits;

(4) Ensuring that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by § 20.2203 of this chapter; and

(5) Ensuring that operations are conducted safely and to assume control for instituting corrective actions including stopping of operations when necessary.

(d) Licensees will have until June 27, 1999, to meet the requirements of paragraph (a) or (b) of this section.

[62 FR 28963, May 28, 1997, as amended at 63 FR 37061, July 9, 1998]

§ 34.43 Training.

(a) The licensee may not permit any individual to act as a radiographer until the individual--

(1) Has received training in the subjects in paragraph (g) of this section, in addition to a minimum of 2 months of on-the-job training, and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in appendix A of this part. (An independent organization that would like to be recognized as a certifying entity shall submit its request to the Director, Office of Federal and State Materials and Environmental Management Programs, by an appropriate method listed in § 30.6(a) of this chapter.); or

(2) The licensee may, until June 27, 1999, allow an individual who has not met the requirements of paragraph (a)(1) of this section, to act as a radiographer after the individual has received training in the subjects outlined in paragraph (g) of this section and demonstrated an understanding of these subjects by successful completion of a written examination that was previously submitted to and approved by the Commission.

(b) In addition, the licensee may not permit any individual to act as a radiographer until the individual--

(1) Has received copies of and instruction in the requirements described in NRC regulations contained in this part; in §§ 30.7, 30.9, and 30.10 of this chapter; in the applicable sections of 10 CFR parts 19 and 20, of this chapter, in applicable DOT regulations as referenced in 10 CFR part 71, in the NRC license(s) under which the radiographer will perform industrial radiography, and the licensee's operating and emergency procedures;

(2) Has demonstrated understanding of the licensee's license and operating and emergency procedures by successful completion of a written or oral examination covering this material.

(3) Has received training in the use of the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments.

(4) Has demonstrated understanding of the use of radiographic exposure devices, sources, survey instruments and associated equipment described in paragraphs (b)(1) and (b)(3) of this section by successful completion of a practical examination covering this material.

(c) The licensee may not permit any individual to act as a radiographer's assistant until the individual--

(1) Has received copies of and instruction in the requirements described in NRC regulations contained in this part, in §§ 30.7, 30.9, and 30.10 of this chapter, in the applicable sections of 10 CFR parts 19 and 20 of this chapter, in applicable DOT regulations as referenced in 10 CFR part 71, in the NRC license(s) under which the radiographer's assistant will perform industrial radiography, and the licensee's operating and emergency procedures;

(2) Has developed competence to use, under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, associated equipment, and radiation survey instruments that the assistant will use; and

(3) Has demonstrated understanding of the instructions provided under (c)(1) of this section by successfully completing a written test on the subjects covered and has demonstrated competence in the use of hardware described in (c)(2) of this section by successful completion of a practical examination on the use of such hardware.

(d) The licensee shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

(e) Except as provided in paragraph (e)(4), the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Commission's regulations, license requirements, and the applicant's operating and emergency procedures are followed. The inspection program must:

(1) Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed 6 months; and

(2) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of § 34.43(b)(3) and the radiographer's assistant must re-demonstrate knowledge of the training requirements of § 34.43(c)(2) by a practical examination before these individuals can next participate in a radiographic operation.

(3) The Commission may consider alternatives in those situations where the individual serves as both radiographer and RSO.

(4) In those operations where a single individual serves as both radiographer and RSO, and

performs all radiography operations, an inspection program is not required.

(f) The licensee shall maintain records of the above training to include certification documents, written and practical examinations, refresher safety training and inspections of job performance in accordance with § 34.79.

(g) The licensee shall include the following subjects required in paragraph (a) of this section:

(1) Fundamentals of radiation safety including--

(i) Characteristics of gamma radiation;

(ii) Units of radiation dose and quantity of radioactivity;

(iii) Hazards of exposure to radiation;

(iv) Levels of radiation from licensed material; and

(v) Methods of controlling radiation dose (time, distance, and shielding);

(2) Radiation detection instruments including--

(i) Use, operation, calibration, and limitations of radiation survey instruments;

(ii) Survey techniques; and

(iii) Use of personnel monitoring equipment;

(3) Equipment to be used including--

(i) Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails).

(ii) Storage, control, and disposal of licensed material; and

(iii) Inspection and maintenance of equipment.

(4) The requirements of pertinent Federal regulations; and

(5) Case histories of accidents in radiography.

(h) Licensees will have until June 27, 1998, to comply with the additional training requirements specified in paragraphs (b)(1) and (c)(1) of this section.

(i) Licensees will have until June 27, 1999 to comply with the certification requirements specified in paragraph (a)(1) of this section. Records of radiographer certification maintained in accordance with § 34.79(a) provide appropriate affirmation of certification requirements specified in paragraph (a)(1) of this section.

[62 FR 28963, May 28, 1997, as amended at 63 FR 37061, July 9, 1998; 68 FR 58805, Oct. 10, 2003; 73 FR 5720, Jan. 31, 2008]

§ 34.45 Operating and emergency procedures.

(a) Operating and emergency procedures must include, as a minimum, instructions in the following:

(1) Appropriate handling and use of licensed sealed sources and radiographic exposure devices so that no person is likely to be exposed to radiation doses in excess of the limits established in 10 CFR part 20 of this chapter "Standards for Protection Against Radiation";

(2) Methods and occasions for conducting radiation surveys;

(3) Methods for controlling access to radiographic areas;

(4) Methods and occasions for locking and securing radiographic exposure devices, transport and storage containers and sealed sources;

(5) Personnel monitoring and the use of personnel monitoring equipment;

(6) Transporting sealed sources to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when needed, and control of the sealed sources during transportation (refer to 49 CFR parts 171-173);

(7) The inspection, maintenance, and operability checks of radiographic exposure devices, survey instruments, transport containers, and storage containers;

(8) Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarm ratemeter alarms unexpectedly.

(9) The procedure(s) for identifying and reporting defects and noncompliance, as required by 10 CFR part 21 of this chapter;

(10) The procedure for notifying proper persons in the event of an accident;

(11) Minimizing exposure of persons in the event of an accident;

(12) Source recovery procedure if licensee will perform source recovery;

(13) Maintenance of records.

(b) The licensee shall maintain copies of current operating and emergency procedures in accordance with §§ 34.81 and 34.89.

§ 34.46 Supervision of radiographers' assistants.

Whenever a radiographer's assistant uses radiographic exposure devices, associated equipment or sealed sources or conducts radiation surveys required by § 34.49(b) to determine that the sealed source has returned to the shielded position after an exposure, the assistant shall be under the personal supervision of a radiographer. The personal supervision must include:

(a) The radiographer's physical presence at the site where the sealed sources are being used;

(b) The availability of the radiographer to give immediate assistance if required; and

(c) The radiographer's direct observation of the assistant's performance of the operations referred to in this section.

§ 34.47 Personnel monitoring.

(a) The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarm ratemeter, and a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

(1) Pocket dosimeters must have a range from zero to 2 millisieverts (200 millirems) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

(2) Each personnel dosimeter must be assigned to and worn only by one individual.

(3) Film badges must be replaced at least monthly and all other personnel dosimeters that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.~~Film badges must be replaced at periods not to exceed one month and other personnel dosimeters processed and evaluated by an accredited NVLAP processor must be replaced at periods not to exceed three months.~~

~~(4) After replacement, each personnel dosimeter must be processed as soon as possible.~~

(b) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with § 34.83.

(c) Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with § 34.83. Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

(d) If an individual's pocket chamber is found to be off-scale, or if his or her electronic personal dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter that requires processing must be sent for processing and evaluation within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within 24 hours. In addition, the individual may not resume work associated with licensed material use until a determination of the individual's radiation dose has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the records maintained in accordance with § 34.83. ~~If an individual's pocket chamber is found to be off-scale, or if his or her electronic personal dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter must be sent for processing within 24 hours. In addition, the individual may not resume work associated with licensed material use until a determination of the individual's radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the records maintained in accordance with § 34.83.~~

(e) If the personnel dosimeter that is required by paragraph (a) of this section is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements in paragraph (a) is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in the records maintained in accordance with § 34.83.

(f) Dosimetry results must be retained in accordance with § 34.83.~~Dosimetry reports received from the accredited NVLAP personnel dosimeter processor must be retained in accordance with § 34.83~~.

(g) Each alarm ratemeter must--

(1) Be checked to ensure that the alarm functions properly (sounds) before using at the start of each shift;

(2) Be set to give an alarm signal at a preset dose rate of 5 mSv/hr (500 mrem/hr); with an accuracy of plus or minus 20 percent of the true radiation dose rate;

(3) Require special means to change the preset alarm function; and

(4) Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarm ratemeter calibrations in accordance with § 34.83.

[62 FR 28963, May 28, 1997, as amended at 65 FR 63751, Oct. 24, 2000; 85 FR 15347, Mar. 18, 2020]

§ 34.49 Radiation surveys.

The licensee shall:

(a) Conduct surveys with a calibrated and operable radiation survey instrument that meets the requirements of § 34.25.

(b) Using a survey instrument meeting the requirements of paragraph (a) of this section, conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey must determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment.

(c) Conduct a survey of the radiographic exposure device with a calibrated radiation survey instrument any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area (as defined in § 34.3), to ensure that the sealed source is in its shielded position.

(d) Maintain records in accordance with § 34.85.

§ 34.51 Surveillance.

During each radiographic operation the radiographer, or the other individual present, as required by § 34.41, shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in 10 CFR part 20 of this chapter, except at permanent radiographic installations where all entryways are locked and the requirements of § 34.33 are met.

§ 34.53 Posting.

All areas in which industrial radiography is being performed must be conspicuously posted as required by § 20.1902 of this chapter. Exceptions listed in § 20.1903 of this chapter do not apply to industrial radiographic operations.

[62 FR 28963, May 28, 1997, as amended at 66 FR 64738, Dec. 14, 2001]

Subpart E--Recordkeeping Requirements

§ 34.61 Records of the specific license for industrial radiography.

Each licensee shall maintain a copy of its license, license conditions, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Commission, or until the Commission terminates the license.

§ 34.63 Records of receipt and transfer of sealed sources.

(a) Each licensee shall maintain records showing the receipts and transfers of sealed sources and devices using DU for shielding and retain each record for 3 years after it is made.

(b) These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for DU), and manufacturer, model, and serial number of each sealed source and/or device, as appropriate.

§ 34.65 Records of radiation survey instruments.

Each licensee shall maintain records of the calibrations of its radiation survey instruments that are required under § 34.25 and retain each record for 3 years after it is made.

§ 34.67 Records of leak testing of sealed sources and devices containing depleted uranium.

Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of becquerels (microcuries). The licensee shall retain each record for 3 years after it is made or until the source in storage is removed.

§ 34.69 Records of quarterly inventory.

(a) Each licensee shall maintain records of the quarterly inventory of sealed sources and of devices containing depleted uranium as required by § 34.29 and retain each record for 3 years after it is made.

(b) The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sealed source and/or devices, and manufacturer, model, and serial number of each sealed source and/or device, as appropriate.

§ 34.71 Utilization logs.

(a) Each licensee shall maintain utilization logs showing for each sealed source the following

information:

(1) A description, including the make, model, and serial number of the radiographic exposure device or transport or storage container in which the sealed source is located;

(2) The identity and signature of the radiographer to whom assigned; and

(3) The plant or site where used and dates of use, including the dates removed and returned to storage.

(b) The licensee shall retain the logs required by paragraph (a) of this section for 3 years after the log is made.

§ 34.73 Records of inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments.

(a) Each licensee shall maintain records specified in § 34.31 of equipment problems found in daily checks and quarterly inspections of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for 3 years after it is made.

(b) The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was done.

§ 34.75 Records of alarm system and entrance control checks at permanent radiographic installations.

Each licensee shall maintain records of alarm system and entrance control device tests required under § 34.33 and retain each record for 3 years after it is made.

§ 34.79 Records of training and certification.

Each licensee shall maintain the following records (of training and certification) for 3 years after the record is made:

(a) Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, and names of individuals conducting and receiving the oral and practical examinations; and

(b) Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the

records must also include a list showing the items checked and any non-compliances observed by the RSO.

§ 34.81 Copies of operating and emergency procedures.

Each licensee shall maintain a copy of current operating and emergency procedures until the Commission terminates the license. Superseded material must be retained for 3 years after the change is made.

§ 34.83 Records of personnel monitoring Procedures.

Each licensee shall maintain the following exposure records specified in § 34.47:

(a) Direct reading dosimeter readings and yearly operability checks required by § 34.47(b) and (c) for 3 years after the record is made.

(b) Records of alarm ratemeter calibrations for 3 years after the record is made.

(c) Personnel dosimeter results ~~received from the accredited NVLAP processor~~ until the Commission terminates the license.

(d) Records of estimates of exposures as a result of: off-scale personal direct reading dosimeters, or lost or damaged personnel dosimeters until the Commission terminates the license.

[62 FR 28963, May 28, 1997, as amended at 65 FR 63752, Oct. 24, 2000; 85 FR 15347, Mar. 18, 2020]

§ 34.85 Records of radiation surveys.

Each licensee shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in § 34.49(c), if that survey is the last one performed in the workday. Each record must be maintained for 3 years after it is made.

§ 34.87 Form of records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 34.89 Location of documents and records.

(a) Each licensee shall maintain copies of records required by this part and other applicable parts of this chapter at the location specified in § 34.13(k).

(b) Each licensee shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite;

(1) The license authorizing the use of licensed material;

(2) A copy of 10 CFR parts 19, 20, and 34 of NRC regulations;

(3) Utilization records for each radiographic exposure device dispatched from that location as required by § 34.71.

(4) Records of equipment problems identified in daily checks of equipment as required by § 34.73(a);

(5) Records of alarm system and entrance control checks required by § 34.75, if applicable;

(6) Records of direct reading dosimeters such as pocket dosimeter and/or electronic personal dosimeters readings as required by § 34.83;

(7) Operating and emergency procedures required by § 34.81;

(8) Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by § 34.65;

(9) Evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters and/or electronic personal dosimeters as required by § 34.83;

(10) Latest survey records required by § 34.85;

(11) The shipping papers for the transportation of radioactive materials required by § 71.5 of this chapter; and

(12) When operating under reciprocity pursuant to § 150.20 of this chapter, a copy of the Agreement State license authorizing the use of licensed materials.

Subpart F--Notifications

§ 34.101 Notifications.

(a) In addition to the reporting requirements specified in § 30.50 and under other sections of this

chapter, such as § 21.21, each licensee shall send a written report to the NRC's Office of Federal and State Materials and Environmental Management Programs, by an appropriate method listed in § 30.6(a) of this chapter, within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

(1) Unintentional disconnection of the source assembly from the control cable;

(2) Inability to retract the source assembly to its fully shielded position and secure it in this position; or

(3) Failure of any component (critical to safe operation of the device) to properly perform its intended function;

(b) The licensee shall include the following information in each report submitted under paragraph (a) of this section, and in each report of overexposure submitted under 10 CFR 20.2203 which involves failure of safety components of radiography equipment:

(1) A description of the equipment problem;

(2) Cause of each incident, if known;

(3) Name of the manufacturer and model number of equipment involved in the incident;

(4) Place, date, and time of the incident;

(5) Actions taken to establish normal operations;

(6) Corrective actions taken or planned to prevent recurrence; and

(7) Qualifications of personnel involved in the incident.

(c) Any licensee conducting radiographic operations or storing radioactive material at any location not listed on the license for a period in excess of 180 days in a calendar year, shall notify the appropriate NRC regional office listed in § 30.6(b)(2) of this chapter prior to exceeding the 180 days.

[62 FR 28963, May 28, 1997, as amended at 67 FR 3585, Jan. 25, 2002; 68 FR 58805, Oct. 10, 2003; 73 FR 5720, Jan. 31, 2008; 83 FR 30285, Jun. 28, 2018]

Subpart G--Exemptions

§ 34.111 Applications for exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant

an exemption from the requirements of the regulations in this part if it determines the exemption is authorized by law and would not endanger life or property or the common defense and security and is otherwise in the public interest.

Subpart H--Violations

§ 34.121 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to these Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act;

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section.

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

§ 34.123 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1952, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under one or more of §§ 161b, 161i, or 161o of the Act. For purposes of Section 223, all the regulations in 10 CFR part 34 are issued under one or more of §§ 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in 10 CFR part 34 that are not issued under sections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 34.1, 34.3, 34.5, 34.8, 34.11, 34.13, 34.111, 34.121, 34.123.

Appendix A to 10 CFR Part 34--Radiographer Certification

TOP

I. Requirements for an Independent Certifying Organization

An independent certifying organization shall:

1. Be an organization such as a society or association, whose members participate in, or have an interest in, the fields of industrial radiography;

2. Make its membership available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability;

3. Have a certification program open to nonmembers, as well as members;

4. Be an incorporated, nationally recognized organization, that is involved in setting national standards of practice within its fields of expertise;

5. Have an adequate staff, a viable system for financing its operations, and a policy-and decision-making review board;

6. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;

7. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;

8. Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;

9. Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;

10. Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

11. Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;

12. Exchange information about certified individuals with the Commission and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and

13. Provide a description to the Commission of its procedures for choosing examination sites and for providing an appropriate examination environment.

II. Requirements for Certification Programs

All certification programs must:

1. Require applicants for certification to (a) receive training in the topics set forth in § 34.43(g) or equivalent Agreement State regulations, and (b) satisfactorily complete a written examination covering these topics;

2. Require applicants for certification to provide documentation that demonstrates that the applicant has: (a) received training in the topics set forth in § 34.43(g) or equivalent Agreement State regulations; (b) satisfactorily completed a minimum period of on-the-job training; and (c) has received verification by an Agreement State or a NRC licensee that the applicant has demonstrated the capability of independently working as a radiographer;

3. Include procedures to ensure that all examination questions are protected from disclosure;

4. Include procedures for denying an application, revoking, suspending, and reinstating a certificate;

5. Provide a certification period of not less than 3 years nor more than 5 years;

6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training.

7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

III. Requirements for Written Examinations

All examinations must be:

1. Designed to test an individual's knowledge and understanding of the topics listed in § 34.43(g)

or equivalent Agreement State requirements;

2. Written in a multiple-choice format;

3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in § 34.43(g).

CHAPTER 33.1-10-07.2
MEDICAL USE OF BYPRODUCT MATERIAL

Section
33.1-10-07.2-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 35

33.1-10-07.2-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 35.

10 Code of Federal Regulations 35.1, 35.2, 35.5, 35.6, 35.7, 35.10, 35.11, 35.12, 35.13, 35.14, 35.15, 35.18, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.49, 35.50, 35.51, 35.55, 35.57, 35.59, 35.60, 35.61, 35.63, 35.65, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.100, 35.190, 35.200, 35.204, 35.290, 35.300, 35.310, 35.315, 35.390, 35.392, 35.394, 35.396, 35.400, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.457, 35.490, 35.491, 35.500, 35.590, 35.600, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.657, 35.690, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047, 35.3067, and 35.3204 are adopted by reference as they exist on September 8, 2021~~January 14, 2019~~, with the following exceptions:

1. Not adopted by reference are 35.11(c)(1) and 35.13(a)(1).

2. Requirements in 10 Code of Federal Regulations 35 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", "NRC regional office", NRC operations center, or "director, office of nuclear material safety and safeguards" appear in 10 Code of Federal Regulations part 35, substitute the words "department of environmental quality", except when referencing licenses or permits issued by the U.S. Nuclear Regulatory Commission, master material licenses issued by the U.S. Nuclear Regulatory Commission, specialty boards recognized by the U.S. Nuclear Regulatory Commission, the Medical Uses Licensee Toolkit Web page, and definition of “agreement state” in 35.2.

4. "Act" includes North Dakota Century Code chapters 23.1-02 and 23.1-03.

5. North Dakota state form number 8418, "application for radioactive material license", must be used instead of NRC form 313 as specified in 10 Code of Federal Regulations part 35~~4~~.

6. For references to 10 Code of Federal Regulations parts 170 and 171, see chapter 33.1-10-11 for applicable fee schedules.

History: Effective January 1, 2019; amended effective July 1, 2021.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

PART 35--MEDICAL USE OF BYPRODUCT MATERIAL

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35.632 Full calibration measurements on teletherapy units.

35.633 Full calibration measurements on remote afterloader units.

35.635 Full calibration measurements on gamma stereotactic radiosurgery units.

35.642 Periodic spot-checks for teletherapy units.

35.643 Periodic spot-checks for remote afterloader units.

35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.

35.647 Additional technical requirements for mobile remote afterloader units.

35.652 Radiation surveys.

35.655 Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

35.657 Therapy-related computer systems.

35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Subpart I--[Reserved]

Subpart J--[Reserved]

Subpart K--Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

35.1000 Other medical uses of byproduct material or radiation from byproduct material.

Subpart L--Records

35.2024 Records of authority and responsibilities for radiation protection programs.

35.2026 Records of radiation protection program changes.

35.2040 Records of written directives.

35.2041 Records for procedures for administrations requiring a written directive.

35.2060 Records of calibrations of instruments used to measure the activity of unsealed byproduct materials.

35.2061 Records of radiation survey instrument calibrations.

35.2063 Records of dosages of unsealed byproduct material for medical use.

35.2067 Records of leaks tests and inventory of sealed sources and brachytherapy sources.

35.2070 Records of surveys for ambient radiation exposure rate.

35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.

35.2080 Records of mobile medical services.

35.2092 Records of decay-in-storage.

35.2204 Records of molybdenum-99, strontium-82, and strontium-85 concentrations.

35.2310 Records of safety instruction.

35.2404 Records of surveys after source implant and removal.

35.2406 Records of brachytherapy source accountability.

35.2432 Records of calibration measurements of brachytherapy sources.

35.2433 Records of decay of strontium-90 sources for ophthalmic treatments.

35.2605 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

35.2610 Records of safety procedures.

35.2630 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

35.2642 Records of periodic spot-checks for teletherapy units.

35.2643 Records of periodic spot-checks for remote afterloader units.

35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.

35.2647 Records of additional technical requirements for mobile remote afterloader units.

35.2652 Records of surveys of therapeutic treatment units.

35.2655 Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

Subpart M--Reports

35.3045 Report and notification of a medical event.

35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.

35.3067 Report of a leaking source.

35.3204 Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

Subpart N--Enforcement

35.4001 Violations.

35.4002 Criminal penalties.

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

Source: 67 FR 20370, Apr. 24, 2002, unless otherwise noted.

[72 FR 55864 Oct. 1, 2007]

Subpart A--General Information

§ 35.1 Purpose and scope.

This part contains the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of parts 19, 20, 21, 30, 71, 170, and 171 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

§ 35.2 Definitions.

Address of use means the building or buildings that are identified on the license and where byproduct material may be received, prepared, used, or stored.

Agreement State means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

Area of use means a portion of an address of use that has been set aside for the purpose of

receiving, preparing, using, or storing byproduct material.

Associate Radiation Safety Officer means an individual who--

(1) Meets the requirements in §§ 35.50 and 35.59; and

(2) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on —

(i) A specific medical use license issued by the Commission or an Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

Authorized medical physicist means an individual who--

Meets the requirements in §§ 35.51(a) and 35.59; or

(2) Is identified as an authorized medical physicist or teletherapy physicist on--

(i) A specific medical use license issued by the Commission or Agreement State;

(ii) A medical use permit issued by a Commission master material licensee;

(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee; or

(iv) A permit issued by a Commission master material license broad scope medical use permittee.

Authorized nuclear pharmacist means a pharmacist who--

(1) Meets the requirements in §§ 35.55(a) and 35.59; or

(2) Is identified as an authorized nuclear pharmacist on--

(i) A specific license issued by the Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(ii) A permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(iv) A permit issued by a Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(4) Is designated as an authorized nuclear pharmacist in accordance with § 32.72(b)(4).

Authorized user means a physician, dentist, or podiatrist who--

(1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or

(2) Is identified as an authorized user on--

(i) A Commission or Agreement State license that authorizes the medical use of byproduct material;

(ii) A permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material;

(iii) A permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or

(iv) A permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

Brachytherapy means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

Brachytherapy source means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Client's address means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with § 35.80.

Cyclotron means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A
cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

Dedicated check source means a radioactive source that is used to assure the constant operation

of a radiation detection or measurement device over several months or years.

Dentist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

High dose-rate remote afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Low dose-rate remote afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

Management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

Manual brachytherapy, as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

Medical event means an event that meets the criteria in § 35.3045(a) or (b).

Medical institution means an organization in which more than one medical discipline is practiced.

Medical use means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user.

Medium dose-rate remote afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Mobile medical service means the transportation of byproduct material to and its medical use at the client's address.

Ophthalmic physicist means an individual who--

(1) Meets the requirements in § 35.433(a)(2) and § 35.59; and

(2) Is identified as an ophthalmic physicist on a—

(i) Specific medical use license issued by the Commission or an Agreement State;

(ii) Permit issued by a Commission or Agreement State broad scope medical use licensee;

(iii) Medical use permit issued by a Commission master material licensee; or

(iv) Permit issued by a Commission master material licensee broad scope medical use permittee.

Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

Patient intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

Pharmacist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

Podiatrist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

Positron Emission Tomography (PET) radionuclide production facility is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer.

Prescribed dosage means the specified activity or range of activity of unsealed byproduct material as documented--

(1) In a written directive; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to §§ 35.100 and 35.200.

Prescribed dose means--

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(3) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Pulsed dose-rate remote afterloader, as used in this part, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but--

(1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(2) Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer means an individual who—

(1) Meets the requirements in §§ 35.50(a) or (c)(1) and 35.59; or

(2) Is identified as a Radiation Safety Officer on--

(i) A specific medical use license issued by the Commission or Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

Sealed source means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

Stereotactic radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to ~~very precisely deliver a therapeutic dose~~deliver a therapeutic dose very precisely to a tissue volume.

Structured educational program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Teletherapy, as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

Temporary job site means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

Therapeutic dosage means a dosage of unsealed byproduct material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic dose means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.

Treatment site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Type of use means use of byproduct material under §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, or 35.1000.

Unit dosage means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Written directive means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in § 35.40.

[69 FR 55737, Sep. 16, 2004; 70 FR 16361, Mar. 30, 2005; 71 FR 15008, Mar. 27, 2006; 72 FR 45151, Aug. 13, 2007; 72 FR 55930 Oct. 1, 2007; 83 FR 33046, Jul. 16, 2018]

§ 35.5 Maintenance of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 35.6 Provisions for the protection of human research subjects.

(a) A licensee may conduct research involving human research subjects only if it uses the byproduct materials specified on its license for the uses authorized on its license.

(b) If the research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the

licensee shall, before conducting research--

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

(c) If the research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its NRC medical use license. The amendment request must include a written commitment that the licensee will, before conducting research--

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent", as defined and described in the Federal Policy, from the human research subject.

(d) Nothing in this section relieves licensees from complying with the other requirements in this part.

[67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002]

§ 35.7 FDA, other Federal, and State requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

§ 35.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.396, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061,

35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047 and 35.3067.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved as follows:

(1) In § 35.12, NRC Form 313, including NRC Form 313A, which licensees may use to provide supplemental information, is approved under control number 3150-0120.

(2) [Reserved]

[67 FR 20370; Apr. 24, 2002, as amended at 70 FR 16361, Mar. 30, 2005]

§ 35.10 Implementation.

(a) A Government agency or a Federally recognized Indian Tribe that possesses and uses accelerator-produced
radioactive material or discrete sources of radium-226 for which a specific medical use license is required by the Atomic Energy Act of 1954, as amended, must comply with the requirements of this part, including provisions that are specific to licensees, on November 30, 2007. All other persons who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required, must comply with the requirements of this part, including provisions that are specific to licensees, on August 8, 2009, or earlier as noticed by the NRC.

(b) [Reserved]

(c) [Reserved]

(d) If a license condition exempted a licensee from a provision of Part 35 on October 24, 2002, then the license condition continues to exempt the licensee from the requirements in the corresponding provision of §§ 35.1-35.4002.

(e) When a requirement in this part differs from the requirement in an existing license condition, the requirement in this part shall govern.

(f) A licensee shall continue to comply with any license condition that requires it to implement procedures required by §§ 35.610, 35.642, 35.643, and 35.645 until there is a license amendment or renewal that modifies the license condition.

[69 FR 55737, Sep. 16, 2004; 70 FR 16361, Mar. 30, 2005; 71 FR 15008, Mar. 27, 2006; 72 FR 55930 Oct. 1, 2007]

§ 35.11 License required.

(a) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) or (c) of this section.

(b) A specific license is not needed for an individual who--

(1) Receives, possesses, uses, or transfers byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.27, unless prohibited by license condition; or

(2) Prepares unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in § 35.27, unless prohibited by license condition.

(c)(1) A Government agency or a Federally recognized Indian Tribe, that possesses and uses accelerator-produced
radioactive material or discrete sources of radium-226 for which a specific medical use license is required in paragraph (a) of this section, may continue to use such materials for medical uses until the date of the NRC's final licensing determination, provided that the person submits a medical use license application on or before December 1, 2008.

(2) Except as provided in paragraph (c)(1) of this section, all other persons, who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required in paragraph (a) of this section, may continue to use this type of material for medical uses permitted under this part until the date of the NRC's final licensing determination, provided that the person submits a medical use license application within 12 months from the waiver expiration date of August 7, 2009 or within 12 months from the date of an earlier_
termination of the waiver as noticed by the NRC, whichever date is earlier.

[72 FR 55930 Oct. 1, 2007]

§ 35.12 Application for license, amendment, or renewal.

(a) An application must be signed by the applicant's or licensee's management.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000 must be made by--

(1) Filing an original NRC Form 313, “Application for Material License,” that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical

physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s); and

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

(c) A request for a license amendment or renewal must be made by--

(1) Submitting an original and one copy of either--

(i) NRC Form 313, "Application for Material License"; or

(ii) A letter containing all information required by NRC Form 313; and

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or amendment for medical use of byproduct material as described in § 35.1000 must also include:

(1) Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from, subparts A through C, L, and M of this part;

(2) Identification of and commitment to follow the applicable radiation safety program requirements in subparts D through H of this part that are appropriate for the specific § 35.1000 medical use;

(3) Any additional specific information on--

(i) Radiation safety precautions and instructions;

(ii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(iii) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(4) Any other information requested by the Commission in its review of the application.

(e) An applicant that satisfies the requirements specified in § 33.13 of this chapter may apply for a Type A specific license of broad scope.

[67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002; 83 FR 33046, Jul. 16, 2018]

§ 35.13 License amendments.

A licensee shall apply for and must receive a license amendment--

(a) Before it receives, prepares, or uses byproduct material for a type of use that is permitted under this part, but is not authorized on the licensee's current license issued under this part; except that—

(1) A Government agency or a Federally recognized Indian Tribe licensee who possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 may continue to use such material for medical uses permitted under this part until the date of the NRC's final licensing determination, provided that the licensee submits an amendment application on or before June 2, 2008.

(2) Except as provided in paragraph (a)(1) of this section, all other licensees who possess and use accelerator-produced radioactive material or discrete sources of radium-226 may continue to use those materials for medical uses permitted under this part until the date of the NRC's final licensing determination, provided that the person submits a medical use license amendment request within 6 months from the waiver expiration date of August 7, 2009 or within 6 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

(b) Before it permits anyone to work as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist under the license, except—

(1) For an authorized user, an individual who meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a);

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in §§ 35.55(a) and 35.59;

(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.51(a) and 35.59;

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist--

(i) On a Commission or Agreement State license or other equivalent permit or license recognized by NRC that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(ii) On a permit issued by a Commission or Agreement State specific license of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(iii) On a permit issued by a Commission master material licensee that is authorized to permit the

use of byproduct material in medical use or in the practice of nuclear pharmacy; or

(iv) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

(5) A physician, podiatrist, or dentist who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or a nuclear pharmacist who used only accelerator-produced radioactive materials in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, and for only those materials and uses performed before these dates.

(c) Before it changes Radiation Safety Officers, except as provided in § 35.24(c);

(d) Before it permits anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties and tasks to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

(e) Before it receives byproduct material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

(f) Before it adds to or changes the areas of use identified in the application or on the license, including areas used in accordance with either § 35.100 or § 35.200 if the change includes addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area. Other areas of use where byproduct material is used only in accordance with either § 35.100 or § 35.200 are exempt;

(g) Before it changes the address(es) of use identified in the application or on the license;

(h) Before it revises procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable, where such revision reduces radiation safety; and

(i) Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

[70 FR 16361, Mar. 30, 2005; 71 FR 15008, Mar. 27, 2006; 72 FR 55930 Oct. 1, 2007; 83 FR 33046, Jul. 16, 2018]

§ 35.14 Notifications.

(a) A licensee shall provide the Commission, no later than 30 days after the date that the licensee

permits an individual to work under the provisions of § 35.13(b) as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist —

(1) A copy of the board certification and, as appropriate, verification of completion of:

(i) Training for the authorized medical physicist under § 35.51(c);

(ii) Any additional case experience required in § 35.390(b)(1)(ii)(G) for an authorized user under § 35.300; or

(iii) Device specific training in § 35.690(c) for the authorized user under § 35.600; or

(2) A copy of the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, the permit issued by a Commission master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC for each individual whom the licensee permits to work under the provisions of this section.

(b) A licensee shall notify the Commission no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety Officer, an authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

(2) The licensee permits an individual qualified to be a Radiation Safety Officer under §§ 35.50 and 35.59 to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with § 35.24(c);

(3) The licensee's mailing address changes;

(4) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § 30.34(b) of this chapter;

(5) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; or

(6) The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not

require a license amendment as provided in § 35.13(i). The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

(c) The licensee shall send the documents required in this section to the appropriate address identified in § 30.6 of this chapter.

[68 FR 58805, Oct. 10, 2003; 70 FR 16361, Mar. 20, 2005; 71 FR 15008, Mar. 27, 2006; 72 FR 55930 Oct. 1, 2007; 83 FR 33046, Jul. 16, 2018]

§ 35.15 Exemptions regarding Type A specific licenses of broad scope.

A licensee possessing a Type A specific license of broad scope for medical use, issued under Part 33 of this chapter, is exempt from--

(a) The provisions of § 35.12(d) regarding the need to file an amendment to the license for medical use of byproduct material, as described in § 35.1000;

(b) The provisions of § 35.13(b);

(c) The provisions of § 35.13(f) regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

(d) The provisions of § 35.14(a);

(e) The provisions of § 35.14(b)(1) for an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, or an ophthalmic physicist;

(f) The provisions of § 35.14(b)(5).

(g) The provisions of § 35.49(a).

[72 FR 55931 Oct. 1, 2007; 83 FR 33046, Jul. 16, 2018]

§ 35.18 License issuance.

(a) The Commission shall issue a license for the medical use of byproduct material if--

(1) The applicant has filed NRC Form 313 "Application for Material License" in accordance with the instructions in § 35.12;

(2) The applicant has paid any applicable fee as provided in Part 170 of this chapter;

(3) The Commission finds the applicant equipped and committed to observe the safety standards

established by the Commission in this Chapter for the protection of the public health and safety; and

(4) The applicant meets the requirements of Part 30 of this chapter.

(b) The Commission shall issue a license for mobile medical service if the applicant:

(1) Meets the requirements in paragraph (a) of this section; and

(2) Assures that individuals or human research subjects to whom unsealed byproduct material or radiation from implants containing byproduct material will be administered may be released following treatment in accordance with § 35.75.

§ 35.19 Specific exemptions

The Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Subpart B--General Administrative Requirements

§ 35.24 Authority and responsibilities for the radiation protection program.

(a) In addition to the radiation protection program requirements of § 20.1101 of this chapter, a licensee's management shall approve in writing--

(1) Requests for a license application, renewal, or amendment before submittal to the Commission;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under § 35.26;

(b) A licensee's management shall appoint a Radiation Safety Officer who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee’s management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee’s management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate

Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

(c) For up to 60 days each year, a licensee may permit an individual qualified to be a Radiation Safety Officer, under §§ 35.50 and 35.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in paragraph (g) of this section, if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of this section and notifies the Commission in accordance with § 35.14(b).

(d) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with paragraph (c) of this section, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of byproduct material permitted by the license.

(e) A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(f) Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of this part, or two or more types of units under Subpart H of this part, shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

(g) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to--

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(h) A licensee shall retain a record of actions taken under paragraphs (a), (b), and (e) of this section in accordance with § 35.2024.

[83 FR 33046, Jul. 16, 2018]

§ 35.26 Radiation protection program changes.

(a) A licensee may revise its radiation protection program without Commission approval if--

(1) The revision does not require a license amendment under § 35.13;

(2) The revision is in compliance with the regulations and the license ;

(3) The revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and

(4) The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with § 35.2026.

§ 35.27 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user, as allowed by § 35.11(b)(1), shall--

(1) In addition to the requirements in § 19.12 of this chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of byproduct material.

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by § 35.11(b)(2), shall--

(1) In addition to the requirements in § 19.12 of this chapter, instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions.

(c) A licensee that permits supervised activities under paragraphs (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.

§ 35.40 Written directives.

(a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

(b) The written directive must contain the patient or human research subject's name and the following information--

(1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

(6) For permanent implant brachytherapy:

(i) Before implantation: the treatment site, the radionuclide, and the total source strength; and

(ii) After implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date; or

(7) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: the treatment site, radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: the radionuclide; treatment site; number of sources; total source strength and exposure time (or the total dose); and date.

(c)(1) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(2) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(d) The licensee shall retain a copy of the written directive in accordance with § 35.2040.

[67 FR 20370, Apr. 24, 2002 as amended at 68 FR 75389, Dec. 31, 2003; 83 FR 33046, Jul. 16, 2018]

§ 35.41 Procedures for administrations requiring a written directive.

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

(b) At a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee's use of byproduct material--

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations;

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by §§ 35.600 or 35.1000;

(5) Determining if a medical event, as defined in § 35.3045, has occurred; and

(6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

(c) A licensee shall retain a copy of the procedures required under paragraph (a) in accordance with § 35.2041.

[72 FR 45151, Aug. 13, 2007; 83 FR 33046, Jul. 16, 2018]

§ 35.49 Suppliers for sealed sources or devices for medical use.

For medical use, a licensee may only use--

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 of this chapter or equivalent requirements of an Agreement State;

(b) Sealed sources or devices non-commercially transferred from a Part 35 licensee or an Agreement State medical use licensee.

(c) Teletherapy sources manufactured and distributed in accordance with a license issued under 10 CFR Part 30 or the equivalent requirements of an Agreement State.

[71 FR 15008, Mar. 27, 2006]

§ 35.50 Training for Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in § 35.24 to be an individual who—

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (d) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1)(i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

(iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection,

mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2)(i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics—

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(B) In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.57, 35.290, or 35.390; and

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(b)(1) Has completed a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas-

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or an Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Commission or an Agreement State license or permit issued by a Commission master material licensee. The full-time radiation safety experience must involve the following—

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of byproduct material; and

(2) This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (d) of this section, and is able to independently fulfill the radiation safety related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

(c)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under §35.51(a), has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and meets the requirements in paragraph (d) of this section; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Commission or an Agreement State license, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State licensee of broad scope, or a permit issued by a Commission master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in paragraph (d) of this section; or

(3) Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by a Commission master material licensee. The individual must also meet the requirements in paragraph (d) of this section.

(d) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

[70 FR 16361, Mar. 30, 2005; 71 FR 1926, Jan. 12, 2006; 71 FR 15008, Mar. 27, 2006; 74 FR 33904, Jul. 14, 2009; 83 FR 33046, Jul. 16, 2018; 86 FR 43397, Aug. 9, 2021; 86 FR 47209, Aug. 24, 2021 (corrected version)]

§ 35.51 Training for an authorized medical physicist.

Except as provided in § 35.57, the licensee shall require the authorized medical physicist to be an individual who—

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(2) Have 2 years of full-time practical training and/or supervised experience in medical physics—

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the Commission or an Agreement State; or

(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in § 35.57, 35.490, or 35.690; and

(3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(b)(1) Holds a master's or doctor's degree in physics, medical physics, other physical science,

engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

(iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (c) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in §§ 35.51, 35.57, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

(c) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

[67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55737, Sep. 16, 2004; 70 FR 16362, Mar. 30, 2005; 71 FR 15008, Mar. 27, 2006; 74 FR 33904, Jul. 14, 2009; 83 FR 33046, Jul. 16, 2018]

§ 35.55 Training for an authorized nuclear pharmacist.

Except as provided in § 35.57, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who--

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been

recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the ~~American Council on Pharmaceutical Education (ACPE)~~ Accreditation Council for Pharmacy Education (ACPE) (previously named the American Council on Pharmaceutical Education) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving--

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid medical events in the administration of byproduct material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

[70 FR 16362, Mar. 30, 2005; 83 FR 33046, Jul. 16, 2018; 86 FR 43397, Aug. 9, 2021; 86 FR 47209, Aug. 24, 2021 (corrected version)]

§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

(a)(1) An individual identified on a Commission or an Agreement State license or a permit issued by a Commission or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2019 need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively, except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in § 35.50(d) or § 35.51(c), as appropriate, for any material or uses for which they were not authorized prior to this date.

(2) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of § 35.50 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in § 35.51, for those materials and uses that these individuals

performed on or before October 24, 2005.

(4) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of §§ 35.50, 35.51 or 35.55, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of this chapter.

(b)(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or an Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of subparts D through H of this part.

(2) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material on a license issued by the Commission or an Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State broad scope licensee, or a permit issued in accordance with a Commission master material broad scope license on or before October 24, 2005~~or a permit issued by a Commission master material license of broad scope on or before October 24, 2005~~, need not comply with the training requirements of Subparts D through H of this part for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

(i) For uses authorized under §§ 35.100 or 35.200, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(ii) For uses authorized under § 35.300, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(iii) For uses authorized under §§ 35.400 or 35.600, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(iv) For uses authorized under § 35.500, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subparts D through H of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.

(c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.

[70 FR 16363, Mar. 30, 2005; 72 FR 55931 Oct. 1, 2007; 74 FR 33905, Jul. 14, 2009; 83 FR 33046, Jul. 16, 2018; 86 FR 43397, Aug. 9, 2021; 86 FR 47209, Aug. 24, 2021 (corrected version)]

§ 35.59 Recentness of training.

The training and experience specified in Subparts B, D, E, F, G, and H of this part must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

[71 FR 15008, Mar. 27, 2006]

Subpart C--General Technical Requirements

§ 35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material

(a) For direct measurements performed in accordance with § 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject.

(b) A licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

(c) A licensee shall retain a record of each instrument calibration required by this section in accordance with § 35.2060.

§ 35.61 Calibration of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 before first use, annually, and following a repair that affects the calibration. A licensee shall--

(1) Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;

(2) Calibrate two separated readings on each scale or decade that will be used to show compliance; and

(3) Conspicuously note on the instrument the date of calibration.

(b) A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

(c) A licensee shall retain a record of each survey instrument calibration in accordance with § 35.2061.

§ 35.63 Determination of dosages of unsealed byproduct material for medical use.

(a) A licensee shall determine and record the activity of each dosage before medical use.

(b) For a unit dosage, this determination must be made by--

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by--

(i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive

Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(iii) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State
requirements.

(c) For other than unit dosages, this determination must be made by--

(1) Direct measurement of radioactivity;

(2) Combination of measurement of radioactivity and mathematical calculations; or

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by:

(i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(ii) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State
requirements.

(d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(e) A licensee shall retain a record of the dosage determination required by this section in accordance with § 35.2063.

[72 FR 55931 Oct. 1, 2007]

§ 35.65 Authorization for calibration, transmission, and reference sources.

(a) Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use:

(1) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations;

(2) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations, providing the redistributed

sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(3) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi);

(4) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 μCI) or 1000 times the quantities in appendix B of part 30 of this chapter; or

(5) Technetium-99m in amounts as needed.

(b) Byproduct material in sealed sources authorized by this provision shall not be:

(1) Used for medical use as defined in § 35.2 except in accordance with the requirements in § 35.500; or

(2) Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this section.

(c) A licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraphs (a) or (b) of this section need not list these sources on a specific medical use license.

[71 FR 15009, Mar. 27, 2006; 83 FR 33046, Jul. 16, 2018]

§ 35.67 Requirements for possession of sealed sources and brachytherapy sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

(b) A licensee in possession of a sealed source shall--

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

(c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 μCi) of radioactive material in the sample.

(d) A licensee shall retain leak test records in accordance with § 35.2067(a).

(e) If the leak test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination, the licensee shall--

(1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in parts 20 and 30 of this chapter; and

(2) File a report within 5 days of the leak test in accordance with § 35.3067.

(f) A licensee need not perform a leak test on the following sources:

(1) Sources containing only byproduct material with a half-life of less than 30 days;

(2) Sources containing only byproduct material as a gas;

(3) Sources containing 3.7 MBq (100 μCi) or less of beta or gamma-emitting material or 0.37 MBq (10 μCi) or less of alpha-emitting material;

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.

(g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with § 35.2067(b).

§ 35.69 Labeling of vials and syringes.

Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

§ 35.70 Surveys of ambient radiation exposure rate.

(a) In addition to the surveys required by Part 20 of this chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed byproduct material requiring a written directive was prepared for use or administered.

(b) A licensee does not need to perform the surveys required by paragraph (a) of this section in an area(s) where patients or human research subjects are confined when they cannot be released under § 35.75.

(c) A licensee shall retain a record of each survey in accordance with § 35.2070.

§ 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[1]

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include--

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with § 35.2075(a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with § 35.2075(b).

[67 FR 20370, Apr. 24, 2002 as amended at 70 FR 16363, Mar. 30, 2005; 72 FR 45151, Aug. 13, 2007]

[1] The current revision of NUREG–1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses" describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

§ 35.80 Provision of mobile medical service.

(a) A licensee providing mobile medical service shall--

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(2) Check instruments used to measure the activity of unsealed byproduct material for proper

function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;

(3) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(4) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Part 20 of this chapter.

(b) A mobile medical service may not have byproduct material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the byproduct material. Byproduct material delivered to the client must be received and handled in conformance with the client's license.

(c) A licensee providing mobile medical services shall retain the letter required in paragraph (a)(1) and the record of each survey required in paragraph (a)(4) of this section in accordance with § 35.2080(a) and (b), respectively.

§ 35.92 Decay-in-storage.

(a) A licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it—

(1) Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(2) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with § 35.2092.

[72 FR 45151, Aug. 13, 2007]

Subpart D--Unsealed Byproduct Material--Written Directive Not Required

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

Except for quantities that require a written directive under § 35.40(b), a licensee may use any

unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is—

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or

(b) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G); or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16363, Mar. 30, 2005; 71 FR 15009, Mar. 27, 2006; 72 FR 55931 Oct. 1, 2007]

§ 35.190 Training for uptake, dilution, and excretion studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(F) of this section; and

(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under §§ 35.290, 35.390, or equivalent Agreement State requirements; or (c)(1)*

(c)(1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, 35.390, or equivalent Agreement State requirements, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under § 35.100. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph (c)(1) of this section.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16363, Mar. 30, 2005; 71 FR 15009, Mar. 27, 2006; 72 FR 45151, Aug. 13, 2007; 74 FR 33905, Jul. 14, 2009; 83 FR 33046, Jul. 16, 2018]

§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is—

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or

(b) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in § 35.290,

or 35.390 and 35.290(c)(1)(ii)(G); or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section;

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16363, Mar. 30, 2005; 71 FR 15009, Mar. 27, 2006; 72 FR 55932 Oct. 1, 2007]

§ 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

(a) A licensee may not administer to humans a radiopharmaceutical that contains:

(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of
molybdenum-99 per millicurie of technetium-99m); or

(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with paragraph (a) of this section.

(c) A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with paragraph (a) of this section.

(d) If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with § 35.2204.

(e) The licensee shall report any measurement that exceeds the limits in paragraph (a) of this

section at the time of generator elution, in accordance with § 35.3204.

[72 FR 55932 Oct. 1, 2007; 83 FR 33046, Jul. 16, 2018]

§ 35.290 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) of this section; and

(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under § 35.390 and meets the requirements in § 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements; or

(c)(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State

requirements. An authorized nuclear pharmacist who meets the requirements in § 35.55 or § 35.57 may provide the supervised work experience for paragraph (c)(1)(ii)(G) of this section. Work experience must involve—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide~~ic~~ purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under §§ 35.100 and 35.200. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph (c)(1) of this section.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16364, Mar. 30, 2005; 71 FR 15009, Mar. 27, 2006; 72 FR 45151, Aug. 13, 2007;

74 FR 33905, Jul. 14, 2009; 83 FR 33046, Jul. 16, 2018]

Subpart E--Unsealed Byproduct Material--Written Directive Required

§ 35.300 Use of unsealed byproduct material for which a written directive is required.

A licensee may use any unsealed byproduct material identified in §35.390(b)(1)(ii)(G) prepared for medical use and for which a written directive is required that is—

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or

(b) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sep. 16, 2004; 71 FR 15009, Mar. 27, 2006; 72 FR 55932 Oct. 1, 2007; 83 FR 33046, Jul. 16, 2018]

§ 35.310 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the

personnel and include—

(1) Patient or human research subject control;

(2) Visitor control, including—

(i) Routine visitation to hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and

(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003]

§ 35.315 Safety precautions.

(a) For each patient or human research subject who cannot be released under § 35.75, a licensee shall—

(1) Quarter the patient or the human research subject either in—

(i) A private room with a private sanitary facility; or

(ii) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released under § 35.75;

(2) Visibly post the patient's or the human research subject's room with a “Radioactive Materials” sign.

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

(4) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and

with no interposed shielding, or handle the material and items as radioactive waste.

(b) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003]

§ 35.390 Training for use of unsealed byproduct material for which a written directive is required.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(1)(ii)(G) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs (b)(1)(i) through (b)(1)(ii)(E) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the ~~Committee on Post-Graduate~~Council on Postdoctoral Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or

(b)(1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages in the same dosage category or categories (*i.e.*, § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involve—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(C) Calculating, measuring and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(F) [Reserved]

(G) Administering dosages of radioactive drugs to patients or human research subjects from the three categories in this paragraph. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under § 35.1000. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status—

(*1*) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

(*2*) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-1312;

(*3*) Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and is able to independently fulfill the radiation

safety-related duties as an authorized user for the medical uses authorized under § 35.300 for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, 35.390, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph (b)(1) of this section.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003; 68 FR 75389, Dec. 31, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16364, Mar. 30, 2005; 71 FR 15009, Mar. 27, 2006; 74 FR 33905, Jul. 14, 2009; 83 FR 33046, Jul. 16, 2018; 85 FR 65656, Oct. 16, 2020]

[2] Experience with at least 3 cases in Category (G)(*2*) also satisfies the requirement in Category (G)(*1*)

§ 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).

Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section and whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page.; or

(b) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(1) or (2), § 35.394, or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training

must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b) must also have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2). The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under § 35.300. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements and has experience in administering dosages as

specified in § 35.390(b)(1)(ii)(G)(1) or § 35.390(b)(1)(ii)(G)(2); or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements, has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or § 35.390(b)(1)(ii)(G)(2), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (c)(1) and (2) of this section.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003; 68 FR 75389, Dec. 31, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16364, Mar. 30, 2005; 71 FR 15009, Mar. 27, 2006; 74 FR 33905, Jul. 14, 2009; 83 FR 33046, Jul. 16, 2018]

§ 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).

Except as provided in 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section, and whose certification has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page.; or

(b) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(2) or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under § 35.300. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements, and has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2); or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements, has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and

must include training and experience specified in paragraphs (c)(1) and (2) of this section.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003; 68 FR 75389, Dec. 31, 2003; 69 FR 55739, Sep. 16, 2004; 70 FR 16365, Mar. 30, 2005; 71 FR 15010. Mar. 27, 2006; 74 FR 33905, Jul. 14, 2009; 83 FR 33046, Jul. 16, 2018]

§ 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

(a) Except as provided in § 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who—

(1) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(3), or equivalent Agreement State requirements; or

(2) Is an authorized user under §§ 35.490, 35.690, or equivalent Agreement State requirements, and who meets the requirements in paragraph (b) of this section; or

(3) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 35.490 or 35.690, and who meets the requirements in paragraph (b) of this section.

(b) The physician—

(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in § 35.390(b)(1)(ii)(G)(3). The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, in the parenteral administrations listed in § 35.390(b)(1)(ii)(G)(3). A supervising authorized user who meets the requirements in §§ 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least three cases of the parenteral administrations as specified in § 35.390(b)(1)(ii)(G)(3); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b)(1) and (2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements. A preceptor authorized user who meets the requirements in § 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (b)(1) and (2) of this section.

[70 FR 16365, Mar. 30, 2005; 71 FR 15010. Mar. 27, 2006; 74 FR 33906, Jul. 14, 2009; 83 FR 33046, Jul. 16, 2018]

Subpart F--Manual Brachytherapy

§ 35.400 Use of sources for manual brachytherapy.

A licensee must use only brachytherapy sources:

(a) Approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(b) In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.

[83 FR 33046, Jul. 16, 2018]

§ 35.404 Surveys after source implant and removal.

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(c) A licensee shall retain a record of the surveys required by paragraphs (a) and (b) of this section in accordance with § 35.2404.

§ 35.406 Brachytherapy sources accountability.

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with § 35.2406.

§ 35.410 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to

personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the--

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient or human research subject control;

(4) Visitor control, including both:

(i) Routine visitation of hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and

(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.415 Safety precautions.

(a) For each patient or human research subject who is receiving brachytherapy and cannot be released under § 35.75, a licensee shall--

(1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

(2) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(b) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source--

(1) Dislodged from the patient; and

(2) Lodged within the patient following removal of the source applicators.

(c) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

§ 35.432 Calibration measurements of brachytherapy sources.

(a) Before the first medical use of a brachytherapy source on or after October 24, 2002, a licensee shall have—

(1) Determined the source output or activity using a dosimetry system that meets the requirements of § 35.630(a);

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(b) Instead of a licensee making its own measurements as required in paragraph (a) of this section, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (a) of this section.

(c) A licensee shall mathematically correct the outputs or activities determined in paragraph (a) of this section for physical decay at intervals consistent with 1 percent physical decay.

(d) A licensee shall retain a record of each calibration in accordance with § 35.2432.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003]

§ 35.433 Strontium-90 sources for ophthalmic treatments.

(a) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph (b) of this section are performed by either:

(1) An authorized medical physicist; or

(2) An individual who:

(i) is identified as an ophthalmic physicist on a specific medical use license issued by the Commission or an Agreement State; permit issued by a Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Commission master material licensee; or permit issued by a Commission master material licensee broad scope medical use permittee; and

(ii) holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(iii) has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(iv) Has documented training in:

(A) The creation, modification, and completion of written directives;

(B) Procedures for administrations requiring a written directive; and

(C) Performing the calibration measurements of brachytherapy sources as detailed in § 35.432.

(b) The individuals who are identified in paragraph (a) of this section must:

(1) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432; and

(2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph (a) of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(c) Licensees must retain a record of the activity of each strontium-90 source in accordance with § 35.2433.

[83 FR 33046, Jul. 16, 2018]

§ 35.457 Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine sealed source positions from radiographic images.

§ 35.490 Training for use of manual brachytherapy sources.

Except as provided in § 35.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee on Post-Graduate~~Council on Postdoctoral Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes—

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, at a medical facility authorized to use byproduct materials under § 35.400, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material;

(F) Using emergency procedures to control byproduct material; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee~~ Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under §35.400. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (b)(1) and (b)(2) of this section.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003; 69 FR 55739, Sep. 16, 2004; 70 FR 16366, Mar. 30, 2005; 71 FR 15010. Mar. 27, 2006; 74 FR 33906, Jul. 14, 2009; 83 FR 33046, Jul. 16, 2018; 85 FR 65656, Oct. 16, 2020]

§ 35.491 Training for ophthalmic use of strontium-90.

Except as provided in § 35.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who—

(a) Is an authorized user under § 35.490 or equivalent Agreement State requirements; or

(b)(1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve—

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.490, 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19326, Apr. 21, 2003; 69 FR 55739, Sep. 16, 2004; 70 FR 16366, Mar. 30, 2005; 71 FR 15011, Mar. 27, 2006; 74 FR 33906, Jul. 14, 2009; 83 FR 33046, Jul. 16, 2018]

Subpart G--Sealed Sources for Diagnosis

§ 35.500 Use of sealed sources and medical devices for diagnosis.

(a) A licensee must use only sealed sources that are not in medical devices for diagnostic medical

uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(b) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.

[83 FR 33046, Jul. 16, 2018]

§ 35.590 Training for use of sealed sources and medical devices for diagnosis.

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source or a device authorized under § 35.500 to be a physician, dentist, or podiatrist who—

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (c) and (d) of this section and whose certification has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

(b) Is an authorized user for uses listed in § 35.200 or equivalent Agreement State requirements; or

(c) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include—

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(d) Has completed training in the use of the device for the uses requested.

[70 FR 16366, Mar. 30, 2005; 83 FR 33046, Jul. 16, 2018]

Subpart H--Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

§ 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

(a) A licensee must only use sealed sources:

(1) Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or

(2) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.

(b) A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(1) Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

[83 FR 33046, Jul. 16, 2018]

§ 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit.

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

(b) A licensee shall retain a record of these surveys in accordance with § 35.2404.

§ 35.605 Installation, maintenance, adjustment, and repair.

(a) Only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Commission or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(d) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with § 35.2605.

§ 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall--

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include--

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(b) A copy of the procedures required by paragraph (a)(4) of this section must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of--

(1) The location of the procedures required by paragraph (a)(4) of this section; and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(d)(1) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

(2) A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in—

(i) The procedures identified in paragraph (a)(4) of this section; and

(ii) The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by paragraph (d) of this section, in accordance with § 35.2310.

(g) A licensee shall retain a copy of the procedures required by paragraphs (a)(4) and (d)(2)(ii) of this section in accordance with § 35.2610.

[83 FR 33046, Jul. 16, 2018]

§ 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will--

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source(s) to be shielded when an entrance door is opened; and

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall--

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require--

(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require--

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(g) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source--

(1) Remaining in the unshielded position; or

(2) Lodged within the patient following completion of the treatment.

§ 35.630 Dosimetry equipment.

(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(b) The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have

affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with § 35.2630.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19326, Apr. 21, 2003]

§ 35.632 Full calibration measurements on teletherapy units.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit--

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of--

(1) The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.633 Full calibration measurements on remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit--

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include, as applicable, determination of:

(1) The output within ± 5 percent;

(2) Source positioning accuracy to within ±1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (b) of this section, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with paragraphs (a) through (e) of this section.

(g) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (g) of this section must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.635 Full calibration measurements on gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit--

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions--

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive

decay;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(3) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of--

(1) The output within ±3 percent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

(7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) Helmet microswitches;

(9) Emergency timing circuits; and

(10) Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent

physical decay for all other radionuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.642 Periodic spot-checks for teletherapy units.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of--

(1) Timer accuracy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b); and

(6) The difference between the measurement made in paragraph (a)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of--

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of

radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section, and a copy of the procedures required by paragraph (b), in accordance with § 35.2642.

§ 35.643 Periodic spot-checks for remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit--

(1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(2) Before each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(b) A licensee shall perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) To satisfy the requirements of paragraph (a) of this section, spot-checks must, at a minimum, assure proper operation of--

(1) Electrical interlocks at each remote afterloader unit room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer accuracy;

(7) Clock (date and time) in the unit's computer; and

(8) Decayed source(s) activity in the unit's computer.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by paragraph (d) of this section and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2643.

§ 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit--

(1) Monthly;

(2) Before the first use of the unit on a given day; and

(3) After each source installation.

(b) A licensee shall--

(1) Perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(2) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(c) To satisfy the requirements of paragraph (a)(1) of this section, spot-checks must, at a minimum--

(1) Assure proper operation of--

(i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(ii) Helmet microswitches;

(iii) Emergency timing circuits; and

(iv) Stereotactic frames and localizing devices (trunnions).

(2) Determine--

(i) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b);

(ii) The difference between the measurement made in paragraph (c)(2)(i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) Source output against computer calculation;

(iv) Timer accuracy and linearity over the range of use;

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must assure proper operation of--

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Timer termination;

(5) Radiation monitors used to indicate room exposures; and

(6) Emergency off buttons.

(e) A licensee shall arrange for the repair of any system identified in paragraph (c) of this section that is not operating properly as soon as possible.

(f) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(g) A licensee shall retain a record of each check required by paragraphs (c) and (d) and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2645.

§ 35.647 Additional technical requirements for mobile remote afterloader units.

(a) A licensee providing mobile remote afterloader service shall--

(1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by § 35.643, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of--

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in paragraph (b) of this section, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in paragraph (b) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by paragraph (b) of this section in accordance with § 35.2647.

§ 35.652 Radiation surveys.

(a) In addition to the survey requirement in § 20.1501 of this chapter, a person licensed under this subpart shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by paragraph (a) of this section in accordance with § 35.2652.

§ 35.655 Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing in accordance with § 35.2655.

[83 FR 33046, Jul. 16, 2018]

§ 35.657 Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally

recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine sealed source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Except as provided in § 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under § 35.600 to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee on Post-Graduate~~Council on Postdoctoral Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes—

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements, at a medical facility that is authorized to use byproduct materials in § 35.600, involving—

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee~~ Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1), (b)(2), and (c) of this section; and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (b)(1) and (b)(2) of this section.

(c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19326, Apr. 21, 2003; 69 FR 55739, Sep. 16, 2004; 70 FR 16366, Mar. 30, 2005; 71 FR 15011, Mar. 27, 2006; 74 FR 33906, Jul. 14, 2009; 83 FR 33046, Jul. 16, 2018; 85 FR 65656, Oct. 16, 2020]

Subpart I--[Reserved]

Subpart J--[Reserved]

Subpart K--Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

§ 35.1000 Other medical uses of byproduct material or radiation from byproduct material.

A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if--

(a) The applicant or licensee has submitted the information required by § 35.12(b) through (d); and

(b) The applicant or licensee has received written approval from the Commission in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.

Subpart L--Records

§ 35.2024 Records of authority and responsibilities for radiation protection programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by § 35.24(e), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by § 35.24(b), for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

(c) For each Associate Radiation Safety Officer appointed under § 35.24(b), the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee’s management.

[83 FR 33046, Jul. 16, 2018]

§ 35.2026 Records of radiation protection program changes.

A licensee shall retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

§ 35.2040 Records of written directives.

A licensee shall retain a copy of each written directive as required by § 35.40 for 3 years.

§ 35.2041 Records for procedures for administrations requiring a written directive.

A licensee shall retain a copy of the procedures required by § 35.41(a) for the duration of the license.

§ 35.2060 Records of calibrations of instruments used to measure the activity of unsealed byproduct material.

A licensee shall maintain a record of instrument calibrations required by § 35.60 for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

§ 35.2061 Records of radiation survey instrument calibrations.

A licensee shall maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years. The record must include the model and serial number of the instrument, the date of

the calibration, the results of the calibration, and the name of the individual who performed the calibration.

§ 35.2063 Records of dosages of unsealed byproduct material for medical use.

(a) A licensee shall maintain a record of dosage determinations required by § 35.63 for 3 years.

(b) The record must contain--

(1) The radiopharmaceutical;

(2) The patient's or human research subject's name, or identification number if one has been assigned;

(3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi);

(4) The date and time of the dosage determination; and

(5) The name of the individual who determined the dosage.

§ 35.2067 Records of leaks tests and inventory of sealed sources and brachytherapy sources.

(a) A licensee shall retain records of leak tests required by § 35.67(b) for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

(b) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

§ 35.2070 Records of surveys for ambient radiation exposure rate.

A licensee shall retain a record of each survey required by § 35.70 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

§ 35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with § 35.75, if the total effective dose equivalent is calculated by--

(1) Using the retained activity rather than the activity administered;

(2) Using an occupancy factor less than 0.25 at 1 meter;

(3) Using the biological or effective half-life; or

(4) Considering the shielding by tissue.

(b) A licensee shall retain a record that the instructions required by § 35.75(b) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

(c) The records required by paragraphs (a) and (b) of this section must be retained for 3 years after the date of release of the individual.

§ 35.2080 Records of mobile medical services.

(a) A licensee shall retain a copy of each letter that permits the use of byproduct material at a client's address, as required by § 35.80(a)(1). Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by § 35.80(a)(4) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

§ 35.2092 Records of decay-in-storage.

A licensee shall maintain records of the disposal of licensed materials, as required by § 35.92, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

§ 35.2204 Records of molybdenum-99, strontium-82, and strontium-85 concentrations.

A licensee shall maintain a record of the molybdenum-99 concentration or strontium-82 and strontium-85 concentration tests required by § 35.204(b) and (c) for 3 years. The record must include:

(a) For each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of

molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement; or

(b) For each measured elution of rubidium-82, the ratio of the measures expressed as kilobecquerel of strontium-82 per megabecquerel of rubidium-82 (or microcuries of strontium-82 per millicurie of rubidium), kilobecquerel of strontium-85 per megabecquerel of rubidium-82 (or microcuries of strontium-85 per millicurie of rubidium), the time and date of the measurement, and the name of the individual who made the measurement.

[72 FR 55932 Oct. 1, 2007]

§ 35.2310 Records of safety instruction.

A licensee shall maintain a record of safety instructions required by §§ 35.310, 35.410, and the operational and safety instructions required by § 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

[83 FR 33046, Jul. 16, 2018]

§ 35.2404 Records of surveys after source implant and removal.

A licensee shall maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

§ 35.2406 Records of brachytherapy source accountability.

(a) A licensee shall maintain a record of brachytherapy source accountability required by § 35.406 for 3 years.

(b) For temporary implants, the record must include--

(1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include--

(1) The number and activity of sources removed from storage, the date they were removed from

storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

§ 35.2432 Records of calibration measurements of brachytherapy sources.

(a) A licensee shall maintain a record of the calibrations of brachytherapy sources required by § 35.432 for 3 years after the last use of the source.

(b) The record must include—

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19326, Apr. 21, 2003]

§ 35.2433 Records of decay of strontium-90 sources for ophthalmic treatments.

(a) A licensee shall maintain a record of the activity of a strontium-90 source required by § 35.433 for the life of the source.

(b) The record must include--

(1) The date and initial activity of the source as determined under § 35.432; and

(2) For each decay calculation, the date and the source activity as determined under § 35.433.

§ 35.2605 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote

afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by § 35.605 for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

§ 35.2610 Records of safety procedures

A licensee shall retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit..

§ 35.2630 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license.

(b) For each calibration, intercomparison, or comparison, the record must include--

(1) The date;

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of § 35.630;

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison.

§ 35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

(a) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by §§ 35.632, 35.633, and 35.635 for 3 years.

(b) The record must include--

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s);

(3) The results and an assessment of the full calibrations;

(4) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(5) The signature of the authorized medical physicist who performed the full calibration.

§ 35.2642 Records of periodic spot-checks for teletherapy units.

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years.

(b) The record must include--

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer linearity and constancy;

(4) The calculated on-off error;

(5) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(6) The determined accuracy of each distance measuring and localization device;

(7) The difference between the anticipated output and the measured output;

(8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.642(b) until the licensee no longer possesses the teletherapy unit.

§ 35.2643 Records of periodic spot-checks for remote afterloader units.

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by § 35.643 for 3 years.

(b) The record must include, as applicable--

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(3) An assessment of timer accuracy;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.643(b) until the licensee no longer possesses the remote afterloader unit.

§ 35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years.

(b) The record must include--

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(3) An assessment of timer linearity and accuracy;

(4) The calculated on-off error;

(5) A determination of trunnion centricity;

(6) The difference between the anticipated output and the measured output;

(7) An assessment of source output against computer calculations;

(8) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and

stereotactic frames and localizing devices (trunnions); and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.645(b) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

§ 35.2647 Records of additional technical requirements for mobile remote afterloader units.

(a) A licensee shall retain a record of each check for mobile remote afterloader units required by § 35.647 for 3 years.

(b) The record must include--

(1) The date of the check;

(2) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(3) Notations accounting for all sources before the licensee departs from a facility;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

§ 35.2652 Records of surveys of therapeutic treatment units.

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit.

(b) The record must include--

(1) The date of the measurements;

(2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(4) The signature of the individual who performed the test.

§ 35.2655 Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall maintain a record of the full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of the use of the unit.

(b) The record must contain--

(1) The inspector's radioactive materials license number;

(2) The date of inspection;

(3) The manufacturer's name and model number and serial number of both the treatment unit and source;

(4) A list of components inspected and serviced, and the type of service; and

(5) The signature of the inspector.

[83 FR 33046, Jul. 16, 2018]

Subpart M--Reports

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which—

(1) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in—

(i) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(A) The total dose delivered differs from the prescribed dose by 20 percent or more;

(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(C) The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more.

(ii) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or

tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following—

(A) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;

(B) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(C) An administration of a dose or dosage to the wrong individual or human research subject;

(D) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(E) A leaking sealed source.

(iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(A) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(B) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

(2) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in—

(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(iii) An administration that includes any of the following:

(A) The wrong radionuclide;

(B) The wrong individual or human research subject;

(C) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

(D) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center[3] no later than the next calendar day after discovery of the medical event.

(d) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event.

(1) The written report must include--

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written

description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(g) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(i) Name of the individual who is the subject of the event; and

(ii) Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and~~Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and~~

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

[68 FR 58805, Oct. 10, 2003; 83 FR 33046, Jul. 16, 2018; 85 FR 33527, Jun. 2, 2020; 85 FR 44685, Jul. 24, 2020]

§ 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.

(a) A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(b) A licensee shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding individual that--

(1) Is greater than 50 mSv (5 rem) total effective dose equivalent; or

(2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(d) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a

written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(1) The written report must include--

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the embryo/fetus or the nursing child;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(2) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(e) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under paragraph (a) or (b) of this section, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(i) Name of the pregnant individual or the nursing child who is the subject of the event; and

(ii) Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and ~~Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and~~

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

[68 FR 58805, Oct. 10, 2003; 85 FR 33527, Jun. 2, 2020; 85 FR 44685, Jul. 24, 2020]

§ 35.3067 Report of a leaking source.

A licensee shall file a report within 5 days if a leak test required by § 35.67 reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office listed in § 30.6 of this chapter, by an appropriate method listed in § 30.6(a) of this chapter, with a copy to the Director, Office of Federal and State Materials and Environmental Management Programs. The written report must include the model number and serial number, if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

[68 FR 58805, Oct. 10, 2003; 73 FR 5720, Jan. 31, 2008]

§ 35.3204 Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

(a) The licensee shall notify by telephone the NRC Operations Center and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in § 35.204(a) at the time of generator elution. The telephone report to the NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

(b) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (a) of this section.

[83 FR 33046, Jul. 16, 2018]

Subpart N--Enforcement

§ 35.4001 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued under those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued under the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

§ 35.4002 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of Section 223, all the regulations in 10 CFR part 35 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in 10 CFR part 35 that are not issued under subsections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 35.1, 35.2, 35.7, 35.8, 35.12, 35.15, 35.18,

35.19, 35.65, 35.100, 35.200, 35.300, 35.4001, and 35.4002.

CHAPTER 33.1-10-10.1
NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS - INSPECTIONS

Section
33.1-10-10.1-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 19

33.1-10-10.1-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 19.

10 Code of Federal Regulations 19.1, 19.2, 19.3, 19.5, 19.11, 19.12, 19.13, 19.14, 19.15, 19.16, 19.17, 19.18, 19.20, 19.31, and 19.32 are adopted by reference as they exist on November 16, 2020~~December 1, 2015~~, with the following exceptions:

1. Not adopted by reference is 10 Code of Federal Regulations 19.14(a).

2. All of the requirements in chapter 33.1-10-10.1 apply to both licensees and registrants. A reference in 10 Code of Federal Regulations part 19 to "license" includes "registration", a reference to "licensee" includes "registrant", a reference to "licensed" includes "registered", and a reference to "licensed radioactive material" includes "registered source of radiation". "Registrant" means any person who is registered with the department and is legally obligated to register with the department pursuant to article 33.1-10 and North Dakota Century Code chapter 23.1-03. "Registration" means the notification of the department of environmental quality of possession of a source of radiation and the furnishing of information with respect thereto, in accordance with North Dakota Century Code chapter 23.1-02.

3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States nuclear regulatory commission", "administrator of the appropriate commission regional office", "administrator of the appropriate regional office", "regional office administrator", "executive director for operations", "regional administrator of the appropriate United States nuclear regulatory commission regional office", or "agency" appear in 10 Code of Federal Regulations part 19, substitute the words "department of environmental quality".

4. "Act" includes North Dakota Century Code chapters 23.1-02 and 23.1-03.

5. State form number 8414, "notice to employees", must be posted in place of United States nuclear regulatory commission form 3 that is specified in 10 Code of Federal Regulations 19.

6. Where 10 Code of Federal Regulations part 19 specifies contacting the United States nuclear regulatory commission, contact the department of environmental quality.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

PART 19--NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTION AND INVESTIGATIONS

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Authority: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, sec. 234, 83 Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282, 2297f); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 19.32 is also issued under sec. 401, 88 Stat. 1254 (42 U.S.C. 5891)

Source: 38 FR 22217, Aug. 17, 1973, unless otherwise noted.

§ 19.1 Purpose.

The regulations in this part establish requirements for notices, instructions, and reports by licensees and regulated entities to individuals participating in NRC-licensed and regulated activities and options available to these individuals in connection with Commission inspections of licensees and regulated entities, and to ascertain compliance with the provisions of the Atomic Energy Act of 1954, as amended, titles II and IV of the Energy Reorganization Act of 1974, and regulations, orders, and licenses thereunder. The regulations in this part also establish the rights and responsibilities of the Commission and individuals during interviews compelled by subpoena as part of agency inspections or investigations under Section 161c of the Atomic Energy Act of 1954, as amended, on any matter within the Commission's jurisdiction.

[55 FR 247, Jan. 4, 1990; 72 FR 49483, Aug. 28, 2007]

§ 19.2 Scope.

(a) The regulations in this part apply to:

(1) All persons who receive, possess, use, or transfer material licensed by the NRC under the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or 72 of this chapter, including persons licensed to operate a production or utilization facility under parts 50 or 52 of this chapter, persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) under part 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter;

(2) All applicants for and holders of licenses (including construction permits and early site permits) under parts 50, 52, and 54 of this chapter;

(3) All applicants for and holders of a standard design approval under subpart E of part 52 of this chapter; and

(4) All applicants for a standard design certification under subpart B of part 52 of this chapter, and those (former) applicants whose designs have been certified under that subpart.

(b) The regulations in this part regarding interviews of individuals under subpoena apply to all investigations and inspections within the jurisdiction of the NRC other than those involving NRC employees or NRC contractors. The regulations in this part do not apply to subpoenas issued under 10 CFR 2.702.

[66 FR 55789, Nov. 2, 2001; 72 FR 49484, Aug. 28, 2007]

§ 19.3 Definitions.

As used in this part:

Act means the Atomic Energy Act of 1954, (68 Stat. 919) including any amendments thereto.

Commission means the United States Nuclear Regulatory Commission.

Exclusion means the removal of counsel representing multiple interests from an interview whenever the NRC official conducting the interview has concrete evidence that the presence of the counsel would obstruct and impede the particular investigation or inspection.

License means a license issued under the regulations in parts 30 through 36,39, 40, 60, 61, 63, 70, or 72 of this chapter, including licenses to manufacture, construct and/or operate a production or utilization facility under parts 50, 52, or 54 of this chapter.

Licensee means the holder of such a license.

Regulated activities means any activity carried on which is under the jurisdiction of the NRC under the Atomic Energy Act of 1954, as amended, or any title of the Energy Reorganization Act of 1972, as amended.

Regulated entities means any individual, person, organization, or corporation that is subject to the regulatory jurisdiction of the NRC, including (but not limited to) an applicant for or holder of a standard design approval under subpart E of part 52 of this chapter or a standard design certification under subpart B of part 52 of this chapter.

Restricted area means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Sequestration means the separation or isolation of witnesses and their attorneys from other witnesses and their attorneys during an interview conducted as part of an investigation, inspection, or other inquiry.

Worker means an individual engaged in activities licensed or regulated by the Commission and controlled by a licensee or regulated entity, but does not include the licensee or regulated entity.

[38 FR 22217, Aug. 17, 1973, as amended at 40 FR 8783, Mar. 3, 1975; 53 FR 31680, Aug. 19, 1988; 55 FR 247, Jan. 4, 1990; 56 FR 23470, May 21, 1991; 56 FR 65948, Dec. 19, 1991; 57 FR 61785, Dec. 29, 1992; 58 FR 7736, Feb. 9, 1993; 66 FR 55789, Nov. 2, 2001; 69 FR 76600, Dec. 22, 2004; 72 FR 49484, Aug. 28, 2007]

§ 19.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 19.5 Communications.

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part should be addressed to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in Appendix D of part 20 of this chapter. Communications, reports, and applications may be delivered in person at the Commission's offices at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland.

[67 FR 67098, Nov. 4, 2002]

§ 19.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in the part under control number 3150-0044.

(b) The approved information collection requirements contained in this part appear in §§ 19.12, 19.13, 19.16, and 19.31. ~~The approved information collection requirements contained in this part appear in §§ 19.13 and 19.16.~~

[62 FR 52185, Oct. 6, 1997; 85 FR 65656, Oct. 16, 2020]

§ 19.11 Posting of notices to workers.

(a) Each licensee (except for a holder of an early site permit under subpart A of part 52 of this chapter, or a holder of a manufacturing license under subpart F of part 52 of this chapter) shall post current copies of the following documents:

(1) The regulations in this part and in part 20 of this chapter;

(2) The license, license conditions, or documents incorporated into a license by reference, and amendments thereto;

(3) The operating procedures applicable to licensed activities;

(4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to subpart B of part 2 of this chapter, and any response from the licensee.

(b) Each applicant for and holder of a standard design approval under subpart E of part 52 of this chapter, each applicant for an early site permit under subpart A of part 52 of this chapter, each applicant for a standard design certification under subpart B of part 52 of this chapter, and each applicant for and holder of a manufacturing license under subpart F of part 52 of this chapter shall post:

(1) The regulations in this part;

(2) The operating procedures applicable to the activities regulated by the NRC which are being conducted by the applicant or holder; and

(3) Any notice of violation, proposed imposition of civil penalty, or order issued under subpart B of part 2 of this chapter, and any response from the applicant or holder.

(c) [Reserved]

(d) If posting of a document specified in paragraphs (a)(1), (2) or (3), or (b)(1) or (2) of this section is not practicable, the licensee or regulated entity may post a notice which describes the document and states where it may be examined.

(e)(1) Each licensee, each applicant for a specific license, each applicant for or holder of a standard design approval under subpart E of part 52 of this chapter, each applicant for an early site permit under subpart A of part 52 of this chapter, and each applicant for a standard design certification under subpart B of part 52 of this chapter shall prominently post NRC Form 3, "Notice to Employees," dated August 1997. Later versions of NRC Form 3 that supersede the August 1997 version shall replace the previously posted version within 30 days of receiving the revised NRC Form 3 from the Commission.

(2) Additional copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of this chapter, by calling (301) 415–7232, via e-mail to *forms@nrc.gov*, or by visiting the NRC's Web site at *http://www.nrc.gov* and selecting forms from the index found on the home page.

(f) Documents, notices, or forms posted under this section shall appear in a sufficient number of places to permit individuals engaged in NRC-licensed or regulated activities to observe them on the way to or from any particular licensed or regulated activity location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(g) Commission documents posted under paragraphs (a)(4) or (b)(3) of this section shall be posted within 2 working days after receipt of the documents from the Commission; the licensee's or regulated entity's response, if any, shall be posted within 2 working days after dispatch by the licensee or regulated entity. These documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

[38 FR 22217, Aug. 17, 1973, as amended at 40 FR 8783, Mar. 3, 1975; 47 FR 30454, July 14, 1982; 58 FR 52408, Oct. 8, 1993; 60 FR 24551, May 9, 1995; 61 FR 6764, Feb. 22, 1996; 62 FR 48166, Sept. 15, 1997; 68 FR 58801, Oct. 10, 2003; 72 FR 49484, Aug. 28, 2007]

§ 19.12 Instruction to workers.

(a) All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) shall be--

(1) Kept informed of the storage, transfer, or use of radiation and/or radioactive material;

(2) Instructed in the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(3) Instructed in, and required to observe, to the extent within the workers control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material;

(4) Instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation and/or radioactive material;

(5) Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material; and

(6) Advised as to the radiation exposure reports which workers may request pursuant to § 19.13.

(b) In determining those individuals subject to the requirements of paragraph (a) of this section, licensees must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the work place.

[60 FR 36043, July 13, 1995]

§ 19.13 Notifications and reports to individuals.

(a) Radiation exposure data for an individual, and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual, shall be reported to the individual as specified in this section. The information reported shall include data and results obtained pursuant to Commission regulations, orders or license conditions, as shown in records maintained by the licensee pursuant to Commission regulations. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the licensee, the name of the individual, the individual's social security number; include the individual's exposure information; and contain the following statement:

This report is furnished to you under the provisions of the Nuclear Regulatory Commission regulation 10 CFR part 19. You should preserve this report for further reference.

(b) Each licensee shall make dose information available to workers as shown in records maintained by the licensee under the provisions of 10 CFR 20.2106. The licensee shall provide an annual report to each individual monitored under 10 CFR 20.1502 of the dose received in that monitoring year if:

(1) The individual’s occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or

(2) The individual requests his or her annual dose report.

(c)(1) At the request of a worker formerly engaged in licensed activities controlled by the licensee, each licensee shall furnish to the worker a report of the worker's exposure to radiation and/or to radioactive material:

(i) As shown in records maintained by the licensee pursuant to § 20.2106 for each year the worker was required to be monitored under the provisions of § 20.1502; and

(ii) For each year the worker was required to be monitored under the monitoring requirements in effect prior to January 1, 1994.

(2) This report must be furnished within 30 days from the time the request is made or within 30 days after the exposure of the individual has been determined by the licensee, whichever is later. This report must cover the period of time that the worker's activities involved exposure to radiation from radioactive material licensed by the Commission and must include the dates and locations of licensed activities in which the worker participated during this period.

(d) When a licensee is required by §§ 20.2202, 20.2203 or 20.2204 of this chapter to report to the Commission any exposure of an individual to radiation or radioactive material, the licensee shall also provide the individual a report on his or her exposure data included in the report to the Commission. This report must be transmitted no later than the transmittal to the Commission.

(e) At the request of a worker who is terminating employment with the licensee that involved exposure to radiation or radioactive materials, during the current calendar quarter or the current year, each licensee shall provide at termination to each worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose must be provided together with a clear indication that this is an estimate.

[38 FR 22217, Aug. 17, 1973, as amended at 40 FR 8783, Mar. 3, 1975; 44 FR 32352, June 6, 1979; 58 FR 67658, Dec. 22, 1993; 59 FR 41642, Aug. 15, 1994; 72 FR 68058, Dec. 4, 2007]

§ 19.14 Presence of representatives of licensees and regulated entities, and workers during inspections.

(a) Each licensee, applicant for a license, applicant for or holder of a standard design approval under subpart E of part 52 of this chapter, applicant for an early site permit under subpart A of part 52 of this chapter, and applicant for a standard design certification under subpart B of part 52 of this chapter shall afford to the Commission at all reasonable times opportunity to inspect materials, activities, facilities, premises, and records under the regulations in this chapter.

(b) During an inspection, Commission inspectors may consult privately with workers as specified in § 19.15. The licensee, regulated entity, or the licensee's or regulated entity's representative may accompany Commission inspectors during other phrases of an inspection.

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during Commission inspections, the licensee or regulated entity shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each workers' representative shall be routinely engaged in NRC-licensed or regulated activities under control of the licensee or regulated entity, and shall have received instructions as specified in § 19.12.

(e) Different representatives of licensees or regulated entities, and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers’ representative at a time may accompany the inspectors.

(f) With the approval of the licensee or regulated entity, and the workers' representative an individual who is not routinely engaged in licensed or regulated activities under control of the license or regulated entity (for example, a consultant to the licensee, the regulated entity, or the workers' representative), shall be afforded the opportunity to accompany Commission inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of this section, Commission inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S.Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or regulated entity to enter that area.

[72 FR 49484, Aug. 28, 2007]

§ 19.15 Consultation with workers during inspections.

(a) Commission inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Commission regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(b) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the act, the regulations in this chapter, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material under the licensee's control. Any such notice in writing shall comply with the requirements of § 19.16(a).

(c) The provisions of paragraph (b) of this section shall not be interpreted as authorization to disregard instructions pursuant to § 19.12.

§ 19.16 Requests by workers for inspections.

(a) Any worker or representative of workers who believes that a violation of the Act, the regulations in this chapter, or license conditions exists or has occurred in license activities with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Administrator of the appropriate Commission Regional Office, or to Commission inspectors. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of workers. A copy shall be provided the licensee by the Regional Office Administrator, or the inspector no later than at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released or made available by the Commission, except for good cause shown.

(b) If, upon receipt of such notice, the Regional Office Administrator determines that the complaint meets the requirements set forth in paragraph (a) of this section, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in the complaint.

[38 FR 22217, Aug. 17, 1973, as amended at 40 FR 8783, Mar. 3, 1975; 47 FR 30454, July 14, 1982; 52 FR 31610, Aug. 21, 1987]

§ 19.17 Inspections not warranted; informal review.

(a) If the Administrator of the appropriate Regional Office determines, with respect to a complaint under § 19.16, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, he shall notify the complainant in writing of such determination. The complainant may obtain review of this determination by submitting a written statement of position to the Executive Director for Operations, either by mail to the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html*, by calling (301) 415-0439, by e-mail to

EIE@nrc.gov, or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. The Executive Director for Operations will provide the licensee with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee may submit an opposing written statement of position with the Executive Director for Operations who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the Executive Director for Operations or his designee may hold an informal conference in which the complainant and the licensee may orally present their views. An informal conference may also be held at the request of the licensee, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Executive Director for Operations shall affirm, modify, or reverse the determination of the Administrator of the appropriate Regional Office and furnish the complainant and the licensee a written notification of his decision and the reason therefore.

(b) If the Administrator of the appropriate Regional Office determines that an inspection is not warranted because the requirements of § 19.16(a) have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of § 19.16(a).

[38 FR 22217, Aug. 17, 1973, as amended at 40 FR 8783, Mar. 3, 1975; 52 FR 31610, Aug. 21, 1987; 67 FR 77652, Dec. 19, 2002; 68 FR 58801, Oct. 10, 2003; 70 FR 69421, Nov. 16, 2005; 72 FR 33386, Jun. 18, 2007]

§ 19.18 Sequestration of witnesses and exclusion of counsel in interviews conducted under subpoena.

(a) All witnesses compelled by subpoena to submit to agency interviews shall be sequestered unless the official conducting the interviews permits otherwise.

(b) Any witness compelled by subpoena to appear at an interview during an agency inquiry may be accompanied, represented, and advised by counsel of his or her choice. However, when the agency official conducting the inquiry determines, after consultation with the Office of the General Counsel, that the agency has concrete evidence that the presence of an attorney representing multiple interests would obstruct and impede the investigation or inspection, the agency official may prohibit that counsel from being present during the interview.

(c) The interviewing official is to provide a witness whose counsel has been excluded under paragraph (b) of this section and the witness's counsel a written statement of the reasons supporting the decision to exclude. This statement, which must be provided no later than five working days after exclusion, must explain the basis for the counsel's exclusion. This statement must also advise the witness of the witness' right to appeal the exclusion decision and obtain an automatic stay of the effectiveness of the subpoena by filing a motion to quash the subpoena with the Commission within five days of receipt of this written statement.

(d) Within five days after receipt of the written notification required in paragraph (c) of this section, a witness whose counsel has been excluded may appeal the exclusion decision by filing a motion to quash the subpoena with the Commission. The filing of the motion to quash will stay the effectiveness of the subpoena pending the Commission's decision on the motion.

(e) If a witness' counsel is excluded under paragraph (b) of this section, the interview may, at the witness' request, either proceed without counsel or be delayed for a reasonable period of time to permit the retention of new counsel. The interview may also be rescheduled to a subsequent date established by the NRC, although the interview shall not be rescheduled by the NRC to a date that precedes the expiration of the time provided under § 19.18(d) for appeal of the exclusion of counsel, unless the witness consents to an earlier date.

[55 FR 247, Jan. 4, 1990, as amended at 56 FR 65948, Dec. 19, 1991; 57 FR 61785, Dec. 29, 1992]

§ 19.20 Employee protection.

Employment discrimination by a licensee, a holder of a certificate of compliance issued under part 76 of this chapter or regulated entity subject to the requirements in this part as delineated in § 19.2(a), or a contractor or subcontractor of a licensee, a holder of a certificate of compliance issued under part 76 of this chapter, or regulated entity subject to the requirements in this part as delineated in § 19.2(a), against an employee for engaging in protected activities under this part or parts 30, 40, 50, 52, 54, 60, 61, 63, 70, 72, 76, or 150 of this chapter is prohibited.

[66 FR 55789, Nov. 2, 2001; 72 FR 49485, Aug. 28, 2007]

§ 19.30 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55071, Nov. 24, 1992]

§ 19.31 Application for exemptions.

The Commission may, upon application by any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law, will not result in undue hazard to life and property.

[72 FR 49485, Aug. 28, 2007]

§ 19.32 Discrimination prohibited.

No person shall on the grounds of sex be excluded from participation in, be denied a license, be denied the benefit of, or be subjected to discrimination under any program or activity carried on which is under the jurisdiction of the NRC under the Atomic Energy Act of 1954, as amended, or under any title of the Energy Reorganization Act of 1974, as amended. This provision will be enforced through agency provisions and regulations similar to those already
established, with respect to racial and other discrimination, under Title VI of the Civil Rights Act of 1964. This remedy is not exclusive, however, and will not prejudice or cut off any other legal remedies available to a discriminatee.

[65 FR 54949, Sept. 12, 2000; 68 FR 75389, Dec. 31, 2003; 72 FR 49485, Aug. 28, 2007]

§ 19.40 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 19 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 19 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 19.1, 19.2, 19.3, 19.4, 19.5, 19.8, 19.16, 19.17, 19.18, 19.30, 19.31, and 19.40.

[57 FR 55071, Nov. 24, 1992]

CHAPTER 33.1-10-11
FEES FOR ISSUANCE OF LICENSE AND REGISTRATION CERTIFICATES AND INSPECTIONS

Section
33.1-10-11-01 Purpose
33.1-10-11-02 Scope
33.1-10-11-03 Exemptions
33.1-10-11-04 Payment of Fees
33.1-10-11-05 Failure by Applicant or Licensee to Pay Prescribed Fees

33.1-10-11-01. Purpose.

This chapter establishes fees charged for the issuance of licenses and registration certificates by the department. This chapter also establishes fees charged to recover costs associated with nonroutine regulatory inspections and surveys of licensees and registrants.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04, 23.1-03-09; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-04, 23.1-03-09; S.L. 2017, ch. 199, § 18

33.1-10-11-02. Scope.

This chapter applies to a person who is an applicant for, or a holder of, a radioactive material license or a registration certificate issued by the department.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04, 23.1-03-09; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04, 23.1-03-09; S.L. 2017, ch. 199, § 18

33.1-10-11-03. Exemptions.

No application fees, license fees, amendment fees, renewal fees, or special project fees, shall be required for:

1. A license authorizing the use of source material as shielding only in devices and containers; provided, however, that all other licensed byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in the device or container will be subject to the fees prescribed in appendix A of this chapter.

2. Nonprofit educational institutions are exempt from the fees prescribed in appendices A and B of this chapter. This exemption does not apply to those radioactive material licenses or machine registration certificates which authorize any of the following:

   a. Human use.

   b. Remunerated services to other persons.

   c. Distribution of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material, or products containing byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material.

   d. Activities performed under a government contract.

3. The department may, upon application by an interested person, or upon its own initiative, grant such exemptions from the requirements of this chapter as it determines are authorized by law and are otherwise in the public interest.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04, 23.1-03-09; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04, 23.1-03-09; S.L. 2017, ch. 199, § 18

33.1-10-11-04. Payment of fees.

The following fees are nonrefundable:

1. **License and registration fees.** The appropriate licensing or registration fee shall accompany the application for licensure or registration when filed with the department. For new radioactive material licenses, the application fee is equal to the appropriate annual fee.

2. **Amendment fees.** The amendment fee given in appendix A category 24 shall accompany the application for amendment when filed with the department.

3. **Reciprocity fee.** The appropriate reciprocity fee shall accompany the written notification as required in chapters 33.1-10-03.1 and 33.1-10-02.

4. **Special project fees.** Fees for special projects are payable upon notification by the department when the review of the project is completed. Special projects mean those projects submitted to the department for review and for which specific fees are not prescribed in this chapter. Special project fees will be based upon the current professional staff hourly rate (thirty-three percent of the current nuclear regulatory commission rate listed in 10 CFR 170).

5. **Annual fees.** Annual fees are required to be paid by all radioactive material licensees no later than January first of each year the license is active, except that the annual fee due on January first of the year following the issuance of a new license shall be prorated to the number of months the license was in effect the first calendar year (example: for a new license issued in May the annual fee due January first would be seven-twelfths [June-December] of the annual fee listed in appendix A).

6. **Inspection and survey fees.** Fees for regulatory inspections and surveys of North Dakota licensees are included in the registration or annual fees for each registration or license type. Nonroutine inspections will require the nonroutine inspection fee to be paid upon notification by the department when the inspection has been completed.

7. **Annual fees for small entities.** If a licensee qualifies as a small entity and provides the department with the proper certification, the small entity fee of sixty percent of the applicable annual fee listed in appendix A shall be paid.

    a. "Small business" means a business entity, including its affiliates, which:

        (1) Is independently owned and operated; and

        (2) Employs fewer than twenty-five full-time employees or has gross annual sales of less than two million five hundred thousand dollars;

    b. "Small entity" includes small business, small organization, and small political subdivision;

    c. "Small organization" means any not-for-profit enterprise that is independently owned and operated and is not dominant in its field; and

    d. "Small political subdivision" means a political subdivision with a population of less than five thousand.

e. A licensee who seeks to establish status as a small entity for purposes of paying the fees required under this chapter shall file a certification statement with the department. The licensee shall:

(1) Certify, on the business's letterhead, that the business meets the conditions in this subsection;

(2) Sign the certification as the chief executive officer of the business or as an official designee; and

(3) Have the certification notarized.

f. A licensee who seeks to qualify as a small entity shall submit the certification with the reduced annual fee payment.

g. For purposes of this chapter, the licensee shall submit a new certification with its annual fee payment each year.

8. **Method of payment.** Fee payments shall be by check, draft, or money order made payable to the department of environmental quality

9. **Submittal of application and fee payment.** The application for licensure or registration shall be accompanied by the fee payment and shall be submitted to:

Department of Environmental Quality
Division of Waste Management~~Air Quality~~
~~918 East Divide Avenue~~4201 Normandy Street, Second Floor
Bismarck, ND 5850~~1~~3-1324~~1-1947~~

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04, 23.1-03-09; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-04, 23.1-03-09; S.L. 2017, ch. 199, § 18

33.1-10-11-05. Failure by applicant or licensee to pay prescribed fees.

1. In any case where the department finds that an applicant or a licensee has failed to pay a prescribed fee required in this chapter, the department will not process any application and may suspend or revoke any license or approval involved or may issue an order with respect to licensed activities as the department determines to be appropriate or necessary in order to carry out the provisions of this chapter and of the North Dakota Century Code.

2. In any case where the department does not receive the prescribed fee by the stated due date, an additional fee shall be levied as stated in category 27 of appendix A.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04, 23.1-03-09; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-04, 23.1-03-09; S.L. 2017, ch. 199, § 18

Appendix A - Schedule of Fees for 2016 Radioactive Material Licenses

Applicants for radioactive material licenses and other regulatory services and holders of radioactive material licenses shall pay the following fees.

Category	Description	Base Fees (USD)		Additional Charges
1. SPECIAL NUCLEAR MATERIAL				
A	Licenses for possession and use of 200 grams or more of plutonium in unsealed form or 350 grams or more of contained U-235 in unsealed form or 200 grams or more of U-233 in unsealed form. This includes applications to terminate licenses as well as licenses authorizing possession only.	Nonroutine inspection Annual fee	Full cost $221,640	Items 23 and/or 27 as applicable
B	Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation (regulated by NRC)	Nonroutine inspection Annual fee	N/A N/A	Items 23 and/or 27 as applicable
C	Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers	Nonroutine inspection Annual fee	$1,370 $1,910	Items 23 and/or 27 as applicable
D	All other special nuclear material licenses except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity	Nonroutine inspection Annual fee	$1,370 $2,830	Items 23 and/or 27 as applicable
2. SOURCE MATERIAL				
A	Licenses for possession and use of source material in recovery operations such as milling, in situ leaching, heap-leaching, refining uranium mill concentrates to uranium hexafluoride, or buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode	Nonroutine inspection Annual fee	Full cost $1,152,420	Items 23 and/or 27 as applicable
B	Licenses for possession, use and or installation of source material for shielding only	Nonroutine inspection Annual fee	$410 $670	Items 23 and/or 27 as applicable
C	All other source material licenses	Nonroutine inspection Annual fee	$1,530 $4,730	Items 23 and/or 27 as applicable
3. BYPRODUCT, NATURALLY OCCURRING OR ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL				
A	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33.1-10-03.1 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution	Nonroutine inspection Annual fee	$3,260 $13,490	Items 23 and/or 27 as applicable
B	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33.1-10-03.1 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution	Nonroutine inspection Annual fee	$2,030 $6,210	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
C	Licenses issued pursuant to chapter 33.1-10-03.1 authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources and devices containing byproduct material or naturally occurring or accelerator-produced radioactive material	Nonroutine inspection Annual fee	$1,940 $13,490	Items 23 and/or 27 as applicable
D	Licenses and approvals issued pursuant to chapter 33.1-10-03.1 authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources or devices not involving processing of byproduct material or naturally occurring or accelerator-produced radioactive material	Nonroutine inspection Annual fee	$1,220 $5,390	Items 23 and/or 27 as applicable
E	Licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units)	Nonroutine inspection Annual fee	$720 $2,440	Items 23 and/or 27 as applicable
F	Licenses for possession and use of less than 370 terabecquerels [10,000 curies] of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes	Nonroutine inspection Annual fee	$790 $2,370	Items 23 and/or 27 as applicable
G	Licenses for possession and use of 370 terabecquerels [10,000 curies] or more of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes	Nonroutine inspection Annual fee	$1,400 $21,610	Items 23 and/or 27 as applicable
H	Licenses issued pursuant to chapter 33.1-10-03.1 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material that require device review to persons exempt from the licensing requirements of chapter 33.1-10-03.1, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licenses of chapter 33.1-10-03.1	Nonroutine inspection Annual fee	$1,070 $7,020	Items 23 and/or 27 as applicable
I	Licenses issued pursuant to chapter 33.1-10-03.1 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require device evaluation to persons exempt from the licensing requirements of chapter 33.1-10-03.1, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of chapter 33.1-10-03.1	Nonroutine inspection Annual fee	$720 $9,740	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
K	Licenses issued pursuant to chapter 33.1-10-03.1 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require sealed source and/or device review to persons generally licensed under this chapter, except specific licenses authorizing for redistribution of items that have been authorized for distribution to persons generally licensed under this chapter	Nonroutine inspection Annual fee	$1,060 $2,700	Items 23 and/or 27 as applicable
L	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33.1-10-03.1 for research and development that do not authorize commercial distribution	Nonroutine inspection Annual fee	$1,220 $4,050	Items 23 and/or 27 as applicable
M	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33.1-10-03.1 for research and development that do not authorize commercial distribution	Nonroutine inspection Annual fee	$930 $3,780	Items 23 and/or 30 as applicable
N	Licenses that authorize services for other licensees, except (1) licenses that authorize calibration or leak testing services only are subject to the fees specified in fee Categories 15 and 16, and (2) licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, and 4C.	Nonroutine inspection Annual fee	$1,060 $6,110	Items 23 and/or 27 as applicable
O	Licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33.1-10-05.1 for industrial radiographic operations	Nonroutine inspection Annual fee	$2,550 $8,250	Items 23 and/or 27 as applicable
P	All other specific byproduct material or naturally occurring or accelerator-produced radioactive material licenses, except as described in item 1 below or listed in Categories 4A through 9	Nonroutine inspection Annual fee	$1,830 $2,370	Items 23 and/or 27 as applicable
	1 Portable x-ray fluorescence analyzers only	Nonroutine inspection Annual fee	$300 $590	Items 23 and/or 27 as applicable
Q.	Registration of a device(s) generally licensed under chapter 33.1-10-03.1	Nonroutine inspection Annual fee	$670 $1,370	Items 23 and/or 27 as applicable
	(Each address or location where the device(s) are used or stored represents a separate general license and requires a separate registration and fee.)			
4. WASTE DISPOSAL AND PROCESSING				

Category	Description	Base Fees (USD)		Additional Charges
A	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring, technologically enhanced, or accelerator-produced radioactive material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material	Nonroutine inspection Annual fee	Full cost $134,720	Items 23 and/or 27 as applicable
B	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring, technologically enhanced, or accelerator-produced radioactive material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.	Nonroutine inspection Annual fee	$2,140 $16,180	Items 23 and/or 27 as applicable
C	Licenses specifically authorizing the receipt of prepackaged waste byproduct material, naturally occurring, technologically enhanced, or accelerator-produced radioactive material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.	Nonroutine inspection Annual fee	$2,140 $7,550	Items 23 and/or 27 as applicable
5. WELL LOGGING				
A	Licenses for possession and use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies	Nonroutine inspection Annual fee	$1,220 $6,750	Items 23 and/or 27 as applicable
B	Licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material, for field flooding tracer studies	Nonroutine inspection Annual fee	Full cost $15,640	Items 23 and/or 27 as applicable
6. NUCLEAR LAUNDRY				
A	Licenses for commercial collection and laundry of items contaminated with byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material	Nonroutine inspection Annual fee	$1,940 $7,290	Items 23 and/or 27 as applicable
7. HUMAN USE OF BYPRODUCT, NATURALLY OCCURRING OR ACCELERATOR-PRODUCED, SOURCE, OR SPECIAL NUCLEAR MATERIAL				
A	Licenses issued pursuant to chapter 33.1-10-03.1 for human use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in sealed sources contained in teletherapy devices	Nonroutine inspection Annual fee	$1,940 $16,770	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
B	Licenses of broad scope issued to medical institutions or two or more physicians pursuant to chapter 33.1-10-03.1 authorizing research and development, including human use of byproduct material, except licenses for byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in sealed sources contained in teletherapy devices	Nonroutine inspection Annual fee	$1,830 $17,550	Items 23 and/or 27 as applicable
C	Other licenses issued pursuant to chapter 33.1-10-03.1 for human use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, and/or special nuclear material, except licenses for byproduct material, source material, naturally occurring or accelerator-produced radioactive material, and special nuclear material in sealed sources contained in teletherapy devices	Nonroutine inspection Annual fee	$1,530 $5,950	Items 23 and/or 27 as applicable
8. VETERINARY MEDICINE				
A	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic procedures only	Nonroutine inspection Annual fee	$1,220 $3,530	Items 23 and/or 27 as applicable
B	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic and/or therapeutic procedures	Nonroutine inspection Annual fee	$1,220 $4,050	Items 23 and/or 27 as applicable
9.	Civil defense licenses for possession and use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material for civil defense activities	Nonroutine inspection Annual fee	$720 $1,910	Items 23 and/or 27 as applicable
10. DEVICE, PRODUCT OR SEALED SOURCE SAFETY EVALUATION (Regulated by NRC)				
11.	Licenses for possession and use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material for civil defense activities	Nonroutine inspection Annual fee	$720 $1,910	Items 23 and/or 27 as applicable
12. SPENT FUEL STORAGE (Regulated by NRC)				
13. IMPORT AND EXPORT LICENSES (Regulated by NRC)				
14.	Reciprocity: Other agreement state and/or NRC licensees who conduct activities in North Dakota under the reciprocity provisions of chapters 33.1-10-03.1 and 33.1-10-19	Annual fee	Same as annual fee for license type	Items 23 and/or 27 as applicable
	(Application fee is due three working days prior to entering the state.)	Nonroutine inspection	Same as inspection fee for license type	
15. SERVICES FOR OTHER LICENSED ENTITIES				
A	Leak test and analysis services (for other licensed entities) only	Nonroutine inspection Annual fee	$930 $1,760	Items 23 and/or 27 as applicable
B	Instrument calibration services (for other licensed entities) only	Nonroutine inspection Annual fee	$930 $1,760	Items 23 and/or 27 as applicable
16.	Combination leak test and analysis services and instrument calibration services (for other licensed entities) only	Nonroutine inspection Annual fee	$1,070 $2,370	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
17.	Calibration and/or reference sources (not for providing service to other licensed entities) only	Nonroutine inspection Annual fee	$670 $1,220	Items 23 and/or 27 as applicable
18.	Storage of radioactive material only	Nonroutine inspection Annual fee	$930 $1,630	Items 23 and/or 27 as applicable
19.	Providing deliberate operations to reduce or remove residual radioactivity from equipment, facilities, and land owned, possessed, or controlled by other persons to a level that permits release of equipment, facilities, and land for unrestricted use and/or termination of a license rendered from a fixed facility or a mobile unit	Nonroutine inspection Annual fee	$1,370 $21,610	Items 23 and/or 27 as applicable
20.	Radiation training courses involving the use of licensed material by the instructor and/or the participants	Annual fee	$540	Item 27 as applicable
21.	Demonstration and sales of devices containing radioactive materials	Annual fee	$540	Item 27 as applicable
22.	Installation, removal, repair, and servicing of devices containing radioactive materials	Annual fee	$2,070	Item 27 as applicable
23.	Multiple offices: Add the following fees per additional office location (This does not apply to additional locations in Category 21 above.)	Annual fee	25 percent of base fee for category type per location	Item 27 as applicable
24.	Administrative fee for all license amendments	Amendment	$280	Item 27 as applicable
25.	Inspection of radioactive materials package shipments to low-level radioactive waste disposal facility	Inspection	Full cost	Item 27 as applicable
26.	Certificate - In vitro testing with radioactive material under general license	Certificate (valid for three years)	$330	Item 27 as applicable
27.	Late payment of any fees described in items 1 through 26 above	From payment due date	$1	An additional fee per day after 30 days late

Note 1: All fee amounts are shown in United States dollars (USD).

Note 2: The fees established under this appendix may be adjusted on an annual basis to account for any increase in the consumer price index published by the department of labor, as of the close of the twelve-month period ending on August thirty-first of each calendar year. Fee adjustments will be rounded off to the nearest dollar amount (example: for a value of 0.50 or greater, the number would be rounded up; for a value of 0.49 or less, the number would be rounded down).

Note 3: A current list of fees established under this appendix will be maintained on the department of environmental quality website.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-09, 28-32-02; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-04, 23.1-03-09; S.L. 2017, ch. 199, § 18

Appendix B
2016 Schedule of Fees for Registration
Certification and Inspection

Applications for registration of radiation machines and other regulatory services shall pay the following fees for each machine that they possess and use at their facilities. The fees cover a three-year registration period and the renewal fee is the amount listed.

Registration Category	Fee/Machine (in U.S. Dollars)
Dentistry	$230
Medical:	
A. Radiographic machine (including computer tomography)	$350
B. Fluoroscopic machine	$530
C. Combined radiographic-fluoroscopic	$700
D. (1) Therapeutic: Linear accelerator (less than 10 MeV)	$530
(2) Therapeutic: Linear accelerator (greater than 10 MeV)	$850
E. Superficial x-ray	$260
Chiropractic	$320
Podiatry	$260
Veterinary medicine	$230
Industrial radiography	$850
Accelerators (industrial and research)	$530
Education and research	$530

Other Registration Fees and Services	Annual Service Fees (in U.S. Dollars)
X-ray services and installers	$530
Radiation training courses	$350
X-ray sales and demonstrations	$530
Combined sales and service (assembler)	$700
Dosimeterists and physicists	$350
Shielding evaluations (routine)	$530 per evaluation
Shielding evaluations (nonroutine)	Full cost
Reciprocity (x-ray producing machines)	$530 per year per machine

Note 1: All fee amounts are shown in United States dollars (USD).

Note 2: The fees established under this appendix may be adjusted on an annual basis to account for any increase in the consumer price index published by the department of labor, as of the close of the twelve-month period ending on August thirty-first of each calendar year. Fee adjustments will be rounded off to the nearest dollar amount (example: for a value of 0.50 or greater, the number would be rounded up; for a value of 0.49 or less, the number would be rounded down).

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History: Effective January 1, 2019.
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Law Implemented: NDCC 23.1-03-04, 23.1-03-09; S.L. 2017, ch. 199, § 18

CHAPTER 33.1-10-12.1
LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

Section
33.1-10-12.1-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 39

33.1-10-12.1-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 39.

10 Code of Federal Regulations 39.1, 39.2, 39.11, 39.13, 39.15, 39.17, 39.31, 39.33, 39.35, 39.37, 39.39, 39.41, 39.43, 39.45, 39.47, 39.49, 39.51, 39.53, 39.55, 39.61, 39.63, 39.65, 39.67, 39.69, 39.71, 39.73, 39.75, 39.77, and 39.91 are adopted by reference as they exist on June 16, 2020~~October 1, 2015~~, with the following exceptions:

1. All of the requirements in chapter 33.1-10-12.1 apply to both licensees and registrants. A reference in 10 Code of Federal Regulations part 39 to "license" includes "registration", a reference to "licensee" includes "registrant", a reference to "licensed" includes "registered", a reference to "licensed material" includes "registered source of radiation", and a reference to "licensed radioactive materials" includes "registered source of radiation". "Registrant" means any person who is registered with the department and is legally obligated to register with the department pursuant to article 33.1-10 and North Dakota Century Code chapter 23.1-03. "Registration" means the notification of the department of environmental quality of possession of a source of radiation and the furnishing of information with respect thereto, in accordance with North Dakota Century Code chapter 23.1-02.

2. Where the words "NRC", "commission", or "NRC regional office" appear in 10 Code of Federal Regulations part 39, substitute the words "department of environmental quality".

3. Requirements in 10 Code of Federal Regulations part 39 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

4. North Dakota state form number 8418, "application for radioactive material license", must be used instead of NRC form 313 as specified in 10 Code of Federal Regulations part 39.

5. For references to 10 Code of Federal Regulations part 170, see chapter 33.1-10-11 for applicable fee schedules.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

PART 39--LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

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Authority: Secs. 53, 57, 62, 63, 65, 69, 81, 82, 161, 182, 183, 186, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Source: 52 FR 8234, Mar. 17, 1987, unless otherwise noted.

Subpart A--General Provisions

§ 39.1 Purpose and scope.

(a) This part prescribes requirements for the issuance of a license authorizing the use of licensed materials including sealed sources, radioactive tracers, radioactive markers, and uranium sinker bars in well logging in a single well. This part also prescribes radiation safety requirements for persons using licensed materials in these operations. The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of parts 19, 20, 21, 30, 40, 70, 71, and 150 of this chapter apply to applicants and licensees subject to this part.

(b) The requirements set out in this part do not apply to the issuance of a license authorizing the use of licensed material in tracer studies involving multiple wells, such as field flooding studies, or to the use of sealed sources auxiliary to well logging but not lowered into wells.

§ 39.2 Definitions.

Energy compensation source (ECS) means a small sealed source, with an activity not exceeding 3.7 MBq [100 microcuries], used within a logging tool, or other tool components, to provide a reference standard to maintain the tool's calibration when in use.

Field station means a facility where licensed material may be stored or used and from which equipment is dispatched to temporary jobsites.

Fresh water aquifer, for the purpose of this part, means a geologic formation that is capable of yielding fresh water to a well or spring.

Injection tool means a device used for controlled subsurface injection of radioactive tracer material.

Irretrievable well logging source means any sealed source containing licensed material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.

Licensed material means byproduct, source, or special nuclear material received, processed, used, or transferred under a license issued by the Commission under the regulations in this chapter.

Logging assistant means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by § 39.67.

Logging supervisor means an individual who uses licensed material or provides personal supervision in the use of licensed material at a temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of the Commission's regulations and the conditions of the license.

Logging tool means a device used subsurface to perform well logging.

Personal supervision means guidance and instruction by a logging supervisor, who is physically present at a temporary jobsite, who is in personal contact with logging assistants, and who can give immediate assistance.

Radioactive marker means licensed material used for depth determination or direction orientation. For purposes of this part, this term includes radioactive collar markers and radioactive iron nails.

Safety review means a periodic review provided by the licensee for its employees on radiation safety aspects of well logging. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.

Sealed source means any licensed material that is encased in a capsule designed to prevent leakage or escape of the licensed material.

Source holder means a housing or assembly into which a sealed source is placed to facilitate the handling and use of the source in well logging.

Subsurface tracer study means the release of unsealed license material or a substance labeled with licensed material in a single well for the purpose of tracing the movement or position of the material or substance in the well or adjacent formation.

Surface casing for protecting fresh water aquifers means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

Temporary jobsite means a place where licensed materials are present for the purpose of performing well logging or subsurface tracer studies.

Tritium neutron generator target source means a tritium source used within a neutron generator tube to produce neutrons for use in well logging applications.

Uranium sinker bar means a weight containing depleted uranium used to pull a logging tool toward the bottom of a well.

Well means a drilled hole in which well logging may be performed. As used in this part, "well" includes drilled holes for the purpose of oil, gas, mineral, groundwater, or geological exploration.

Well logging means all operations involving the lowering and raising of measuring devices or tools which contain licensed material or are used to detect licensed materials in wells for the purpose of obtaining information about the well or adjacent formations which may be used in oil, gas, mineral, groundwater, or geological exploration.

[52 FR 8234, Mar. 17, 1987, as amended at 65 FR 20344, Apr. 17, 2000]

§ 39.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission, other than a written interpretation by the General Counsel, will be recognized to be binding upon the Commission.

§ 39.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0130.

(b) The approved information collection requirements contained in this part appear in §§ 39.11, 39.13, 39.15, 39.17, 39.31, 39.33, 39.35, 39.37, 39.39, 39.43, 39.51, 39.61, 39.63, 39.65, 39.67, 39.73, 39.75, 39.77, and 39.91.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 39.11, NRC Form 313 is approved under control 3150-0120.

(2) [Reserved]

[62 FR 52187, Oct. 6, 1997, as amended at 67 FR 67099, Nov. 4, 2002]

Subpart B--Specific Licensing Requirements

§ 39.11 Application for a specific license.

A person, as defined in § 30.4 of this chapter, shall file an application for a specific license authorizing the use of licensed material in well logging on Form NRC 313, "Application for Material License." Each application for a license, other than a license exempted from part 170 of this chapter, must be accompanied by the fee prescribed in § 170.31 of this chapter. The

application must be sent to the appropriate NRC Regional Office listed in appendix D of part 20 of this chapter.

§ 39.13 Specific licenses for well logging.

The Commission will approve an application for a specific license for the use of licensed material in well logging if the applicant meets the following requirements:

(a) The applicant shall satisfy the general requirements specified in § 30.33 of this chapter for byproduct material, in § 40.32 of this chapter for source material, and in § 70.23 of this chapter for special nuclear material, as appropriate, and any special requirements contained in this part.

(b) The applicant shall develop a program for training logging supervisors and logging assistants and submit to the Commission a description of this program which specifies the--

(1) Initial training;

(2) On-the-job training;

(3) Annual safety reviews provided by the licensee;

(4) Means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the Commission's regulations and licensing requirements and the applicant's operating and emergency procedures; and

(5) Means the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

(c) The applicant shall submit to the Commission written operating and emergency procedures as described in § 39.63 or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

(d) The applicant shall establish and submit to the Commission its program for annual inspections of the job performance of each logging supervisor to ensure that the Commission's regulations, license requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained for 3 years after each annual internal inspection.

(e) The applicant shall submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

(f) If an applicant wants to perform leak testing of sealed sources, the applicant shall identify the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant shall establish procedures to be followed and submit a

description of these procedures to the Commission. The description must include the--

(1) Instruments to be used;

(2) Methods of performing the analysis; and

(3) Pertinent experience of the person who will analyze the wipe samples.

§ 39.15 Agreement with well owner or operator.

(a) A licensee may perform well logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement must identify who will meet the following requirements:

(1) If a sealed source becomes lodged in the well, a reasonable effort will be made to recover it.

(2) A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture.

(3) The radiation monitoring required in § 39.69(a) will be performed.

(4) If the environment, any equipment, or personnel are contaminated with licensed material, they must be decontaminated before release from the site or release for unrestricted use; and

(5) If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within 30 days:

(i) Each irretrievable well logging source must be immobilized and sealed in place with a cement plug.

(ii) A means to prevent inadvertent intrusion on the source, unless the source is not accessible to any subsequent drilling operations; and

(iii) A permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The size of the plaque must be at least 17 cm [7 inches] square and 3 mm [$^{1}/_{8}$-inch] thick. The plaque must contain--

(A) The word "CAUTION";

(B) The radiation symbol (the color requirement in § 20.1901(a) need not be met);

(C) The date the source was abandoned;

(D) The name of the well owner or well operator, as appropriate;

(E) The well name and well identification number(s) or other designation;

(F) An identification of the sealed source(s) by radionuclide and quantity;

(G) The depth of the source and depth to the top of the plug; and

(H) An appropriate warning, such as, "DO NOT RE-ENTER THIS WELL."

(b) The licensee shall retain a copy of the written agreement for 3 years after the completion of the well logging operation.

(c) A licensee may apply, pursuant to § 39.91, for Commission approval, on a case-by-case basis, of proposed procedures to abandon an irretrievable well logging source in a manner not otherwise authorized in paragraph (a)(5) of this section.

(d) A written agreement between the licensee and the well owner or operator is not required if the licensee and the well owner or operator are part of the same corporate structure or otherwise similarly affiliated. However, the licensee shall still otherwise meet the requirements in paragraphs (a)(1) through (a)(5).

[52 FR 8234, Mar. 17, 1987, as amended at 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993; 65 FR 20344, Apr. 17, 2000]

§ 39.17 Request for written statements.

Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Commission's request, submit written statements, signed under oath or affirmation, to enable the Commission to determine whether or not the license should be modified, suspended, or revoked.

Subpart C--Equipment

§ 39.31 Labels, security, and transportation precautions.

(a) *Labels*. (1) The licensee may not use a source, source holder, or logging tool that contains licensed material unless the smallest component that is transported as a separate piece of equipment with the licensed material inside bears a durable, legible, and clearly visible marking or label. The marking or label must contain the radiation symbol specified in § 20.1901(a), without the conventional color requirements, and the wording "DANGER (or CAUTION) RADIOACTIVE MATERIAL."

(2) The licensee may not use a container to store licensed material unless the container has

securely attached to it a durable, legible, and clearly visible label. The label must contain the radiation symbol specified in § 20.1901(a) of this chapter and the wording "CAUTION (or DANGER), RADIOACTIVE MATERIAL, NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)."

(3) The licensee may not transport licensed material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in 10 CFR part 71.

(b) *Security precautions during storage and transportation*. (1) The licensee shall store each source containing licensed material in a storage container or transportation package. The container or package must be locked and physically secured to prevent tampering or removal of licensed material from storage by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.

(2) The licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.

[52 FR 8234, Mar. 17, 1987, as amended at 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

§ 39.33 Radiation detection instruments.

(a) The licensee shall keep a calibrated and operable radiation survey instrument capable of detecting beta and gamma radiation at each field station and temporary jobsite to make the radiation surveys required by this part and by part 20 of this chapter. To satisfy this requirement, the radiation survey instrument must be capable of measuring 0.001 mSv (0.1 mrem) per hour through at least 0.5 mSv (50 mrem) per hour.

(b) The licensee shall have available additional calibrated and operable radiation detection instruments sensitive enough to detect the low radiation and contamination levels that could be encountered if a sealed source ruptured. The licensee may own the instruments or may have a procedure to obtain them quickly from a second party.

(c) The licensee shall have each radiation survey instrument required under paragraph (a) of this section calibrated--

(1) At intervals not to exceed 6 months and after instrument servicing;

(2) For linear scale instruments, at two points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and

(3) So that an accuracy within plus or minus 20 percent of the calibration standard can be demonstrated on each scale.

(d) The licensee shall retain calibration records for a period of 3 years after the date of calibration for inspection by the Commission.

[52 FR 8234, Mar. 17, 1987, as amended at 63 FR 39483, July 23, 1998]

§ 39.35 Leak testing of sealed sources.

(a) *Testing and recordkeeping requirements*. Each licensee who uses a sealed source shall have the source tested for leakage periodically. The licensee shall keep a record of leak test results in units of microcuries and retain the record for inspection by the Commission for 3 years after the leak test is performed.

(b) *Method of testing.* The wipe of a sealed source must be performed using a leak test kit or method approved by the Commission or an Agreement State. The wipe sample must be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 Bq [0.005 microcuries] of radioactive material on the test sample and must be performed by a person approved by the Commission or an Agreement State to perform the analysis.

(c) *Test frequency.* (1) Each sealed source (except an energy compensation source (ECS)) must be tested at intervals not to exceed 6 months. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested.

(2) Each ECS that is not exempt from testing in accordance with paragraph (e) of this section must be tested at intervals not to exceed 3 years. In the absence of a certificate from a transferor that a test has been made within the 3 years before the transfer, the ECS may not be used until tested.

(d) *Removal of leaking source from service.* (1) If the test conducted pursuant to paragraphs (a) and (b) of this section reveals the presence of 185 Bq [0.005 microcuries] or more of removable radioactive material, the licensee shall remove the sealed source from service immediately and have it decontaminated, repaired, or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. The licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions.

(2) The licensee shall submit a report to the appropriate NRC Regional Office listed in appendix D of part 20 of this chapter, within 5 days of receiving the test results. The report must describe the equipment involved in the leak, the test results, any contamination which resulted from the leaking source, and the corrective actions taken up to the time the report is made.

(e) *Exemptions from testing requirements*. The following sealed sources are exempt from the periodic leak test requirements set out in paragraphs (a) through (d) of this section:

(1) Hydrogen-3 (tritium) sources;

(2) Sources containing licensed material with a half-life of 30 days or less;

(3) Sealed sources containing licensed material in gaseous form;

(4) Sources of beta- or gamma-emitting radioactive material with an activity of 3.7 MBq [100 microcuries] or less; and

(5) Sources of alpha- or neutron-emitting radioactive material with an activity of 0.37 MBq [10 microcuries] or less.

[52 FR 8234, Mar. 17, 1987, as amended at 65 FR 20344, Apr. 17, 2000]

§ 39.37 Physical inventory.

Each licensee shall conduct a semi-annual physical inventory to account for all licensed material received and possessed under the license. The licensee shall retain records of the inventory for 3 years from the date of the inventory for inspection by the Commission. The inventory must indicate the quantity and kind of licensed material, the location of the licensed material, the date of the inventory, and the name of the individual conducting the inventory. Physical inventory records may be combined with leak test records.

§ 39.39 Records of material use.

(a) Each licensee shall maintain records for each use of licensed material showing--

(1) The make, model number, and a serial number or a description of each sealed source used;

(2) In the case of unsealed licensed material used for subsurface tracer studies, the radionuclide and quantity of activity used in a particular well and the disposition of any unused tracer materials;

(3) The identity of the logging supervisor who is responsible for the licensed material and the identity of logging assistants present; and

(4) The location and date of use of the licensed material.

(b) The licensee shall make the records required by paragraph (a) of this section available for inspection by the Commission. The licensee shall retain the records for 3 years from the date of the recorded event.

§ 39.41 Design and performance criteria for sources.

(a) A licensee may use a sealed source for use in well logging applications if--

(1) The sealed source is doubly encapsulated;

(2) The sealed source contains licensed material whose chemical and physical forms are as insoluble and nondispersible as practical; and

(3) Meets the requirements of paragraph (b), (c), or (d) of this section.

(b) For a sealed source manufactured on or before July 14,1989, a licensee may use the sealed source, for use in well logging applications if it meets the requirements of USASI N5.10-1968, "Classification of Sealed Radioactive Sources," or the requirements in paragraph (c) or (d) of this section.

(c) For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well logging applications if it meets the oil-well logging requirements of ANSI/HPS N43.6-1997, "Sealed Radioactive Sources-Classification."

(d) For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well logging applications, if--

(1) The sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

(i) *Temperature*. The test source must be held at -40º C for 20 minutes, 600º C for 1 hour, and then be subject to a thermal shock test with a temperature drop from 600º C to 20º C within 15 seconds.

(ii) *Impact Test*. A 5 kg steel hammer, 2.5 cm in diameter, must be dropped from a height of 1 m onto the test source.

(iii) *Vibration test*. The test source must be subject to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes.

(iv) *Puncture test*. A 1 gram hammer and pin, 0.3 cm pin diameter, must be dropped from a height of 1 m onto the test source.

(v) *Pressure test*. The test source must be subject to an external pressure of 1.695×10^7 pascals [24,600 pounds per square inch absolute].

(e) The requirements in paragraph (a), (b), (c), and (d) of this section do not apply to sealed sources that contain licensed material in gaseous form.

(f) The requirements in paragraphs (a), (b), (c), and (d) of this section do not apply to energy compensation sources (ECS). ECSs must be registered with the Commission under § 32.210 of this chapter or with an Agreement State.

[65 FR 20345, Apr. 17, 2000]

§ 39.43 Inspection, maintenance, and opening of a source or source holder.

(a) Each licensee shall visually check source holders, logging tools, and source handling tools, for defects before each use to ensure that the equipment is in good working condition and that required labeling is present. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: the date of check, name of inspector, equipment involved, defects found, and repairs made. These records must be retained for 3 years after the defect is found.

(b) Each licensee shall have a program for semiannual visual inspection and routine maintenance of source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars to ensure that the required labeling is legible and that no physical damage is visible. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: date, equipment involved, inspection and maintenance operations performed, any defects found, and any actions taken to correct the defects. These records must be retained for 3 years after the defect is found.

(c) Removal of a sealed source from a source holder or logging tool, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee unless a written procedure developed pursuant to § 39.63 has been approved either by the Commission pursuant to § 39.13(c) or by an Agreement State.

(d) If a sealed source is stuck in the source holder, the licensee may not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the Commission or an Agreement State to perform this operation.

(e) The opening, repair, or modification of any sealed source must be performed by persons specifically approved to do so by the Commission or an Agreement State.

§ 39.45 Subsurface tracer studies.

(a) The licensee shall require all personnel handling radioactive tracer material to use protective gloves and, if required by the license, other protective clothing and equipment. The licensee shall take precautions to avoid ingestion or inhalation of radioactive tracer material and to avoid contamination of field stations and temporary jobsites.

(b) A licensee may not knowingly inject licensed material into fresh water aquifers unless specifically authorized to do so by the Commission.

§ 39.47 Radioactive markers.

The licensee may use radioactive markers in wells only if the individual markers contain quantities of licensed material not exceeding the quantities specified in § 30.71 of this chapter. The use of markers is subject only to the requirements of § 39.37.

§ 39.49 Uranium sinker bars.

The licensee may use a uranium sinker bar in well logging applications only if it is legibly impressed with the words "CAUTION--RADIOACTIVE--DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND."

[65 FR 20345, Apr. 17, 2000]

§ 39.51 Use of a sealed source in a well without a surface casing.

The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved by the Commission pursuant to § 39.13(c) or by an Agreement State.

§ 39.53 Energy compensation source.

The licensee may use an energy compensation source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of licensed material not exceeding 3.7 MBq [100 microcuries].

(a) For well logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of §§ 39.35, 39.37 and 39.39.

(b) For well logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of §§ 39.15, 39.35, 39.37, 39.39, 39.51, and 39.77.

[65 FR 20345, Apr. 17, 2000]

§ 39.55 Tritium neutron generator target source.

(a) Use of a tritium neutron generator target source, containing quantities not exceeding 1,110 GBq [30 curies] and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of this part except §§ 39.15, 39.41, and 39.77.

(b) Use of a tritium neutron generator target source, containing quantities exceeding 1,110 GBq [30 curies] or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of this part except § 39.41.

[65 FR 20345, Apr. 17, 2000; 68 FR 75390, Dec. 31, 2003]

Subpart D--Radiation Safety Requirements

§ 39.61 Training.

(a) The licensee may not permit an individual to act as a logging supervisor until that person--

(1) Has completed training in the subjects outlined in paragraph (e) of this section;

(2) Has received copies of, and instruction in--

(i) The NRC regulations contained in the applicable sections of parts 19, 20, and 39 of this chapter;

(ii) The NRC license under which the logging supervisor will perform well logging; and

(iii) The licensee's operating and emergency procedures required by § 39.63;

(3) Has completed on-the-job training and demonstrated competence in the use of licensed materials, remote handling tools, and radiation survey instruments by a field evaluation; and

(4) Has demonstrated understanding of the requirements in paragraphs (a) (1) and (2) of this section by successfully completing a written test.

(b) The licensee may not permit an individual to act as a logging assistant until that person--

(1) Has received instruction in applicable sections of parts 19 and 20 of this chapter;

(2) Has received copies of, and instruction in, the licensee's operating and emergency procedures required by § 39.63;

(3) Has demonstrated understanding of the materials listed in paragraphs (b) (1) and (2) of this section by successfully completing a written or oral test; and

(4) Has received instruction in the use of licensed materials, remote handling tools, and radiation survey instruments, as appropriate for the logging assistant's intended job responsibilities.

(c) The licensee shall provide safety reviews for logging supervisors and logging assistants at least once during each calendar year.

(d) The licensee shall maintain a record on each logging supervisor's and logging assistant's training and annual safety review. The training records must include copies of written tests and dates of oral tests given after July 14, 1987. The training records must be retained until 3 years following the termination of employment. Records of annual safety reviews must list the topics

discussed and be retained for 3 years.

(e) The licensee shall include the following subjects in the training required in paragraph (a)(1) of this section:

(1) Fundamentals of radiation safety including--

(i) Characteristics of radiation;

(ii) Units of radiation dose and quantity of radioactivity;

(iii) Hazards of exposure to radiation;

(iv) Levels of radiation from licensed material;

(v) Methods of controlling radiation dose (time, distance, and shielding); and

(vi) Radiation safety practices, including prevention of contamination, and methods of decontamination.

(2) Radiation detection instruments including--

(i) Use, operation, calibration, and limitations of radiation survey instruments;

(ii) Survey techniques; and

(iii) Use of personnel monitoring equipment;

(3) Equipment to be used including--

(i) Operation of equipment, including source handling equipment and remote handling tools;

(ii) Storage, control, and disposal of licensed material; and

(iii) Maintenance of equipment.

(4) The requirements of pertinent Federal regulations. And

(5) Case histories of accidents in well logging.

§ 39.63 Operating and emergency procedures.

Each licensee shall develop and follow written operating and emergency procedures that cover--

(a) The handling and use of licensed materials including the use of sealed sources in wells without surface casing for protecting fresh water aquifers, if appropriate;

(b) The use of remote handling tools for handling sealed sources and radioactive tracer material except low-activity calibration sources;

(c) Methods and occasions for conducting radiation surveys, including surveys for detecting contamination, as required by § 39.67(c) - (e);

(d) Minimizing personnel exposure including exposures from inhalation and ingestion of licensed tracer materials;

(e) Methods and occasions for locking and securing stored licensed materials;

(f) Personnel monitoring and the use of personnel monitoring equipment;

(g) Transportation of licensed materials to field stations or temporary jobsites, packaging of licensed materials for transport in vehicles, placarding of vehicles when needed, and physically securing licensed materials in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal;

(h) Picking up, receiving, and opening packages containing licensed materials, in accordance with § 20.1906 of this chapter;

(i) For the use of tracers, decontamination of the environment, equipment, and personnel;

(j) Maintenance of records generated by logging personnel at temporary jobsites;

(k) The inspection and maintenance of sealed sources, source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars as required by § 39.43;

(l) Identifying and reporting to NRC defects and noncompliance as required by Part 21 of this chapter;

(m) Actions to be taken if a sealed source is lodged in a well;

(n) Notifying proper persons in the event of an accident; and

(o) Actions to be taken if a sealed source is ruptured including actions to prevent the spread of contamination and minimize inhalation and ingestion of licensed materials and actions to obtain suitable radiation survey instruments as required by § 39.33(b).

[52 FR 8234, Mar. 17, 1987, as amended at 67 FR 77652, Dec. 19, 2002]

§ 39.65 Personnel monitoring.

(a) The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that person wears a personnel dosimeter at all times during the handling of licensed radioactive materials. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and all other personnel dosimeters that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent. ~~The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that person wears, at all times during the handling of licensed radioactive materials, a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and other personnel dosimeters replaced at least quarterly. After replacement, each personnel dosimeter must be promptly processed.~~

(b) The licensee shall provide bioassay services to individuals using licensed materials in subsurface tracer studies if required by the license.

(c)The licensee shall retain records of personnel dosimeters required by paragraph (a) of this section and bioassay results for inspection until the Commission authorizes disposition of the records.

[52 FR 8234, Mar. 17, 1987, as amended at 65 FR 63752, Oct. 24, 2000; 85 FR 15347, Mar. 18, 2020]

§ 39.67 Radiation surveys.

(a) The licensee shall make radiation surveys, including but not limited to the surveys required under paragraphs (b) through (e) of this section, of each area where licensed materials are used and stored.

(b) Before transporting licensed materials, the licensee shall make a radiation survey of the position occupied by each individual in the vehicle and of the exterior of each vehicle used to transport the licensed materials.

(c) If the sealed source assembly is removed from the logging tool before departure from the temporary jobsite, the licensee shall confirm that the logging tool is free of contamination by energizing the logging tool detector or by using a survey meter.

(d) If the licensee has reason to believe that, as a result of any operation involving a sealed source, the encapsulation of the sealed source could be damaged by the operation, the licensee shall conduct a radiation survey, including a contamination survey, during and after the operation.

(e) The licensee shall make a radiation survey at the temporary jobsite before and after each subsurface tracer study to confirm the absence of contamination.

(f) The results of surveys required under paragraphs (a) through (e) of this section must be recorded and must include the date of the survey, the name of the individual making the survey, the identification of the survey, instrument used, and the location of the survey. The licensee shall retain records of surveys for inspection by the Commission for 3 years after they are made.

§ 39.69 Radioactive contamination control.

(a) If the licensee detects evidence that a sealed source has ruptured or licensed materials have caused contamination, the licensee shall initiate immediately the emergency procedures required by § 39.63.

(b) If contamination results from the use of licensed material in well logging, the licensee shall decontaminate all work areas, equipment, and unrestricted areas.

(c) During efforts to recover a sealed source lodged in the well, the licensee shall continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well, if any, to check for contamination resulting from damage to the sealed source.

Subpart E--Security, Records, Notifications

§ 39.71 Security.

(a) A logging supervisor must be physically present at a temporary jobsite whenever licensed materials are being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the jobsite in order to obtain assistance if a source becomes lodged in a well.

(b) During well logging, except when radiation sources are below ground or in shipping or storage containers, the logging supervisor or other individual designated by the logging supervisor shall maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in § 20.1003 of this chapter.

[52 FR 8234, Mar. 17, 1987, as amended at 63 FR 39483, July 23, 1998]

§ 39.73 Documents and records required at field stations.

Each licensee shall maintain the following documents and records at the field station:

(a) A copy of parts 19, 20, and 39 of NRC regulations;

(b) The license authorizing the use of licensed material;

(c) Operating and emergency procedures required by § 39.63;

(d) The record of radiation survey instrument calibrations required by § 39.33;

(e) The record of leak test results required by § 39.35;

(f) Physical inventory records required by § 39.37;

(g) Utilization records required by § 39.39;

(h) Records of inspection and maintenance required by § 39.43;

(i) Training records required by § 39.61(d); and

(j) Survey records required by § 39.67.

§ 39.75 Documents and records required at temporary jobsites.

Each licensee conducting operations at a temporary jobsite shall maintain the following documents and records at the temporary jobsite until the well logging operation is completed:

(a) Operating and emergency procedures required by § 39.63.

(b) Evidence of latest calibration of the radiation survey instruments in use at the site required by § 39.33.

(c) Latest survey records required by §§ 39.67 (b), (c), and (e).

(d) The shipping papers for the transportation of radioactive materials required by § 71.5 of this chapter; and

(e) When operating under reciprocity pursuant to § 150.20 of this chapter, a copy of the Agreement State license authorizing use of licensed materials.

§ 39.77 Notification of incidents and lost sources; abandonment procedures for irretrievable sources.

(a) The licensee shall immediately notify the appropriate NRC Regional Office by telephone and subsequently, within 30 days, by confirmation in writing, using an appropriate method listed in § 30.6(a) of this chapter, if the licensee knows or has reason to believe that a sealed source has been ruptured. The written confirmation must designate the well or other location, describe the magnitude and extent of the escape of licensed materials, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

(b) The licensee shall notify the Commission of the theft or loss of radioactive materials, radiation overexposures, excessive levels and concentrations of radiation, and certain other accidents as required by §§ 20.2201 - 20.2202, § 20.2203 and § 30.50 of this chapter.

(c) If a sealed source becomes lodged in a well, and when it becomes apparent that efforts to recover the sealed source will not be successful, the licensee shall--

(1) Notify the appropriate NRC Regional Office by telephone of the circumstances that resulted in the inability to retrieve the source and--

(i) Obtain NRC approval to implement abandonment procedures; or

(ii) That the licensee implemented abandonment before receiving NRC approval because the licensee believed there was an immediate threat to public health and safety; and

(2) Advise the well owner or operator, as appropriate, of the abandonment procedures under § 39.15 (a) or (c); and

(3) Either ensure that abandonment procedures are implemented within 30 days after the sealed source has been classified as irretrievable or request an extension of time if unable to complete the abandonment procedures.

(d) The licensee shall, within 30 days after a sealed source has been classified as irretrievable, make a report in writing to the appropriate NRC Regional Office. The licensee shall send a copy of the report to each appropriate State or Federal agency that issued permits or otherwise approved of the drilling operation. The report must contain the following information:

(1) Date of occurrence;

(2) A description of the irretrievable well logging source involved including the radionuclide and its quantity, chemical, and physical form;

(3) Surface location and identification of the well;

(4) Results of efforts to immobilize and seal the source in place;

(5) A brief description of the attempted recovery effort;

(6) Depth of the source;

(7) Depth of the top of the cement plug;

(8) Depth of the well;

(9) The immediate threat to public health and safety justification for implementing abandonment if prior NRC approval was not obtained in accordance with paragraph (c)(1)(ii) of this section;

(10) Any other information, such as a warning statement, contained on the permanent identification plaque; and

(11) State and Federal agencies receiving copy of this report.

[52 FR 8234, Mar. 17, 1987, as amended at 56 FR 64980, Dec. 13, 1991; 58 FR 67660, Dec. 22, 1993; 65 FR 20345, Apr. 17, 2000; 68 FR 58806, Oct. 10, 2003]

Subpart F--Exemptions

§ 39.91 Applications for exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Subpart G--Enforcement

§ 39.101 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of

this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55074, Nov. 24, 1992]

§ 39.103 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 39 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 39 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 39.1, 39.2, 39.5, 39.8, 39.13, 39.91, 39.101, and 39.103.

[57 FR 55074, Nov. 24, 1992]

CHAPTER 33.1-10-13.1
PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Section
33.1-10-13.1-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 71

33.1-10-13.1-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 71.

10 Code of Federal Regulations 71.0, 71.3, 71.4, 71.5, 71.7, 71.8, 71.9, 71.10, 71.12, 71.13, 71.14, 71.15, 71.17, 71.21, 71.22, 71.23, 71.47, 71.81, 71.83, 71.85, 71.87, 71.88, 71.89, 71.91, 71.93, 71.95, 71.97, 71.101, 71.103, 71.105, 71.106, 71.127, 71.129, 71.131, 71.133, 71.135, and 71.137 and appendix A to part 71 are adopted by reference as they exist on December 30, 2021~~December 30, 2019~~, with the following exceptions:

1. Not adopted by reference are 10 Code of Federal Regulations 71.0(d), 71.14(b), 71.85(a)-(c), 71.91(b), 71.101(c)(2), (d), and (e).

2. Requirements in 10 Code of Federal Regulations part 71 that apply to "licensed material" or "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States nuclear regulatory commission", or "administrator of the appropriate regional office" appear in 10 Code of Federal Regulations part 71, substitute the words "department of environmental quality" except when used in 10 Code of Federal Regulations 71.5(b), 71.10, 71.17(c)(3) and (e), 71.85(c), 71.88(a)(4), 71.93(c), 71.95, 71.97(c), and (c)(3)(iii), and (f).

4. Where the words “ATTN: Document Control Desk, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards” appear in 10 Code of Federal Regulations 71.101(c)(1), substitute the words “department of environmental quality.”

5. The terms “certificate of compliance, compliance holder or applicant” used in 10 Code of Federal Regulations 71.91(c) and (d), 71.101(a)-(c), 71.103(a), and 71.135 apply only to the U.S. Nuclear Regulatory Commission (NRC) as the NRC is the sole authority for issuing a package’s Certificate of Compliance.

6. 10 Code of Federal Regulations 71.9 employee protection also applies to violations of North Dakota Century Code chapters 23.1-02 and 23.1-03.

7. State form number 8414, "notice to employees", must be posted instead of United States nuclear regulatory commission form 3 that is specified in 10 Code of Federal Regulations part 71.

History: Effective January 1, 2019; amended effective July 1, 2021.
General Authority: NDCC 28-32-02; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 28-32-02

PART 71--PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

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Appendix A to Part 71--Determination of A_1 and A_2

Authority: Secs. 53, 57, 62, 63, 81, 161, 182, 183, 68 Stat. 930, 932, 933, 935, 948, 953, 954, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2077, 2092, 2093, 2111, 2201, 2232, 2233, 2297f); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109–58, 119 Stat. 594 (2005). Section 71.97 also issued under sec. 301, Pub. L. 96– 295, 94 Stat. 789–790.

Source: 60 FR 50264, Sept. 28, 1995, unless otherwise noted.

[72 FR 63974, Nov. 14, 2007; 73 FR 63572, Oct. 24, 2008]

Subpart A--General Provisions

Source: 69 FR 3786, Jan. 26, 2004, unless otherwise noted.

§ 71.0 Purpose and scope.

(a) This part establishes--

(1) Requirements for packaging, preparation for shipment, and transportation of licensed material; and

(2) Procedures and standards for NRC approval of packaging and shipping procedures for fissile material and for a quantity of other licensed material in excess of a Type A quantity.

(b) The packaging and transport of licensed material are also subject to other parts of this chapter (e.g., 10 CFR parts 20, 21, 30, 40, 70, and 73) and to the regulations of other agencies (e.g., the U.S. Department of Transportation (DOT) and the U.S. Postal Service)[1] having jurisdiction over means of transport. The requirements of this part are in addition to, and not in substitution for, other requirements.

(c) The regulations in this part apply to any licensee authorized by specific or general license issued by the Commission to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the NRC license, or transports that material on public highways. No provision of this part authorizes possession of licensed material.

(d)(1) Exemptions from the requirement for license in § 71.3 are specified in § 71.14. General licenses for which no NRC package approval is required are issued in §§ 71.21 through 71.23. The general license in § 71.17 requires that an NRC certificate of compliance or other package approval be issued for the package to be used under this general license.

(2) Application for package approval must be completed in accordance with subpart D of this part, demonstrating that the design of the package to be used satisfies the package approval standards contained in subpart E of this part, as related to the tests of subpart F of this part.

(3) A licensee transporting licensed material, or delivering licensed material to a carrier for transport, shall comply with the operating control requirements of subpart G of this part; the quality assurance requirements of subpart H of this part; and the general provisions of subpart A of this part, including DOT regulations referenced in § 71.5.

(e) The regulations of this part apply to any person holding, or applying for, a certificate of compliance, issued pursuant to this part, for a package intended for the transportation of radioactive material, outside the confines of a licensee's facility or authorized place of use.

(f) The regulations in this part apply to any person required to obtain a certificate of compliance, or an approved compliance plan, pursuant to part 76 of this chapter, if the person delivers radioactive material to a common or contract carrier for transport or transports the material outside the confines of the person's plant or other authorized place of use.

(g) This part also gives notice to all persons who knowingly provide to any licensee, certificate holder, quality assurance program approval holder, applicant for a license, certificate, or quality assurance program approval, or to a contractor, or subcontractor of any of them, components, equipment, materials, or other goods or services, that relate to a licensee's, certificate holder's, quality assurance program approval holder's, or applicant's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 71.8.

[1] Postal Service Manual (Domestic Mail Manual), section 124, which is incorporated by reference at 39 CFR 111.1.

[80 FR 34011, Jun. 12, 2015]

§ 71.1 Communications and records.

(a) Except where otherwise specified, all communications and reports concerning the regulations in this part and applications filed under them should be sent by mail addressed: ATTN: Document Control Desk, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, or CD–ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html;* by e-mail to *MSHD.Resource@nrc.gov;* or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. If the submission date falls on a Saturday, Sunday, or a Federal

holiday, the next Federal working day becomes the official due date.

(b) Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[69 FR 3786, Jan. 26, 2004; 69 FR 58038, Sept. 29, 2004; 70 FR 69421, Nov. 16, 2005; 72 FR 33386, Jun. 18, 2007; 74 FR 62683, Dec. 1, 2009; 75 FR 73945, Nov. 30, 2010; 79 FR 75741, Dec. 19, 2014; 80 FR 74981, Dec. 1, 2015; 84 FR 65639, Nov. 29, 2109; 84 FR 66561, Dec. 5, 2019]

§ 71.2 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission, other than a written interpretation by the General Counsel, will be recognized to be binding upon the Commission.

§ 71.3 Requirement for license.

Except as authorized in a general license or a specific license issued by the Commission, or as exempted in this part, no licensee may--

(a) Deliver licensed material to a carrier for transport; or

(b) Transport licensed material.

§ 71.4 Definitions.

The following terms are as defined here for the purpose of this part. To ensure compatibility with international transportation standards, all limits in this part are given in terms of dual units: The International System of Units (SI) followed or preceded by U.S. standard or customary units. The U.S. customary units are not exact equivalents but are rounded to a convenient value, providing a functionally equivalent unit. For the purpose of this part, either unit may be used.

A_1 means the maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Appendix A, Table A-1, of this part, or may be derived in accordance with the procedures prescribed in Appendix A of this part.

A_2 means the maximum activity of radioactive material, other than special form material, LSA, and SCO material, permitted in a Type A package. This value is either listed in Appendix A, Table A-1, of this part, or may be derived in accordance with the procedures prescribed in

Appendix A of this part.

Carrier means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

Certificate holder means a person who has been issued a certificate of compliance or other package approval by the Commission.

Certificate of Compliance (CoC) means the certificate issued by the Commission under subpart D of this part which approves the design of a package for the transportation of radioactive material.

Close reflection by water means immediate contact by water of sufficient thickness for maximum reflection of neutrons.

Consignment means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

Containment system means the assembly of components of the packaging intended to retain the radioactive material during transport.

Contamination means the presence of a radioactive substance on a surface in quantities in excess of 0.4 Bq/cm^2 ($1x10^{-5}$ $\mu Ci/cm^2$) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm^2 ($1x10^{-6}$ $\mu Ci/cm^2$) for all other alpha emitters.

(1) *Fixed contamination* means contamination that cannot be removed from a surface during normal conditions of transport.

(2) *Non-fixed contamination* means contamination that can be removed from a surface during normal conditions of transport.

Conveyance means:

(1) For transport by public highway or rail any transport vehicle or large freight container;

(2) For transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

(3) For transport by any aircraft.

Criticality Safety Index (CSI) means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages, overpacks or freight containers containing fissile material during transportation. Determination of the criticality safety index is described in §§ 71.22, 71.23, and 71.59. The criticality safety index for an overpack, freight container, consignment or conveyance containing fissile material packages is the arithmetic sum of the criticality safety

indices of all the fissile material packages contained within the overpack, freight container, consignment or conveyance.

Deuterium means, for the purposes of §§ 71.15 and 71.22, deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

DOT means the U.S. Department of Transportation.

Exclusive use means the sole use by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.

Fissile material means the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium and natural uranium or depleted uranium, that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in §71.15.

Graphite means, for the purposes of §§ 71.15 and 71.22, graphite with a boron equivalent content less than 5 parts per million and density greater than 1.5 grams per cubic centimeter.

Indian Tribe means and Indian of Alaska native Tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

Licensed material means byproduct, source, or special nuclear material received, possessed, used, or transferred under a general or specific license issued by the Commission pursuant to the regulations in this chapter.

Low Specific Activity (LSA) material means radioactive material with limited specific activity which is nonfissile or is excepted under § 71.15, and which satisfies the descriptions and limits set forth in the following section. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. The LSA material must be in one of three groups:

(1) LSA-I.

(i) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides that are intended to be processed for the use of these radionuclides;

(ii) Natural uranium, depleted uranium, natural thorium or their compounds or mixtures, provided they are unirradiated and in solid or liquid form;

(iii) Radioactive material other than fissile material, for which the A_2 value is unlimited; or

(iv) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with appendix A.

(2) LSA-II.

(i) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or

(ii) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 10^{-4} A_2/g for solids and gases, and 10^{-5} A_2/g for liquids.

(3) LSA-III. Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of § 71.77, in which:

(i) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.);

(ii) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that even under loss of packaging, the loss of radioactive material per package by leaching when placed in water for 7 days will not exceed 0.1 A_2; and

(iii) The estimated average specific activity of the solid, excluding any shielding material, does not exceed 2×10^{-3} A_2/g.

Low toxicity alpha emitters means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.

Maximum normal operating pressure means the maximum gauge pressure that would develop in the containment system in a period of 1 year under the heat condition specified in §71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

Natural thorium means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

Normal form radioactive material means radioactive material that has not been demonstrated to qualify as "special form radioactive material."

Optimum interspersed hydrogenous moderation means the presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.

Package means the packaging together with its radioactive contents as presented for transport.

(1) Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package means a fissile material packaging together with its fissile material contents.

(2) Type A package means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the DOT regulations in 49 CFR part 173.

(3) Type B package means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lbs/in^2) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in §71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in §71.19.

Packaging means the assembly of components necessary to ensure compliance with the packaging requirements of this part. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

Special form radioactive material means radioactive material that satisfies the following conditions:

(1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(2) The piece or capsule has at least one dimension not less than 5 mm (0.2 in); and

(3) It satisfies the requirements of §71.75. A special form encapsulation designed in accordance with the requirements of § 71.4 in effect on June 30, 1983 (see 10 CFR part 71, revised as of January 1, 1983), and constructed before July 1, 1985; a special form encapsulation designed in accordance with the requirements of § 71.4 in effect on March 31, 1996 (see 10 CFR part 71, revised as of January 1, 1996), and constructed before April 1, 1998; and special form material that was successfully tested before September 10, 2015 in accordance with the requirements of § 71.75(d) of this section in effect before September 10, 2015 may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

Specific activity of a radionuclide means the radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

Spent nuclear fuel or Spent fuel means fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least 1 year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.

State means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Surface Contaminated Object (SCO) means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:

(1) SCO-I: A solid object on which:

(i) The nonfixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4 Bq/cm^2 (10^4 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.4 Bq/cm^2 (10^{-5} microcurie/cm^2) for all other alpha emitters;

(ii) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4 x 10^4 Bq/cm^2 (1.0 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or 4 x 10^3 Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters; and

(iii) The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4 x 10^4 Bq/cm^2 (1 microcurie/cm^2) for beta
and gamma and low toxicity alpha emitters, or 4 x 10^3 Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters.

(2) SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

(i) The nonfixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 400 Bq/cm^2 (10^2 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters or 40 Bq/cm^2 (10^3 microcurie/cm^2) for all other alpha emitters;

(ii) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 8 x 10^5 Bq/cm2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or 8 x 10^4 Bq/cm^2 (2 microcuries/cm^2) for all other alpha

emitters; and

(iii) The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 8 x 10^5 Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or 8 x 10^4 Bq/cm^2 (2 microcuries/cm^2) for all other alpha emitters.

Transport index (TI) means the dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at 1 meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at 1 meter (3.3 ft)).

Tribal official means the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

Type A quantity means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material, or A_2, for normal form radioactive material, where A_1 and A_2 are given in Table A-1 of this part, or may be determined by procedures described in Appendix A of this part.

Type B quantity means a quantity of radioactive material greater than a Type A quantity.

Unirradiated uranium means uranium containing not more than 2 x 10^3 Bq of plutonium per gram of uranium-235, not more than 9 x 10^6 Bq of fission products per gram of uranium-235, and not more than 5 x 10^{-3} g of uranium-236 per gram of uranium-235.

Uranium – natural, depleted, enriched.

(1) Natural uranium means uranium (which may be chemically separated) with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235 and the remainder by weight essentially uranium-238).

(2) Depleted uranium means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(3) Enriched uranium means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

[69 FR 3787, Jan. 26, 2004; 69 FR 58038, Sep. 29, 2004; 77 FR 34204, Jun. 11, 2012; 80 FR 34011, Jun. 12, 2015; 80 FR 48684, Aug. 14, 2015; 80 FR 74981, Dec. 1, 2015; 82 FR 52825, Nov. 15, 2017; 86 FR 67839, Nov. 30, 2021]

§ 71.5 Transportation of licensed material.

(a) Each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in 49 CFR parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

(1) The licensee shall particularly note DOT regulations in the following areas:

(i) Packaging--49 CFR part 173: subparts A, B, and I.

(ii) Marking and labeling--49 CFR part 172: subpart D; and §§ 172.400 through 172.407 and §§ 172.436 through 172.441 of subpart E.

(iii) Placarding--49 CFR part 172: subpart F, especially §§ 172.500 through 172.519 and 172.556; and appendices B and C.

(iv) Accident reporting--49 CFR part 171: §§ 171.15 and 171.16.

(v) Shipping papers and emergency information--49 CFR part 172: subparts C and G.

(vi) Hazardous material employee training--49 CFR part 172: subpart H.

(vii) Security plans--49 CFR part 172: subpart I.

(viii) Hazardous material shipper/carrier registration--49 CFR part 107: subpart G.

(2) The licensee shall also note DOT regulations pertaining to the following modes of transportation:

(i) Rail--49 CFR part 174: subparts A through D and K.

(ii) Air--49 CFR part 175.

(iii) Vessel--49 CFR part 176: subparts A through F and M.

(iv) Public Highway--49 CFR part 177 and parts 390 through 397.

(b) If DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the DOT specified in paragraph (a) of this section to the same extent as if the shipment or transportation were subject to DOT regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

§ 71.6 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0008.

(b) The approved information collection requirements contained in this part appear in §§ 71.5, 71.7, 71.9, 71.12, 71.17, 71.19, 71.22, 71.23, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.47, 71.85, 71.87, 71.89, 71.91, 71.93, 71.95, 71.97, 71.101, 71.103, 71.105, 71.106, 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, 71.125, 71.127, 71.129, 71.131, 71.133, 71.135, 71.137, and appendix A, paragraph II.

[75 FR 73945, Nov. 30, 2010; 80 FR 34012, Jun. 12, 2015]

§ 71.7 Completeness and accuracy of information.

(a) Information provided to the Commission by a licensee, certificate holder, or an applicant for a license or CoC; or information required by statute or by the Commission's regulations, orders, license or CoC conditions, to be maintained by the licensee or certificate holder, must be complete and accurate in all material respects.

(b) Each licensee, certificate holder, or applicant for a license or CoC must notify the Commission of information identified by the licensee, certificate holder, or applicant for a license or CoC as having, for the regulated activity, a significant implication for public health and safety or common defense and security. A licensee, certificate holder, or an applicant for a license or CoC violates this paragraph only if the licensee, certificate holder, or applicant for a license or CoC fails to notify the Commission of information that the licensee, certificate holder, or applicant for a license or CoC has identified as having a significant implication for public health and safety or common defense and security. Notification must be provided to the Administrator of the appropriate Regional Office within 2 working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.

§ 71.8 Deliberate misconduct.

(a) This section applies to any--

(1) Licensee;

(2) Certificate holder;

(3) Quality assurance program approval holder;

(4) Applicant for a license, certificate, or quality assurance program approval;

(5) Contractor (including a supplier or consultant) or subcontractor, to any person identified in paragraph (a)(4) of this section; or

(6) Employees of any person identified in paragraphs (a)(1) through (a)(5) of this section.

(b) A person identified in paragraph (a) of this section who knowingly provides to any entity, listed in paragraphs (a)(1) through (a)(5) of this section, any components, materials, or other goods or services that relate to a licensee's, certificate holder's, quality assurance program approval holder's, or applicant's activities subject to this part may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate holder, quality assurance program approval holder, or any applicant to be in violation of any rule, regulation, or order; or any term, condition or limitation of any license, certificate, or approval issued by the Commission; or

(2) Deliberately submit to the NRC, a licensee, a certificate holder, quality assurance program approval holder, an applicant for a license, certificate or quality assurance program approval, or a licensee's, applicant's, certificate holder's, or quality assurance program approval holder's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

(c) A person who violates paragraph (b)(1) or (b)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

(d) For the purposes of paragraph (b)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee, certificate holder, quality assurance program approval holder, or applicant for a license, certificate, or quality assurance program approval to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license or certificate issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate holder, quality assurance program approval holder, applicant, or the contractor or subcontractor of any of them.

§ 71.9 Employee protection.

(a) Discrimination by a Commission licensee, certificate holder, an applicant for a Commission license or a CoC, or a contractor or subcontractor of any of these, against an employee for engaging in certain protected activities, is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended.

(1) The protected activities include, but are not limited to:

(i) Providing the Commission or his or her employer information about alleged violations of either of the statutes named in paragraph (a) of this section or possible violations of requirements imposed under either of those statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) of this section or under these requirements if the employee has identified the alleged illegality to the employer;

(iii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) of this section; and

(v) Assisting or participating in, or is about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee's assistance or participation.

(3) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraph (a), (e), or (f) of this section by a Commission licensee, certificate holder, applicant for a Commission license or a CoC, or a contractor or subcontractor of any of these may be grounds for:

(1) Denial, revocation, or suspension of the license or the CoC;

(2) Imposition of a civil penalty on the licensee, applicant, or a contractor or subcontractor of the licensee or applicant; or

(3) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each licensee, certificate holder, and applicant for a license or CoC must prominently post the current revision of NRC Form 3, "Notice to Employees," referenced in §19.11(c) of this chapter. This form must be posted at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. The premises must be posted not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license or CoC, and for 30 days following license or CoC termination.

(2) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in Appendix D to part 20 of this chapter or by calling the NRC Publishing Services Branch at 301-415-5877.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in a protected activity as defined in paragraph (a)(1) of this section including, but not limited to, providing information to the NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

[72 FR 63975, Nov. 14, 2007; 79 FR 66605, Nov. 10, 2014]

§ 71.10 Public inspection of application.

Applications for approval of a package design under this part, which are submitted to the Commission, may be made available for public inspection, in accordance with provisions of parts 2 and 9 of this chapter. This includes an application to amend or revise an existing package design, any associated documents and drawings submitted with the application, and any responses to NRC requests for additional information.

§ 71.11 Protection of Safeguards Information

Each licensee, certificate holder, or applicant for a Certificate of Compliance for a transportation package for transport of irradiated reactor fuel, strategic special nuclear material, a critical mass of special nuclear material, or byproduct material in quantities determined by the Commission through order or regulation to be significant to the public health and safety or the common defense and security, shall protect Safeguards Information against unauthorized disclosure in accordance with the requirements in § 73.21 and the requirements of § 73.22 or § 73.23 of this chapter, as applicable.

[73 FR 63572, Oct. 24, 2008]

Subpart B--Exemptions

Source: 69 FR 3786, Jan. 26, 2004, unless otherwise noted.

§ 71.12 Specific exemptions.

On application of any interested person or on its own initiative, the Commission may grant any exemption from the requirements of the regulations in this part that it determines is authorized by law and will not endanger life or property nor the common defense and security.

§ 71.13 Exemption of physicians.

Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from § 71.5 with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under this exemption must be licensed under 10 CFR part 35 or the equivalent Agreement State regulations.

§ 71.14 Exemption for low-level materials.

(a) A licensee is exempt from all the requirements of this part with respect to shipment or carriage of the following low-level materials:

(1) Natural material and ores containing naturally occurring radionuclides that are either in their natural state, or have only been processed for purposes other than for the extraction of the radionuclides, and which are not intended to be processed for the use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the applicable radionuclide activity concentration values specified in appendix A, Table A-2, or Table A-3 of this part.

(2) Materials for which the activity concentration is not greater than the activity concentration values specified in appendix A, Table A-2, or Table A-3 of this part, or for which the consignment activity is not greater than the limit for an exempt consignment found in appendix A, Table A-2, or Table A-3 of this part.

(3) Non-radioactive solid objects with radioactive substances present on any surfaces in quantities not in excess of the levels cited in the definition of contamination in § 71.4.

(b) A licensee is exempt from all the requirements of this part, other than §§ 71.5 and 71.88, with respect to shipment or carriage of the following packages, provided the packages do not contain any fissile material, or the material is exempt from classification as fissile material under § 71.15:

(1) A package that contains no more than a Type A quantity of radioactive material;

(2) A package transported within the United States that contains no more than 0.74 TBq (20 Ci) of special form plutonium-244; or

(3) The package contains only LSA or SCO radioactive material, provided--

(i) That the LSA or SCO material has an external radiation dose of less than or equal to 10 mSv/h (1 rem/h), at a distance of 3 m from the unshielded material; or

(ii) That the package contains only LSA-I or SCO-I material.

[80 FR 34012, Jun. 12, 2015]

§ 71.15 Exemption from classification as fissile material.

Fissile material meeting the requirements of at least one of the paragraphs (a) through (f) of this section are exempt from classification as fissile material and from the fissile material package standards of §§ 71.55 and 71.59, but are subject to all other requirements of this part, except as noted.

(a) Individual package containing 2 grams or less fissile material.

(b) Individual or bulk packaging containing 15 grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid nonfissile material.

(c)(1) Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:

(i) There is at least 2000 grams of solid nonfissile material for every gram of fissile material, and

(ii) There is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material.

(2) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid nonfissile material.

(d) Uranium enriched in uranium-235 to a maximum of 1 percent by weight, and with total plutonium and uranium-233 content of up to 1 percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5 percent of the uranium mass, and that the fissile material is distributed homogeneously and does not form a lattice arrangement within the package.

(e) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2 percent by mass, with a total plutonium and uranium-233 content not exceeding 0.002 percent of the mass

of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material must be contained in at least a DOT Type A package.

(f) Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than 20 percent by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

[80 FR 34012, Jun. 12, 2015]

§ 71.16 [Reserved]

Subpart C--General Licenses

Source: 69 FR 3792, Jan. 26, 2004, unless otherwise noted.

§ 71.17 General license: NRC-approved package.

(a) A general license is issued to any licensee of the Commission to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the NRC.

(b) This general license applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the provisions of subpart H of this part.

(c) Each licensee issued a general license under paragraph (a) of this section shall—

(1) Maintain a copy of the Certificate of Compliance, or other approval of the package, and the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;

(2) Comply with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of subparts A, G, and H of this part; and

(3) Submit in writing before the first use of the package to: ATTN: Document Control Desk, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in § 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.

(d) This general license applies only when the package approval authorizes use of the package under this general license.

(e) For a Type B or fissile material package, the design of which was approved by NRC before April 1, 1996, the general license is subject to the additional restrictions of § 71.19.

[75 FR 73945, Nov. 30, 2010; 79 FR 75741, Dec. 19, 2014; 80 FR 34012, Jun. 12, 2015; 84 FR 65639, Nov. 29, 2019; 84 FR 66561, Dec. 5, 2019]

§ 71.18 [Reserved]

§ 71.19 Previously approved package.

(a) [Reserved]

(b) A Type B(U) package, a Type B(M) package, or a fissile material package, previously approved by the NRC but without the designation "- 85" in the identification number of the NRC CoC, may be used under the general license of § 71.17 with the following additional conditions:

(1) Fabrication of the package is satisfactorily completed by April 1, 1999, as demonstrated by application of its model number in accordance with § 71.85(c);

(2) A package used for a shipment to a location outside the United States is subject to multilateral approval as defined in DOT regulations at 49 CFR 173.403; and

(3) A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

(c) A Type B(U) package, a Type B(M) package, or a fissile material package previously approved by the NRC with the designation "-85" in the identification number of the NRC CoC, may be used under the general license of § 71.17 with the following additional conditions:

(1) Fabrication of the package must be satisfactorily completed by December 31, 2006, as demonstrated by application of its model number in accordance with § 71.85(c); and

(2) After December 31, 2003, a package used for a shipment to a location outside the United States is subject to multilateral approval as defined in DOT regulations at 49 CFR 173.403.

(d) NRC will approve modifications to the design and authorized contents of a Type B package, or a fissile material package, previously approved by NRC, provided--

(1) The modifications of a Type B package are not significant with respect to the design, operating characteristics, or safe performance of the containment system, when the package is subjected to the tests specified in §§ 71.71 and 71.73;

(2) The modifications of a fissile material package are not significant, with respect to the prevention of criticality, when the package is subjected to the tests specified in §§ 71.71 and 71.73; and

(3) The modifications to the package satisfy the requirements of this part.

(e) NRC will revise the package identification number to designate previously approved package designs as B, BF, AF, B(U), B(M), B(U)F, B(M)F, B(U)-85, B(U)F-85, B(M)-85, B(M)F-85, or AF-85 as appropriate, and with the identification number suffix "-96" after receipt of an application demonstrating that the design meets the requirements of this part.

[80 FR 34012, Jun. 12, 2015]

§ 71.21 General license: Use of foreign approved package.

(a) A general license is issued to any licensee of the Commission to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority certificate, that has been revalidated by the DOT as meeting the applicable requirements of 49 CFR 171.23.

(b) Except as otherwise provided in this section, the general license applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the applicable provisions of subpart H of this part.

(c) This general license applies only to shipments made to or from locations outside the United States.

(d) Each licensee issued a general license under paragraph (a) of this section shall—

(1) Maintain a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate, relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and

(2) Comply with the terms and conditions of the certificate and revalidation, and with the applicable requirements of subparts A, G, and H of this part.

[80 FR 34012, Jun. 12, 2015]

§ 71.22 General license: Fissile material.

(a) A general license is issued to any licensee of the Commission to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The fissile material need not be contained in a package which meets the standards of subparts E and F of this part; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(b) The general license applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the provisions of subpart H of this part.

(c) The general license applies only when a package's contents:

(1) Contain no more than a Type A quantity of radioactive material; and

(2) Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

(d) The general license applies only to packages containing fissile material that are labeled with a

CSI which:

(1) Has been determined in accordance with paragraph (e) of this section;

(2) Has a value less than or equal to 10; and

(3) For a shipment of multiple packages containing fissile material, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

(e)(1) The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10\left[\frac{\text{grams of } ^{235}U}{X} + \frac{\text{grams of } ^{233}U}{Y} + \frac{\text{grams of Pu}}{Z}\right];$$

(2) The calculated CSI must be rounded up to the first decimal place;

(3) The values of X, Y, and Z used in the CSI equation must be taken from Tables 71-1 or 71-2, as appropriate;

(4) If Table 71-2 is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium must be assumed to be zero; and

(5) Table 71-1 values for X, Y, and Z must be used to determine the CSI if:

(i) Uranium-233 is present in the package;

(ii) The mass of plutonium exceeds 1 percent of the mass of uranium-235;

(iii) The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or

(iv) Substances having a moderating effectiveness (i.e., an average hydrogen density greater than H_2O) (e.g., certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

Table 71-1. Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment per § 71.22(e)

Fissile material	Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to H_2O	Fissile material mass mixed with moderating substances having an average hydrogen density greater than H_2O[a]

	(grams)	(grams)
^{235}U (X)	60	38
^{233}U (Y)	43	27
^{239}Pu or ^{241}Pu (Z)	37	24

[a] When mixtures of moderating substances are present, the lower mass limits shall be used if more than 15 percent of the moderating substance has an average hydrogen density greater than H_2O.

Table 71-2. Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment per § 71.22(e)

Uranium enrichment in weight percent of ^{235}U not exceeding	Fissile material mass of ^{235}U (X) (grams)
24	60
20	63
15	67
11	72
10	76
9.5	78
9	81
8.5	82
8	85
7.5	88
7	90
6.5	93
6	97
5.5	102
5	108
4.5	114
4	120
3.5	132
3	150
2.5	180
2	246

1.5	408
1.35	480
1	1,020
0.92	1,800

[69 FR 3786, Jan. 26, 2004; 69 FR 58038, Sept. 29, 2004]

§ 71.23 General license: Plutonium-beryllium special form material.

(a) A general license is issued to any licensee of the Commission to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section. This material need not be contained in a package which meets the standards of subparts E and F of this part; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(b) The general license applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the provisions of subpart H of this part.

(c) The general license applies only when a package's contents:

(1) Contain no more than a Type A quantity of radioactive material; and

(2) Contain less than 1000 g of plutonium, provided that: plutonium-239, plutonium-241, or any combination of these
radionuclides, constitutes less than 240 g of the total quantity of plutonium in the package.

(d) The general license applies only to packages labeled with a CSI which:

(1) Has been determined in accordance with paragraph (e) of this section;

(2) Has a value less than or equal to 100; and

(3) For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

(e)(1) The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10\left[\frac{\text{grams of } {}^{239}\text{Pu} + \text{grams of } {}^{241}\text{Pu}}{24}\right]; \text{ and}$$

(2) The calculated CSI must be rounded up to the first decimal place.

§ 71.24 [Reserved]

§ 71.25 [Reserved]

Subpart D--Application for Package Approval

§ 71.31 Contents of application.

(a) An application for an approval under this part must include, for each proposed packaging design, the following information:

(1) A package description as required by § 71.33;

(2) A package evaluation as required by § 71.35; and

(3) A quality assurance program description, as required by § 71.37, or a reference to a previously approved quality assurance program.

(b) Except as provided in § 71.13, an application for modification of a package design, whether for modification of the packaging or authorized contents, must include sufficient information to demonstrate that the proposed design satisfies the package standards in effect at the time the application is filed.

(c) The applicant shall identify any established codes and standards proposed for use in package design, fabrication, assembly, testing, maintenance, and use. In the absence of any codes and standards, the applicant shall describe and justify the basis and rationale used to formulate the package quality assurance program.

[80 FR 34012, Jun. 12, 2015]

§ 71.33 Package description.

The application must include a description of the proposed package in sufficient detail to identify the package accurately and provide a sufficient basis for evaluation of the package. The description must include --

(a) With respect to the packaging --

(1) Classification as Type B(U), Type B(M), or fissile material packaging;

(2) Gross weight;

(3) Model number;

(4) Identification of the containment system;

(5) Specific materials of construction, weights, dimensions, and fabrication methods of --

(i) Receptacles;

(ii) Materials specifically used as nonfissile neutron absorbers or moderators;

(iii) Internal and external structures supporting or protecting receptacles;

(iv) Valves, sampling ports, lifting devices, and tie-down devices; and

(v) Structural and mechanical means for the transfer and dissipation of heat; and

(6) Identification and volumes of any receptacles containing coolant.

(b) With respect to the contents of the package --

(1) Identification and maximum radioactivity of radioactive constituents;

(2) Identification and maximum quantities of fissile constituents;

(3) Chemical and physical form;

(4) Extent of reflection, the amount and identity of nonfissile materials used as neutron absorbers or moderators, and the atomic ratio of moderator to fissile constituents;

(5) Maximum normal operating pressure;

(6) Maximum weight;

(7) Maximum amount of decay heat; and

(8) Identification and volumes of any coolants.

§ 71.35 Package evaluation.

The application must include the following:

(a) A demonstration that the package satisfies the standards specified in subparts E and F of this part;

(b) For a fissile material package, the allowable number of packages that may be transported in the same vehicle in accordance with § 71.59; and

(c) For a fissile material shipment, any proposed special controls and precautions for transport,

loading, unloading, and handling and any proposed special controls in case of an accident or delay.

§ 71.37 Quality assurance.

(a) The applicant shall describe the quality assurance program (see Subpart H of this part) for the design, fabrication, assembly, testing, maintenance, repair, modification, and use of the proposed package.

(b) The applicant shall identify any specific provisions of the quality assurance program that are applicable to the particular package design under consideration, including a description of the leak testing procedures.

§ 71.38 Renewal of a certificate of compliance or quality assurance program approval.

(a) Except as provided in paragraph (b) of this section, each Certificate of Compliance or Quality Assurance Program Approval expires at the end of the day, in the month and year stated in the approval.

(b) In any case in which a person, not less than 30 days before the expiration of an existing Certificate of Compliance or Quality Assurance Program Approval issued pursuant to the part, has filed an application in proper form for renewal of either of those approvals, the existing Certificate of Compliance or Quality Assurance Program Approval for which the renewal application was filed shall not be deemed to have expired until final action on the application for renewal has been taken by the Commission.

(c) In applying for renewal of an existing Certificate of Compliance or Quality Assurance Program Approval, an applicant may be required to submit a consolidated application that incorporates all changes to its program that, are incorporated by reference in the existing approval or certificate, into as few referenceable documents as reasonably achievable.

[80 FR 34012, Jun. 12, 2015]

§ 71.39 Requirement for additional information.

The Commission may at any time require additional information in order to enable it to determine whether a license, certificate of compliance, or other approval should be granted, renewed, denied, modified, suspended, or revoked.

Subpart E--Package Approval Standards

§ 71.41 Demonstration of compliance.

(a) The effects on a package of the tests specified in § 71.71 ("Normal conditions of transport"), and the tests specified in § 71.73 ("Hypothetical accident conditions"), and § 71.61 ("Special requirements for Type B packages containing more than 10^5 A_2"), must be evaluated by

subjecting a specimen or scale model to a specific test, or by another method of demonstration acceptable to the Commission, as appropriate for the particular feature being considered.

(b) Taking into account the type of vehicle, the method of securing or attaching the package, and the controls to be exercised by the shipper, the Commission may permit the shipment to be evaluated together with the transporting vehicle.

(c) Environmental and test conditions different from those specified in §§ 71.71 and 71.73 may be approved by the Commission if the controls proposed to be exercised by the shipper are demonstrated to be adequate to provide equivalent safety of the shipment.

(d) Packages for which compliance with the other provisions of these regulations is impracticable shall not be transported except under special package authorization. Provided the applicant demonstrates that compliance with the other provisions of the regulations is impracticable and that the requisite standards of safety established by these regulations have been demonstrated through means alternative to the other provisions, a special package authorization may be approved for one-time shipments. The applicant shall demonstrate that the overall level of safety in transport for these shipments is at least equivalent to that which would be provided if all the applicable requirements had been met.

[60 FR 50264, Sept. 28, 1995 as amended at 69 FR 3794, Jan. 26, 2004]

§ 71.43 General standards for all packages.

(a) The smallest overall dimension of a package may not be less than 10 cm (4 in).

(b) The outside of a package must incorporate a feature, such as a seal, that is not readily breakable and that, while intact, would be evidence that the package has not been opened by unauthorized persons.

(c) Each package must include a containment system securely closed by a positive fastening device that cannot be opened unintentionally or by a pressure that may arise within the package.

(d) A package must be made of materials and construction that assure that there will be no significant chemical, galvanic, or other reaction among the packaging components, among package contents, or between the packaging components and the package contents, including possible reaction resulting from inleakage of water, to the maximum credible extent. Account must be taken of the behavior of materials under irradiation.

(e) A package valve or other device, the failure of which would allow radioactive contents to escape, must be protected against unauthorized operation and, except for a pressure relief device, must be provided with an enclosure to retain any leakage.

(f) A package must be designed, constructed, and prepared for shipment so that under the tests specified in § 71.71 ("Normal conditions of transport") there would be no loss or dispersal of radioactive contents, no significant increase in external surface radiation levels, and no

substantial reduction in the effectiveness of the packaging.

(g) A package must be designed, constructed, and prepared for transport so that in still air at 38°C (100°F) and in the shade, no accessible surface of a package would have a temperature exceeding 50°C (122°F) in a nonexclusive use shipment, or 85°C (185°F) in an exclusive use shipment.

(h) A package may not incorporate a feature intended to allow continuous venting during transport.

§ 71.45 Lifting and tie-down standards for all packages.

(a) Any lifting attachment that is a structural part of a package must be designed with a minimum safety factor of three against yielding when used to lift the package in the intended manner, and it must be designed so that failure of any lifting device under excessive load would not impair the ability of the package to meet other requirements of this subpart. Any other structural part of the package that could be used to lift the package must be capable of being rendered inoperable for lifting the package during transport, or must be designed with strength equivalent to that required for lifting attachments.

(b) Tie-down devices:

(1) If there is a system of tie-down devices that is a structural part of the package, the system must be capable of withstanding, without generating stress in any material of the package in excess of its yield strength, a static force applied to the center of gravity of the package having a vertical component of 2 times the weight of the package with its contents, a horizontal component along the direction in which the vehicle travels of 10 times the weight of the package with its contents, and a horizontal component in the transverse direction of 5 times the weight of the package with its contents.

(2) Any other structural part of the package that could be used to tie down the package must be capable of being rendered inoperable for tying down the package during transport, or must be designed with strength equivalent to that required for tie-down devices.

(3) Each tie-down device that is a structural part of a package must be designed so that failure of the device under excessive load would not impair the ability of the package to meet other requirements of this part.

§ 71.47 External radiation standards for all packages.

(a) Except as provided in paragraph (b) of this section, each package of radioactive materials offered for transportation must be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 mSv/h (200 mrem/h) at any point on the external surface of the package, and the transport index does not exceed 10.

(b) A package that exceeds the radiation level limits specified in paragraph (a) of this section

must be transported by exclusive use shipment only, and the radiation levels for such shipment must not exceed the following during transportation:

(1) 2 mSv/h (200 mrem/h) on the external surface of the package, unless the following conditions are met, in which case the limit is 10 mSv/h (1000 mrem/h):

(i) The shipment is made in a closed transport vehicle;

(ii) The package is secured within the vehicle so that its position remains fixed during transportation; and

(iii) There are no loading or unloading operations between the beginning and end of the transportation;

(2) 2 mSv/h (200 mrem/h) at any point on the outer surface of the vehicle, including the top and underside of the vehicle; or in the case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load or enclosure, if used, and on the lower external surface of the vehicle; and

(3) 0.1 mSv/h (10 mrem/h) at any point 2 meters (80 in) from the outer lateral surfaces of the vehicle (excluding the top and underside of the vehicle); or in the case of a flat-bed style vehicle, at any point 2 meters (6.6 feet) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and

(4) 0.02 mSv/h (2 mrem/h) in any normally occupied space, except that this provision does not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices in conformance with 10 CFR 20.1502.

(c) For shipments made under the provisions of paragraph (b) of this section, the shipper shall provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions must be included with the shipping paper information.

(d) The written instructions required for exclusive use shipments must be sufficient so that, when followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public.

§ 71.51 Additional requirements for Type B packages.

(a) A Type B package, in addition to satisfying the requirements of §§ 71.41 through 71.47, must be designed, constructed, and prepared for shipment so that under the tests specified in:

(1) Section 71.71 ("Normal conditions of transport"), there would be no loss or dispersal of radioactive contents--as demonstrated to a sensitivity of 10^{-6} A_2 per hour, no significant increase in external surface radiation levels, and no substantial reduction in the effectiveness of the packaging; and

(2) Section 71.73 ("Hypothetical accident conditions"), there would be no escape of krypton-85 exceeding 10 A_2 in 1 week, no escape of other radioactive material exceeding a total amount A_2 in 1 week, and no external radiation dose rate exceeding 10 mSv/h (1 rem/h) at 1 m (40 in) from the external surface of the package.

(b) Where mixtures of different radionuclides are present, the provisions of appendix A, paragraph IV of this part shall apply, except that for Krypton-85, an effective A_2 value equal to 10 A_2 may be used.

(c) Compliance with the permitted activity release limits of paragraph (a) of this section may not depend on filters or on a mechanical cooling system.

(d) For packages which contain radioactive contents with activity greater than 10^5 A_2, the requirements of § 71.61 must be met.

[60 FR 50264, Sept. 28, 1995 as amended at 69 FR 3794, Jan. 26, 2004]

§ 71.53 [Reserved]

[62 FR 5913, Feb. 10, 1997; 69 FR 3794, January 26, 2004]

§ 71.55 General requirements for fissile material packages.

(a) A package used for the shipment of fissile material must be designed and constructed in accordance with §§ 71.41 through 71.47. When required by the total amount of radioactive material, a package used for the shipment of fissile material must also be designed and constructed in accordance with § 71.51.

(b) Except as provided in paragraph (c) or (g) of this section, a package used for the shipment of fissile material must be so designed and constructed and its contents so limited that it would be subcritical if water were to leak into the containment system, or liquid contents were to leak out of the containment system so that, under the following conditions, maximum reactivity of the fissile material would be attained:

(1) The most reactive credible configuration consistent with the chemical and physical form of the material;

(2) Moderation by water to the most reactive credible extent; and

(3) Close full reflection of the containment system by water on all sides, or such greater reflection of the containment system as may additionally be provided by the surrounding material of the packaging.

(c) The Commission may approve exceptions to the requirements of paragraph (b) of this section if the package incorporates special design features that ensure that no single packaging error would permit leakage, and if appropriate measures are taken before each shipment to ensure that

the containment system does not leak.

(d) A package used for the shipment of fissile material must be so designed and constructed and its contents so limited that under the tests specified in § 71.71 ("Normal conditions of transport") --

(1) The contents would be subcritical;

(2) The geometric form of the package contents would not be substantially altered;

(3) There would be no leakage of water into the containment system unless, in the evaluation of undamaged packages under § 71.59(a)(1), it has been assumed that moderation is present to such an extent as to cause maximum reactivity consistent with the chemical and physical form of the material; and

(4) There will be no substantial reduction in the effectiveness of the packaging, including:

(i) No more than 5 percent reduction in the total effective volume of the packaging on which nuclear safety is assessed;

(ii) No more than 5 percent reduction in the effective spacing between the fissile contents and the outer surface of the packaging; and

(iii) No occurrence of an aperture in the outer surface of the packaging large enough to permit the entry of a 10 cm (4 in) cube.

(e) A package used for the shipment of fissile material must be so designed and constructed and its contents so limited that under the tests specified in § 71.73 ("Hypothetical accident conditions"), the package would be subcritical. For this determination, it must be assumed that:

(1) The fissile material is in the most reactive credible configuration consistent with the damaged condition of the package and the chemical and physical form of the contents;

(2) Water moderation occurs to the most reactive credible extent consistent with the damaged condition of the package and the chemical and physical form of the contents; and

(3) There is full reflection by water on all sides, as close as is consistent with the damaged condition of the package.

(f) For fissile material package designs to be transported by air:

(1) The package must be designed and constructed, and its contents limited so that it would be subcritical, assuming reflection by 20 cm (7.9 in) of water but no water inleakage, when subjected to sequential application of:

(i) The free drop test in § 71.73(c)(1);

(ii) The crush test in § 71.73(c)(2);

(iii) A puncture test, for packages of 250 kg or more, consisting of a free drop of the specimen through a distance of 3 m (120 in) in a position for which maximum damage is expected at the conclusion of the test sequence, onto the upper end of a solid, vertical, cylindrical, mild steel probe mounted on an essentially unyielding, horizontal surface. The probe must be 20 cm (7.9 in) in diameter, with the striking end forming the frustum of a right circular cone with the dimensions of 30 cm height, 2.5 cm top diameter, and a top edge rounded to a radius of not more than 6 mm (0.25 in). For packages less than 250 kg, the puncture test must be the same, except that a 250 kg probe must be dropped onto the specimen which must be placed on the surface; and

(iv) The thermal test in § 71.73(c)(4), except that the duration of the test must be 60 minutes.

(2) The package must be designed and constructed, and its contents limited, so that it would be subcritical, assuming reflection by 20 cm (7.9 in) of water but no water inleakage, when subjected to an impact on an unyielding surface at a velocity of 90 m/s normal to the surface, at such orientation so as to result in maximum damage. A separate, undamaged specimen can be used for this evaluation.

(3) Allowance may not be made for the special design features in paragraph (c) of this section, unless water leakage into or out of void spaces is prevented following application of the tests in paragraphs (f)(1) and (f)(2) of this section, and subsequent application of the immersion test in § 71.73(c)(5).

(g) Packages containing uranium hexafluoride only are excepted from the requirements of paragraph (b) of this section provided that:

(1) Following the tests specified in § 71.73 ("Hypothetical accident conditions"), there is no physical contact between the valve body and any other component of the packaging, other than at its original point of attachment, and the valve remains leak tight;

(2) There is an adequate quality control in the manufacture, maintenance, and repair of packagings;

(3) Each package is tested to demonstrate closure before each shipment; and

(4) The uranium is enriched to not more than 5 weight percent uranium-235.

[60 FR 50264, Sept. 28, 1995; 61 FR 28724, June 6, 1996; 69 FR 3794, Jan. 26, 2004]

§ 71.57 [Reserved]

§ 71.59 Standards for arrays of fissile material packages.

(a) A fissile material package must be controlled by either the shipper or the carrier during transport to assure that an array of such packages remains subcritical. To enable this control, the

designer of a fissile material package shall derive a number "N" based on all the following conditions being satisfied, assuming packages are stacked together in any arrangement and with close full reflection on all sides of the stack by water:

(1) Five times "N" undamaged packages with nothing between the packages would be subcritical;

(2) Two times "N" damaged packages, if each package were subjected to the tests specified in § 71.73 ("Hypothetical accident conditions") would be subcritical with optimum interspersed hydrogenous moderation; and

(3) The value of "N" cannot be less than 0.5.

(b) The CSI must be determined by dividing the number 50 by the value of "N" derived using the procedures specified in paragraph (a) of this section. The value of the CSI may be zero provided that an unlimited number of packages are subcritical, such that the value of "N" is effectively equal to infinity under the procedures specified in paragraph (a) of this section. Any CSI greater than zero must be rounded up to the first decimal place.

(c) For a fissile material package which is assigned a CSI value--

(1) Less than or equal to 50, that package may be shipped by a carrier in a nonexclusive use conveyance, provided the sum of the CSIs is limited to less than or equal to 50.

(2) Less than or equal to 50, that package may be shipped by a carrier in an exclusive use conveyance, provided the sum of the CSIs is limited to less than or equal to 100.

(3) Greater than 50, that package must be shipped by a carrier in an exclusive use conveyance, provided the sum of the CSIs is limited to less than or equal to 100.

[69 FR 3795, Jan. 26, 2004]

§ 71.61 Special requirements for Type B packages containing more than 10^5A_2.

A Type B package containing more than 10^5A_2 must be designed so that its undamaged containment system can withstand an external water pressure of 2 MPa (290 psi) for a period of not less than 1 hour without collapse, buckling, or inleakage of water.

[69 FR 3795, Jan. 26, 2004]

§ 71.63 Special requirement for plutonium shipments.

Shipments containing plutonium must be made with the contents in solid form, if the contents contain greater than 0.74 TBq (20 Ci) of plutonium.

[69 FR 3795, Jan. 26, 2004]

§ 71.64 Special requirements for plutonium air shipments.

(a) A package for the shipment of plutonium by air subject to § 71.88(a)(4), in addition to satisfying the requirements of §§ 71.41 through 71.63, as applicable, must be designed, constructed, and prepared for shipment so that under the tests specified in --

(1) Section 71.74 ("Accident conditions for air transport of plutonium") --

(i) The containment vessel would not be ruptured in its post-tested condition, and the package must provide a sufficient degree of containment to restrict accumulated loss of plutonium contents to not more than an A_2 quantity in a period of 1 week;

(ii) The external radiation level would not exceed 10 mSv/h (1 rem/h) at a distance of 1 m (40 in) from the surface of the package in its post-tested condition in air; and

(iii) A single package and an array of packages are demonstrated to be subcritical in accordance with this part, except that the damaged condition of the package must be considered to be that which results from the plutonium accident tests in § 71.74, rather than the hypothetical accident tests in § 71.73; and

(2) Section 71.74(c), there would be no detectable leakage of water into the containment vessel of the package.

(b) With respect to the package requirements of paragraph (a), there must be a demonstration or analytical assessment showing that --

(1) The results of the physical testing for package qualification would not be adversely affected to a significant extent by --

(i) The presence, during the tests, of the actual contents that will be transported in the package; and

(ii) Ambient water temperatures ranging from 0.6°C (+33°F) to 38°C (+100°F) for those qualification tests involving water, and ambient atmospheric temperatures ranging from -40°C (-40°F) to +54°C (+130°F) for the other qualification tests.

(2) The ability of the package to meet the acceptance standards prescribed for the accident condition sequential tests would not be adversely affected if one or more tests in the sequence were deleted.

§ 71.65 Additional requirements.

The Commission may, by rule, regulation, or order, impose requirements on any licensee, in addition to those established in this part, as it deems necessary or appropriate to protect public health or to minimize danger to life or property.

Subpart F--Package, Special Form, and LSA-III Tests[2]

§ 71.70 Incorporations by reference.

(a) The materials listed in this section are incorporated by reference in the corresponding sections noted and made a part of the regulations in part 71. These incorporations by reference were approved by the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they exist on the date of the approval. A notice of any changes made to the material incorporated by reference will be published in the Federal Register, and the material must be available to the public. The materials can be examined, by appointment, at the NRC's Technical Library, which is located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852; telephone: 301–415–7000; email: *Library.Resource@nrc.gov*. The materials are also available from the sources listed below. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 1–202–741–6030 or go to *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(b) International Organization for Standardization, ISO Central Secretariat, Chemin de Blandonnet 8 CP 401, 1214 Vernier, Geneva, Switzerland; email: *central@iso.org*; phone: +41 22 749 01 11; Web site: *http://www.iso.org*.

(1) ISO 9978:1992(E), "Radiation protection—Sealed radioactive sources—Leakage test methods," First Edition (February 15, 1992), incorporation by reference approved for § 71.75(a), is available for purchase from the American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, 212–642–4900, *http://www.ansi.org, or info@ansi.org*.

(2) ISO 2919:1999(E), "Radiation protection—Sealed radioactive sources—General requirements and classification," Second Edition (February 15, 1999), incorporation by reference approved for § 71.75(d), is available on *http://www.amazon.com*.

[80 FR 34013, Jun. 12, 2015; 80 FR 48684, Aug. 14, 2015]

§ 71.71 Normal conditions of transport.

(a) *Evaluation*. Evaluation of each package design under normal conditions of transport must include a determination of the effect on that design of the conditions and tests specified in this section. Separate specimens may be used for the free drop test, the compression test, and the penetration test, if each specimen is subjected to the water spray test before being subjected to any of the other tests.

(b) *Initial conditions*. With respect to the initial conditions for the tests in this section, the demonstration of compliance with the requirements of this part must be based on the ambient temperature preceding and following the tests remaining constant at that value between -29°C (-20°F) and +38°C (+100°F) which is most unfavorable for the feature under consideration. The initial internal pressure within the containment system must be considered to be the maximum normal operating pressure, unless a lower internal pressure consistent with the ambient

temperature considered to precede and follow the tests is more unfavorable.

(c) *Conditions and tests*.

(1) *Heat.* An ambient temperature of 38°C (100°F) in still air, and insolation according to the following table:

INSOLATION DATA

Form and location of surface	Total insolation for a 12-hour period (g cal/cm^2)
Flat surfaces transported horizontally;	
Base	None
Other surfaces	800
Flat surfaces not transported horizontally	200
Curved surfaces	400

(2) *Cold*. An ambient temperature of -40°C (-40°F) in still air and shade.

(3) *Reduced external pressure*. An external pressure of 25 kPa (3.5 lbf/in^2) absolute.

(4) *Increased external pressure*. An external pressure of 140 kPa (20 lbf/in^2) absolute.

(5) *Vibration*. Vibration normally incident to transport.

(6) *Water spray*. A water spray that simulates exposure to rainfall of approximately 5 cm/h (2 in/h) for at least 1 hour.

(7) *Free drop*. Between 1.5 and 2.5 hours after the conclusion of the water spray test, a free drop through the distance specified below onto a flat, essentially unyielding, horizontal surface, striking the surface in a position for which maximum damage is expected.

Criteria for Free Drop Test (Weight/Distance)

Package weight		Free drop distance	
Kilograms	**(Pounds)**	**Meters**	**(Feet)**
Less than 5,000	(Less than 11,000)	1.2	(4)
5,000 to 10,000	(11,000 to 22,000)	0.9	(3)
10,000 to 15,000	(22,000 to 33,100)	0.6	(2)
More than 15,000	(More than 33,100)	0.3	(1)

(8) *Corner drop*. A free drop onto each corner of the package in succession, or in the case of a

cylindrical package onto each quarter of each rim, from a height of 0.3 m (1 ft) onto a flat, essentially unyielding, horizontal surface. This test applies only to fiberboard, wood, or fissile material rectangular packages not exceeding 50 kg (110 lbs) and fiberboard, wood, or fissile material cylindrical packages not exceeding 100 kg (220 lbs).

(9) *Compression*. For packages weighing up to 5000 kg (11,000 lbs), the package must be subjected, for a period of 24 hours, to a compressive load applied uniformly to the top and bottom of the package in the position in which the package would normally be transported. The compressive load must be the greater of the following:

(i) The equivalent of 5 times the weight of the package; or

(ii) The equivalent of 13 kPa (2 lbf/in^2) multiplied by the vertically projected area of the package.

(10) *Penetration*. Impact of the hemispherical end of a vertical steel cylinder of 3.2 cm (1.25 in) diameter and 6 kg (13 lbs) mass, dropped from a height of 1 m (40 in) onto the exposed surface of the package that is expected to be most vulnerable to puncture. The long axis of the cylinder must be perpendicular to the package surface.

[2] The package standards related to the tests in this subpart are contained in subpart E of this part.

[81 FR 86910, Dec. 2, 2016]

§ 71.73 Hypothetical accident conditions.

(a) *Test procedures*. Evaluation for hypothetical accident conditions is to be based on sequential application of the tests specified in this section, in the order indicated, to determine their cumulative effect on a package or array of packages. An undamaged specimen may be used for the water immersion tests specified in paragraph (c)(6) of this section.

(b) *Test conditions*. With respect to the initial conditions for the tests, except for the water immersion tests, to demonstrate compliance with the requirements of this part during testing, the ambient air temperature before and after the tests must remain constant at that value between -29°C (-20°F) and +38°C (+100°F) which is most unfavorable for the feature under consideration. The initial internal pressure within the containment system must be the maximum normal operating pressure, unless a lower internal pressure, consistent with the ambient temperature assumed to precede and follow the tests, is more unfavorable.

(c) *Tests*. Tests for hypothetical accident conditions must be conducted as follows:

(1) *Free Drop*. A free drop of the specimen through a distance of 9 m (30 ft) onto a flat, essentially unyielding, horizontal surface, striking the surface in a position for which maximum damage is expected.

(2) *Crush*. Subjection of the specimen to a dynamic crush test by positioning the specimen on a

flat, essentially unyielding horizontal surface so as to suffer maximum damage by the drop of a 500-kg (1100-lb) mass from 9 m (30 ft) onto the specimen. The mass must consist of a solid mild steel plate 1 m (40 in) by 1 m (40 in) and must fall in a horizontal attitude. The crush test is required only when the specimen has a mass not greater than 500 kg (1100 lb), an overall density not greater than 1000 kg/m^3 (62.4 lb/ft^3) based on external dimension, and radioactive contents greater than 1000 A_2 not as special form radioactive material. For packages containing fissile material, the radioactive contents greater than 1000 A_2 criterion does not apply.

(3) *Puncture*. A free drop of the specimen through a distance of 1 m (40 in) in a position for which maximum damage is expected, onto the upper end of a solid, vertical, cylindrical, mild steel bar mounted on an essentially unyielding, horizontal surface. The bar must be 15 cm (6 in) in diameter, with the top horizontal and its edge rounded to a radius of not more than 6 mm (0.25 in), and of a length as to cause maximum damage to the package, but not less than 20 cm (8 in) long. The long axis of the bar must be vertical.

(4) *Thermal*. Exposure of the specimen fully engulfed, except for a simple support system, in a hydrocarbon fuel/air fire of sufficient extent, and in sufficiently quiescent ambient conditions, to provide an average emissivity coefficient of at least 0.9, with an average flame temperature of at least 800°C (1475°F) for a period of 30 minutes, or any other thermal test that provides the equivalent total heat input to the package and which provides a time averaged environmental temperature of 800°C. The fuel source must extend horizontally at least 1 m (40 in), but may not extend more than 3 m (10 ft), beyond any external surface of the specimen, and the specimen must be positioned 1 m (40 in) above the surface of the fuel source. For purposes of calculation, the surface absorptivity coefficient must be either that value which the package may be expected to possess if exposed to the fire specified or 0.8, whichever is greater; and the convective coefficient must be that value which may be demonstrated to exist if the package were exposed to the fire specified. Artificial cooling may not be applied after cessation of external heat input, and any combustion of materials of construction, must be allowed to proceed until it terminates naturally.

(5) *Immersion--fissile material*. For fissile material subject to § 71.55, in those cases where water inleakage has not been assumed for criticality analysis, immersion under a head of water of at least 0.9 m (3 ft) in the attitude for which maximum leakage is expected.

(6) *Immersion--all packages*. A separate, undamaged specimen must be subjected to water pressure equivalent to immersion under a head of water of at least 15 m (50 ft). For test purposes, an external pressure of water of 150 kPa (21.7 lbf/in^2) gauge is considered to meet these conditions.

[69 FR 3795, Jan. 26, 2004]

§ 71.74 Accident conditions for air transport of plutonium.

(a) *Test conditions--Sequence of tests*. A package must be physically tested to the following conditions in the order indicated to determine their cumulative effect.

(1) Impact at a velocity of not less than 129 m/sec (422 ft/sec) at a right angle onto a flat, essentially unyielding, horizontal surface, in the orientation (e.g., side, end, corner) expected to result in maximum damage at the conclusion of the test sequence.

(2) A static compressive load of 31,800 kg (70,000 lbs) applied in the orientation expected to result in maximum damage at the conclusion of the test sequence. The force on the package must be developed between a flat steel surface and a 5 cm (2 in) wide, straight, solid, steel bar. The length of the bar must be at least as long as the diameter of the package, and the longitudinal axis of the bar must be parallel to the plane of the flat surface. The load must be applied to the bar in a manner that prevents any members or devices used to support the bar from contacting the package.

(3) Packages weighing less than 227 kg (500 lbs) must be placed on a flat, essentially unyielding, horizontal surface, and subjected to a weight of 227 kg (500 lbs) falling from a height of 3 m (10 ft) and striking in the position expected to result in maximum damage at the conclusion of the test sequence. The end of the weight contacting the package must be a solid probe made of mild steel. The probe must be the shape of the frustum of a right circular cone, 30 cm (12 in) long, 20 cm (8 in) in diameter at the base, and 2.5 cm (1 in) in diameter at the end. The longitudinal axis of the probe must be perpendicular to the horizontal surface. For packages weighing 227 kg (500 lbs) or more, the base of the probe must be placed on a flat, essentially unyielding horizontal surface, and the package dropped from a height of 3 m (10 ft) onto the probe, striking in the position expected to result in maximum damage at the conclusion of the test sequence.

(4) The package must be firmly restrained and supported such that its longitudinal axis is inclined approximately 45° to the horizontal. The area of the package that made first contact with the impact surface in paragraph (a)(1) of this section must be in the lowermost position. The package must be struck at approximately the center of its vertical projection by the end of a structural steel angle section falling from a height of at least 46 m (150 ft). The angle section must be at least 1.8 m (6 ft) in length with equal legs at least 13 cm (5 in) long and 1.3 cm (0.5 in) thick. The angle section must be guided in such a way as to fall end-on, without tumbling. The package must be rotated approximately 90° about its longitudinal axis and struck by the steel angle section falling as before.

(5) The package must be exposed to luminous flames from a pool fire of JP-4 or JP-5 aviation fuel for a period of at least 60 minutes. The luminous flames must extend an average of at least 0.9 m (3 ft) and no more than 3 m (10 ft) beyond the package in all horizontal directions. The position and orientation of the package in relation to the fuel must be that which is expected to result in maximum damage at the conclusion of the test sequence. An alternate method of thermal testing may be substituted for this fire test, provided that the alternate test is not of shorter duration and would not result in a lower heating rate to the package. At the conclusion of the thermal test, the package must be allowed to cool naturally or must be cooled by water sprinkling, whichever is expected to result in maximum damage at the conclusion of the test sequence.

(6) Immersion under at least 0.9 m (3 ft) of water.

(b) *Individual free-fall impact test*.

(1) An undamaged package must be physically subjected to an impact at a velocity not less than the calculated terminal free-fall velocity, at mean sea level, at a right angle onto a flat, essentially unyielding, horizontal surface, in the orientation (e.g., side, end, corner) expected to result in maximum damage.

(2) This test is not required if the calculated terminal free-fall velocity of the package is less than 129 m/sec (422 ft/sec), or if a velocity not less than either 129 m/sec (422 ft/sec) or the calculated terminal free-fall velocity of the package is used in the sequential test of paragraph (a)(1) of this section.

(c) Individual deep submersion test. An undamaged package must be physically submerged and physically subjected to an external water pressure of at least 4 MPa (600 lbs/in^2).

§ 71.75 Qualification of special form radioactive material.

(a) Special form radioactive materials must meet the test requirements of paragraph (b) of this section. Each solid radioactive material or capsule specimen to be tested must be manufactured or fabricated so that it is representative of the actual solid material or capsule that will be transported, with the proposed radioactive content duplicated as closely as practicable. Any differences between the material to be transported and the test material, such as the use of non-radioactive contents, must be taken into account in determining whether the test requirements have been met. In addition:

(1) A different specimen may be used for each of the tests;

(2) The specimen may not break or shatter when subjected to the impact, percussion, or bending tests;

(3) The specimen may not melt or disperse when subjected to the heat test;

(4) After each test, leaktightness or indispersibility of the specimen must be determined by a method no less sensitive than the leaching assessment procedure prescribed in paragraph (c) of this section. For a capsule resistant to corrosion by water, and which has an internal void volume greater than 0.1 milliliter, an alternative to the leaching assessment is a demonstration of leaktightness of x10^{-4} torr-liter/s (1.3xx10^{-4} atm-cm^3/s) based on air at 25°C (77°F) and one atmosphere differential pressure for solid radioactive content, or x10^{-6} torr-liter/s (1.30xx10^{-6} atm-cm^3/s) for liquid or gaseous radioactive content; and

(5) A specimen that comprises or simulates radioactive material contained in a sealed capsule need not be subjected to the leaktightness procedure specified in this section, provided it is alternatively subjected to any of the tests prescribed in ISO/TR4826-1979(E), "Sealed radioactive sources leak test methods" which is available from the American National Standards Institute, 1430 Broadway, New York, N.Y. 10018.

(b) *Test methods*. (1) *Impact Test*. The specimen must fall onto the target from a height of 9 m (30 ft) or greater in the orientation expected to result in maximum damage. The target must be a flat, horizontal surface of such mass and rigidity that any increase in its resistance to displacement or deformation, on impact by the specimen, would not significantly increase the damage to the specimen.

(2) *Percussion Test*. (i) The specimen must be placed on a sheet of lead that is supported by a smooth solid surface, and struck by the flat face of a steel billet so as to produce an impact equivalent to that resulting from a free drop of 1.4 kg (3 lbs) through 1 m (40 in);

(ii) The flat face of the billet must be 25 millimeters (mm) (1 inch) in diameter with the edges rounded off to a radius of 3 mm±0.3 mm(.12 in±0.012 in);

(iii) The lead must be hardness number 3.5 to 4.5 on the Vickers scale and thickness 25 mm (1 in) or greater, and must cover an area greater than that covered by the specimen;

(iv) A fresh surface of lead must be used for each impact; and

(v) The billet must strike the specimen so as to cause maximum damage.

(3) *Bending test*. (i) This test applies only to long, slender sources with a length of 10 cm (4 inches) or greater and a length to width ratio of 10 or greater;

(ii) The specimen must be rigidly clamped in a horizontal position so that one half of its length protrudes from the face of the clamp;

(iii) The orientation of the specimen must be such that the specimen will suffer maximum damage when its free end is struck by the flat face of a steel billet;

(iv) The billet must strike the specimen so as to produce an impact equivalent to that resulting from a free vertical drop of 1.4 kg (3 lbs) through 1 m (40 in); and

(v) The flat face of the billet must be 25 mm (1 inch) in diameter with the edges rounded off to a radius of 3 mm±0.3 mm (.12 in±0.012 in).

(4) *Heat test*. The specimen must be heated in air to a temperature of not less than 800°C (1475°F), held at that temperature for a period of 10 minutes, and then allowed to cool.

(c) *Leaching assessment methods*. (1) For indispersible solid material --

(i) The specimen must be immersed for 7 days in water at ambient temperature. The water must have a pH of 6-8 and a maximum conductivity of 10 micromho per centimeter at 20° (68°F);

(ii) The water with specimen must then be heated to a temperature of 50°C±5°C (122°F±9°F) and maintained at this temperature for 4 hours.

(iii) The activity of the water must then be determined;

(iv) The specimen must then be stored for at least 7 days in still air of relative humidity not less than 90 percent at 30°C (86°F);

(v) The specimen must then be immersed in water under the same conditions as in paragraph (c)(1)(i) of this section, and the water with specimen must be heated to 50°C±5°C (122°F±9°F) and maintained at that temperature for 4 hours;

(vi) The activity of the water must then be determined. The sum of the activities determined here and in paragraph (c)(1)(iii) of this section must not exceed 2 kilobecquerels (kBq) (0.05 microcurie (μCi)).

(2) For encapsulated material --

(i) The specimen must be immersed in water at ambient temperature. The water must have a pH of 6-8 and a maximum conductivity of 10 micromho per centimeter;

(ii) The water and specimen must be heated to a temperature of 50°C±5°C (122°F±9°F) and maintained at this temperature for 4 hours;

(iii) The activity of the water must then be determined;

(iv) The specimen must then be stored for at least 7 days in still air at a temperature of 30°C (86°F) or greater;

(v) The process in paragraph (c)(2)(i), (ii), and (iii) of this section must be repeated; and

(vi) The activity of the water must then be determined. The sum of the activities determined here and in paragraph (c)(2)(iii) of this section must not exceed 2 kilobecquerels (kBq) (0.05 microcurie (Ci)).

(d) A specimen that comprises or simulates radioactive material contained in a sealed capsule need not be subjected to --

(1) The impact test and the percussion test of this section, provided that the specimen is alternatively subjected to the Class 4 impact test prescribed in ISO 2919-1980(e), "Sealed Radioactive Sources Classification" (see § 71.75(a)(5) for statement of availability); and

(2) The heat test of this section, provided the specimen is alternatively subjected to the Class 6 temperature test specified in the International Organization for Standardization document ISO 2919-1980(e), "Sealed Radioactive Sources Classification."

[80 FR 34013, Jun. 12, 2015]

§ 71.77 Qualification of LSA-III Material

(a) LSA-III material must meet the test requirements of paragraph (b) of this section. Any differences between the specimen to be tested and the material to be transported must be taken into account in determining whether the test requirements have been met.

(b) *Leaching Test*. (1) The specimen, representing no less than the entire contents of the package, must be immersed for 7 days in water at ambient temperature;

(2) The volume of water to be used in the test must be sufficient to ensure that at the end of the test period the free volume of the unabsorbed and unreacted water remaining will be at least 10% of the volume of the specimen itself;

(3) The water must have an initial pH of 6-8 and a maximum conductivity 10 micromho/cm at 20°C (68°F); and

(4) The total activity of the free volume of water must be measured following the 7 day immersion test and must not exceed 0.1 A_2.

Subpart G--Operating Controls and Procedures

§ 71.81 Applicability of operating controls and procedures.

A licensee subject to this part, who, under a general or specific license, transports licensed material or delivers licensed material to a carrier for transport, shall comply with the requirements of this subpart G, with the quality assurance requirements of subpart H of this part, and with the general provisions of subpart A of this part.

§ 71.83 Assumptions as to unknown properties.

When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

§ 71.85 Preliminary determinations.

Before the first use of any packaging for the shipment of licensed material --

(a) The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging;

(b) Where the maximum normal operating pressure will exceed 35 kPa (5 lbf/in^2) gauge, the licensee shall test the containment system at an internal pressure at least 50 percent higher than the maximum normal operating pressure, to verify the capability of that system to maintain its structural integrity at that pressure; and

(c) The licensee shall conspicuously and durably mark the packaging with its model number,

serial number, gross weight, and a package identification number assigned by NRC. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the Commission.

(d) The licensee shall ascertain that the determinations in paragraphs (a) through (c) of this section have been made.

[80 FR 34013, Jun. 12, 2015]

§ 71.87 Routine determinations.

Before each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this part and of the license. The licensee shall determine that --

(a) The package is proper for the contents to be shipped;

(b) The package is in unimpaired physical condition except for superficial defects such as marks or dents;

(c) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

(d) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(e) Any pressure relief device is operable and set in accordance with written procedures;

(f) The package has been loaded and closed in accordance with written procedures;

(g) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

(h) Any structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose, unless it satisfies the design requirements of § 71.45;

(i) The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable, and within the limits specified in DOT regulations in 49 CFR 173.443;

(j) External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in § 71.47 at any time during transportation; and

(k) Accessible package surface temperatures will not exceed the limits specified in § 71.43(g) at any time during transportation.

§ 71.88 Air transport of plutonium.

(a) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this part or included indirectly by citation of 49 CFR chapter I, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air or delivered to a carrier for air transport unless:

(1) The plutonium is contained in a medical device designed for individual human application; or

(2) The plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in Appendix A, Table A-2, of this part, and in which the radioactivity is essentially uniformly distributed; or

(3) The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form, and is shipped in accordance with § 71.5; or

(4) The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the Commission.

(b) Nothing in paragraph (a) of this section is to be interpreted as removing or diminishing the requirements of § 73.24 of this chapter.

(c) For a shipment of plutonium by air which is subject to paragraph (a)(4) of this section, the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.

[69 FR 3795, Jan. 26, 2004]

§ 71.89 Opening instructions.

Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with 10 CFR 20.1906(e).

§ 71.91 Records.

(a) Each licensee shall maintain, for a period of 3 years after shipment, a record of each shipment of licensed material not exempt under § 71.14, showing where applicable --

(1) Identification of the packaging by model number and serial number;

(2) Verification that there are no significant defects in the packaging, as shipped;

(3) Volume and identification of coolant;

(4) Type and quantity of licensed material in each package, and the total quantity of each shipment;

(5) For each item of irradiated fissile material --

(i) Identification by model number and serial number;

(ii) Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and

(iii) Any abnormal or unusual condition relevant to radiation safety;

(6) Date of the shipment;

(7) For fissile packages and for Type B packages, any special controls exercised;

(8) Name and address of the transferee;

(9) Address to which the shipment was made; and

(10) Results of the determinations required by § 71.87 and by the conditions of the package approval.

(b) Each certificate holder shall maintain, for a period of 3 years after the life of the packaging to which they apply, records identifying the packaging by model number, serial number, and date of manufacture.

(c) The licensee, certificate holder, and an applicant for a CoC, shall make available to the Commission for inspection, upon reasonable notice, all records required by this part. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

(d) The licensee, certificate holder, and an applicant for a CoC shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by § 71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. These records must be retained for 3 years after the life of the packaging to which they apply.

[69 FR 3796, Jan. 26, 2004; 80 FR 34013, Jun. 12, 2015]

§ 71.93 Inspection and tests.

(a) The licensee, certificate holder, and applicant for a CoC shall permit the Commission, at all

reasonable times, to inspect the licensed material, packaging, premises, and facilities in which the licensed material or packaging is used, provided, constructed, fabricated, tested, stored, or shipped.

(b) The licensee, certificate holder, and applicant for a CoC shall perform, and permit the Commission to perform, any tests the Commission deems necessary or appropriate for the administration of the regulations in this chapter.

(c) The certificate holder and applicant for a CoC shall notify the NRC, in accordance with § 71.1, 45 days in advance of starting fabrication of the first packaging under a CoC. This paragraph applies to any packaging used for the shipment of licensed material which has either--

(1) A decay heat load in excess of 5 kW; or

(2) A maximum normal operating pressure in excess of 103 kPa (15 lbf/in^2) gauge.

[69 FR 3796, Jan. 26, 2004]

§ 71.95 Reports.

(a) The licensee, after requesting the certificate holder's input, shall submit a written report to the Commission of--

(1) Instances in which there is a significant reduction in the effectiveness of any NRC-approved Type B or Type AF packaging during use; or

(2) Details of any defects with safety significance in any NRC-approved Type B or fissile material packaging, after first use.

(3) Instances in which the conditions of approval in the Certificate of Compliance were not observed in making a shipment.

(b) The licensee shall submit a written report to the Commission of instances in which the conditions in the certificate of compliance were not followed during a shipment.

(c) Each licensee shall submit, in accordance with § 71.1, a written report required by paragraph (a) or (b) of this section within 60 days of the event or discovery of the event. The licensee shall also provide a copy of each report submitted to the NRC to the applicable certificate holder. Written reports prepared under other regulations may be submitted to fulfill this requirement if the reports contain all the necessary information, and the appropriate distribution is made. Using an appropriate method listed in § 71.1(a), the licensee shall report to: ATTN: Document Control Desk, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards. These written reports must include the following:

(1) A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned

to prevent recurrence.

(2) A clear, specific, narrative description of the event that occurred so that knowledgeable readers conversant with the requirements of part 71, but not familiar with the design of the packaging, can understand the complete event. The narrative description must include the following specific information as appropriate for the particular event.

(i) Status of components or systems that were inoperable at the start of the event and that contributed to the event;

(ii) Dates and approximate times of occurrences;

(iii) The cause of each component or system failure or personnel error, if known;

(iv) The failure mode, mechanism, and effect of each failed component, if known;

(v) A list of systems or secondary functions that were also affected for failures of components with multiple functions;

(vi) The method of discovery of each component or system failure or procedural error;

(vii) For each human performance-related root cause, a discussion of the cause(s) and circumstances;

(viii) The manufacturer and model number (or other identification) of each component that failed during the event; and

(ix) For events occurring during use of a packaging, the quantities and chemical and physical form(s) of the package contents.

(3) An assessment of the safety consequences and implications of the event. This assessment must include the availability of other systems or components that could have performed the same function as the components and systems that failed during the event.

(4) A description of any corrective actions planned as a result of the event, including the means employed to repair any defects, and actions taken to reduce the probability of similar events occurring in the future.

(5) Reference to any previous similar events involving the same packaging that are known to the licensee or certificate holder.

(6) The name and telephone number of a person within the licensee's organization who is knowledgeable about the event and can provide additional information.

(7) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(d) Report legibility. The reports submitted by licensees and/or certificate holders under this section must be of sufficient quality to permit reproduction and micrographic processing.

[60 FR 50264, Sept. 28, 1995, as amended at 67 FR 3585, Jan. 25, 2002; 68 FR 58818, Oct. 10, 2003; 69 FR 3796, Jan. 26, 2004; 75 FR 73945, Nov. 30, 2010; 79 FR 75741, Dec. 19, 2014; 84 FR 65639, Nov. 29, 2019; 84 FR 66561, Dec. 5, 2019]

§ 71.97 Advance notification of shipment of irradiated reactor fuel and nuclear waste.

(a)(1) As specified in paragraphs (b), (c) and (d) of this section, each licensee shall provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material, within or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(2) As specified in paragraphs (b), (c), and (d) of this section, after June 11, 2013, each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in paragraph (c)(3)(iii) of this section, or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, of delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(b) Advance notification is also required under this section for the shipment of licensed material, other than irradiated fuel, meeting the following three conditions:

(1) The licensed material is required by this part to be in Type B packaging for transportation;

(2) The licensed material is being transported to or across a State boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

(3) The quantity of licensed material in a single package exceeds the least of the following:

(i) 3000 times the A_1 value of the radionuclides as specified in appendix A, Table A-1 for special form radioactive material;

(ii) 3000 times the A_2 value of the radionuclides as specified in appendix A, Table A-1 for normal form radioactive material; or

(iii) 1000 TBq (27,000 Ci).

(c) *Procedures for submitting advance notification.*

(1) The notification must be made in writing to:

(i) The office of each appropriate governor or governor's designee;

(ii) The office of each appropriate Tribal official of Tribal official's designee; and

(iii) The Director, Office of Nuclear Security and Incident Response.

(2) A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(3) A notification delivered by any other means than mail must reach the office of the governor or of the governor's designee or the Tribal official or Tribal official's designee at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(i) ~~A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306).~~Reserved.

(ii) Contact information for each State, including telephone and mailing addresses of governors and governors' designees, and participating Tribes, including telephone and mailing addresses of Tribal officials and Tribal official's designees, is available on the NRC Web site at: https://scp.nrc.gov/special/designee.pdf.

(iii) A list of the names and mailing addresses of the governors' designees and Tribal official's designees of participating Tribes is available on request from the Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(4) The licensee shall retain a copy of the notification as a record for 3 years.

(d) *Information to be furnished in advance notification of shipment*. Each advance notification of shipment of irradiated reactor fuel or nuclear waste must contain the following information:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;

(2) A description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in the regulations of DOT in 49 CFR 172.202 and 172.203(d);

(3) The point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;

(4) The 7-day period during which arrival of the shipment at State boundaries or Tribal reservation boundaries is estimated to occur;

(5) The destination of the shipment, and the 7-day period during which arrival of the shipment is estimated to occur; and

(6) A point of contact, with a telephone number, for current shipment information.

(e) *Revision notice*. A licensee who finds that schedule information previously furnished to a governor or governor's designee or a Tribal official of Tribal official's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor's designee or the Tribal official or the Tribal official's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for 3 years.

(f) *Cancellation notice*. (1) Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, and to the Director, Office of Nuclear Security and Incident Response.

(2) The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for 3 years.

[60 FR 50264, Sept. 28, 1995, as amended at 67 FR 3586, Jan. 25, 2002; 68 FR 58818, Oct. 10, 2003; 74 FR 62683, Dec. 1, 2009; 75 FR 73945, Nov. 30, 2010; 77 FR 34204, Jun. 11, 2012; 78 FR 17021, Mar. 19, 2013; 79 FR 75741, Dec. 19, 2014; 80 FR 74981, Dec. 1, 2015; 83 FR 30285, Jun. 28, 2018; 83 FR 57231, Nov. 21, 2018]

§ 71.99 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of --

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or (3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of --

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section; or

(iv) Any term , condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

§ 71.100 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 71 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 71 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 71.0, 71.2, 71.4, 71.6, 71.7, 71.10, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.40, 71.41, 71.43, 71.45, 71.47, 71.51, 71.55, 71.59, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99, and 71.100.

[69 FR 3796, Jan. 26, 2004]

Subpart H--Quality Assurance

Source: 69 FR 3797, Jan. 26, 2004, unless otherwise noted.

§ 71.101 Quality assurance requirements.

(a) *Purpose.* This subpart describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this subpart, “quality assurance” comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each certificate holder and applicant for a package approval is responsible for satisfying the quality assurance requirements that apply to design, fabrication, testing, and modification of packaging subject to this subpart. Each licensee is responsible for satisfying the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to this subpart.

(b) *Establishment of program.* Each licensee, certificate holder, and applicant for a CoC shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of §§ 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee, certificate holder, and applicant for a CoC shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

(c) *Approval of program.* (1) Before the use of any package for the shipment of licensed material subject to this subpart, each licensee shall obtain Commission approval of its quality assurance program. Using an appropriate method listed in § 71.1(a), each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, by submitting the description to: ATTN: Document Control Desk, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards.

(2) Before the fabrication, testing, or modification of any package for the shipment of licensed material subject to this subpart, each licensee, certificate holder, or applicant for a CoC shall obtain Commission approval of its quality assurance program. Each certificate holder or applicant for a CoC shall, in accordance with § 71.1, file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied.

(d) *Existing package designs.* The provisions of this paragraph deal with packages that have been approved for use in accordance with this part before January 1, 1979, and which have been designed in accordance with the provisions of this part in effect at the time of application for package approval. Those packages will be accepted as having been designed in accordance with a quality assurance program that satisfies the provisions of paragraph (b) of this section.

(e) *Existing packages.* The provisions of this paragraph deal with packages that have been approved for use in accordance with this part before January 1, 1979, have been at least partially fabricated before that date, and for which the fabrication is in accordance with the provisions of this part in effect at the time of application for approval of package design. These packages will be accepted as having been fabricated and assembled in accordance with a quality assurance program that satisfies the provisions of paragraph (b) of this section.

(f) *Previously approved programs.* A Commission-approved quality assurance program that satisfies the applicable criteria of subpart H of this part, Appendix B of part 50 of this chapter, or subpart G of part 72 of this chapter, and that is established, maintained, and executed regarding transport packages, will be accepted as satisfying the requirements of paragraph (b) of this section. Before first use, the licensee, certificate holder, and applicant for a CoC shall notify the NRC, in accordance with § 71.1, of its intent to apply its previously approved subpart H, Appendix B, or subpart G quality assurance program to transportation activities. The licensee, certificate holder, and applicant for a CoC shall identify the program by date of submittal to the Commission, Docket Number, and date of Commission approval.

(g) *Radiography containers.* A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of § 34.31(b) of this chapter or equivalent Agreement State requirement, is deemed to satisfy the requirements of §§ 71.17(b) and 71.101(b).

[75 FR 73945, Nov. 30, 2010; 79 FR 75741, Dec. 19, 2014; 80 FR 34013, Jun. 12, 2015; 84 FR 65639, Nov. 29, 2019; 84 FR 66561, Dec. 5, 2019]

§ 71.103 Quality assurance organization.

(a) The licensee,[2] certificate holder, and applicant for a Certificate of Compliance shall be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a Certificate of Compliance may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(b) The quality assurance functions are--

(1) Assuring that an appropriate quality assurance program is established and effectively executed; and

(2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.

(c) The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to--

(1) Identify quality problems;

(2) Initiate, recommend, or provide solutions; and

(3) Verify implementation of solutions.

(d) The persons and organizations performing quality assurance functions shall report to a management level that assures that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided.

(e) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.

(f) Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.

[2] While the term "licensee" is used in these criteria, the requirements are applicable to whatever design, fabrication, assembly, and testing of the package is accomplished with respect to a package before the time a package approval is issued.

[80 FR 34014, Jun. 12, 2015]

§ 71.105 Quality assurance program.

(a) The licensee, certificate holder, and applicant for a CoC shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of §§ 71.101 through 71.137. The licensee, certificate holder, and applicant for a CoC shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee, certificate holder, and applicant for a CoC shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(b) The licensee, certificate holder, and applicant for a CoC, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee, certificate holder, and applicant for a CoC shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee, certificate holder, and applicant for a CoC shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

(c) The licensee, certificate holder, and applicant for a CoC shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

(1) The impact of malfunction or failure of the item to safety;

(2) The design and fabrication complexity or uniqueness of the item;

(3) The need for special controls and surveillance over processes and equipment;

(4) The degree to which functional compliance can be demonstrated by inspection or test; and

(5) The quality history and degree of standardization of the item.

(d) The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are

executing.

§ 71.106 Changes to quality assurance program.

(a) Each quality assurance program approval holder shall submit, in accordance with § 71.1(a), a description of a proposed change to its NRC-approved quality assurance program that will reduce commitments in the program description as approved by the NRC. The quality assurance program approval holder shall not implement the change before receiving NRC approval.

(1) The description of a proposed change to the NRC-approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of subpart H of this part.

(2) [Reserved]

(b) Each quality assurance program approval holder may change a previously approved quality assurance program without prior NRC approval, if the change does not reduce the commitments in the quality assurance program previously approved by the NRC. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the NRC every 24 months, in accordance with § 71.1(a). In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:

(1) The use of a quality assurance standard approved by the NRC that is more recent than the quality assurance standard in the certificate holder's or applicant's current quality assurance program at the time of the change;

(2) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting responsibilities;

(3) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities;

(4) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality assurance program approval holder has committed to on record; and

(5) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(c) Each quality assurance program approval holder shall maintain records of quality assurance program changes.

[80 FR 34014, Jun. 12, 2015]

§ 71.107 Package design control.

(a) The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that applicable regulatory requirements and the package design, as specified in the license or CoC for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the materials, parts, and components of the packaging that are important to safety.

(b) The licensee, certificate holder, and applicant for a CoC shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures, among participating design organizations, for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design, by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee, certificate holder, and applicant for a CoC shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee, certificate holder, and applicant for a CoC shall apply design control measures to the following:

(1) Criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses;

(2) Compatibility of materials;

(3) Accessibility for inservice inspection, maintenance, and repair;

(4) Features to facilitate decontamination; and

(5) Delineation of acceptance criteria for inspections and tests.

(c) The licensee, certificate holder, and applicant for a CoC shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the CoC require prior NRC approval.

§ 71.109 Procurement document control.

The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that adequate quality is required in the documents for procurement of material, equipment, and services, whether purchased by the licensee, certificate holder, and applicant for a CoC or by its contractors or subcontractors. To the extent necessary, the licensee, certificate holder, and applicant for a CoC shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this part.

§ 71.111 Instructions, procedures, and drawings.

The licensee, certificate holder, and applicant for a CoC shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

§ 71.113 Document control.

The licensee, certificate holder, and applicant for a CoC shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes, that prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed.

§ 71.115 Control of purchased material, equipment, and services.

(a) The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products on delivery.

(b) The licensee, certificate holder, and applicant for a CoC shall have available documentary evidence that material and equipment conform to the procurement specifications before installation or use of the material and equipment. The licensee, certificate holder, and applicant for a CoC shall retain, or have available, this documentary evidence for the life of the package to which it applies. The licensee, certificate holder, and applicant for a CoC shall assure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment.

(c) The licensee, certificate holder, and applicant for a CoC shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services.

§ 71.117 Identification and control of materials, parts, and components.

The licensee, certificate holder, and applicant for a CoC shall establish measures for the identification and control of materials, parts, and components. These measures must assure that identification of the item is maintained by heat number, part number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective materials, parts, and components.

§ 71.119 Control of special processes.

The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that special processes, including welding, heat treating, and nondestructive testing are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

§ 71.121 Internal inspection.

The licensee, certificate holder, and applicant for a CoC shall establish and execute a program for inspection of activities affecting quality by or for the organization performing the activity, to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The inspection must be performed by individuals other than those who performed the activity being inspected. Examination, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If direct inspection of processed material or products is not carried out, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when quality control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the licensee's designated representative and beyond which work should not proceed without the consent of its designated representative, are required, the specific hold points must be indicated in appropriate documents.

§ 71.123 Test control.

The licensee, certificate holder, and applicant for a CoC shall establish a test program to assure that all testing required to demonstrate that the packaging components will perform satisfactorily in service is identified and performed in accordance with written test procedures that incorporate the requirements of this part and the requirements and acceptance limits contained in the package approval. The test procedures must include provisions for assuring that all prerequisites for the given test are met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. The licensee, certificate holder, and applicant for a CoC shall document and evaluate the test results to assure that test requirements have been satisfied.

§ 71.125 Control of measuring and test equipment.

The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting

quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy within necessary limits.

§ 71.127 Handling, storage, and shipping control.

The licensee, certificate holder, and applicant for a CoC shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.

§ 71.129 Inspection, test, and operating status.

(a) The licensee, certificate holder, and applicant for a CoC shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests.

(b) The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

§ 71.131 Nonconforming materials, parts, or components.

The licensee, certificate holder, and applicant for a CoC shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

§ 71.133 Corrective action.

The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

§ 71.135 Quality assurance records.

The licensee, certificate holder, and applicant for a Certificate of Compliance shall maintain sufficient written records to describe the activities affecting quality. These records must include changes to the quality assurance program as required by § 71.106, the instructions, procedures,

and drawings required by § 71.111 to prescribe quality assurance activities, and closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee, certificate holder, and applicant for a Certificate of Compliance shall retain these records for 3 years beyond the date when the licensee, certificate holder, and applicant for a Certificate of Compliance last engage in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures or instructions is superseded, the licensee, certificate holder, and applicant for a Certificate of Compliance shall retain the superseded material for 3 years after it is superseded.

[80 FR 34014, Jun. 12, 2015]

§ 71.137 Audits.

The licensee, certificate holder, and applicant for a CoC shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, must be taken where indicated.

Appendix A to Part 71--Determination of A_1 and A_2

I. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations, are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) value. The Terabecquerel values are the regulatory standard. The curie values are for information only and are not intended to be the regulatory standard. Where values of A_1 and A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

II. a. For individual radionuclides whose identities are known, but which are not listed in Table A-1, the A_1 and A_2 values contained in Table A-3 may be used. Otherwise, the licensee shall obtain prior Commission approval of the A_1 and A_2 values for radionuclides not listed in Table A-1, before shipping the material.

b. For individual radionuclides whose identities are known, but which are not listed in Table A-2, the exempt material activity concentration and exempt consignment activity values contained in Table A-3 may be used. Otherwise, the licensee shall obtain prior Commission approval of the exempt material activity concentration and exempt consignment activity values for radionuclides not listed in Table A-2, before shipping the material.

c. The licensee shall submit requests for prior approval, described under paragraphs II(a) and II(b) of this Appendix, to the Commission, in accordance with § 71.1 of this part.

III. In the calculations of A_1 and A_2 for a radionuclide not in Table A-1, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter radionuclide has a half-life either longer than 10 days, or longer than that of the parent radionuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A_1 or A_2 value to be applied, shall be those corresponding to the parent radionuclide of that chain. In the case of radioactive decay chains in which any daughter radionuclide has a half-life either longer than 10 days, or greater than that of the parent radionuclide, the parent and those daughter radionuclides shall be considered as mixtures of different radionuclides.

IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

a. For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} \leq 1$$

where B(i) is the activity of radionuclide i in special form**,** and $A_1(i)$ is the A_1 value for radionuclide i.

b. For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_2(i)} \leq 1$$

where B(i) is the activity of radionuclide i in normal form**,** and $A_2(i)$ is the A_2 value for radionuclide i.

c. If the package contains both special and normal form radioactive material, the activity that may be transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} + \sum_j \frac{C(j)}{A_2(j)} \leq 1$$

where B(i) is the activity of radionuclide i as special form radioactive material, $A_1(i)$ is the A_1 value for radionuclide i, C(j) is the activity of radionuclide j as normal form radioactive material, and $A_2(j)$ is the A_2 value for radionuclide j.

d. Alternatively, the A_1 value for mixtures of special form material may be determined as follows:

$$A_1 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity for radionuclide i in the mixture and $A_1(i)$ is the appropriate A_1 value for radionuclide i.

e. Alternatively, the A_2 value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity for radionuclide i in the mixture and $A_2(i)$ is the appropriate A_2 value for radionuclide i.

f. The exempt activity concentration for mixtures of nuclides may be determined as follows:

$$\text{Exempt activity concentration for mixture} = \frac{1}{\sum_i \frac{f(i)}{[A](i)}}$$

where f(i) is the fraction of activity concentration of radionuclide i in the mixture and [A](i) is the activity concentration for exempt material containing radionuclide i.

g. The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

$$\text{Exempt consignment activity limit for mixture} = \frac{1}{\sum_i \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide i in the mixture and A(i) is the activity limit for exempt consignments for radionuclide i.

V. a. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped, and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

b. When the identity of each radionuclide is known but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest [A] (activity concentration for exempt material) or A (activity limit for exempt consignment) value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV of this appendix. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest [A] or A values for the alpha emitters and beta/gamma emitters, respectively.

Table A-1—A_1 and A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Ac-225 (a)	Actinium (89)	$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.1X10^{3}$	$5.8X10^{4}$
Ac-227 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-5}$	$2.4X10^{-3}$	2.7	$7.2X10^{1}$
Ac-228		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.4X10^{4}$	$2.2X10^{6}$
Ag-105	Silver (47)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Ag-108m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.7X10^{-1}$	$2.6X10^{1}$
Ag-110m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.8X10^{2}$	$4.7X10^{3}$
Ag-111		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Al-26	Aluminum (13)	$1.0X10^{-1}$	2.7	$1.0X10^{-1}$	2.7	$7.0X10^{-4}$	$1.9X10^{-2}$
Am-241	Americium (95)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.3X10^{-1}$	3.4
Am-242m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.6X10^{-1}$	$1.0X10^{1}$
Am-243 (a)		5.0	$1.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.4X10^{-3}$	$2.0X10^{-1}$
Ar-37	Argon (18)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.7X10^{3}$	$9.9X10^{4}$
Ar-39		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	1.3	$3.4X10^{1}$
Ar-41		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.5X10^{6}$	$4.2X10^{7}$
As-72	Arsenic (33)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$6.2X10^{4}$	$1.7X10^{6}$
As-73		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.2X10^{2}$	$2.2X10^{4}$

As-74		1.0	$2.7X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$3.7X10^{3}$	$9.9X10^{4}$
As-76		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.8X10^{4}$	$1.6X10^{6}$
As-77		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.9X10^{4}$	$1.0X10^{6}$
At-211 (a)	Astatine (85)	$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.6X10^{4}$	$2.1X10^{6}$
Au-193	Gold (79)	7.0	$1.9X10^{2}$	2.0	$5.4X10^{1}$	$3.4X10^{4}$	$9.2X10^{5}$
Au-194		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.5X10^{4}$	$4.1X10^{5}$
Au-195		$1.0X10^{1}$	$2.7X10^{2}$	6.0	$1.6X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Au-198		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.0X10^{3}$	$2.4X10^{5}$
Au-199		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{3}$	$2.1X10^{5}$
Ba-131 (a)	Barium (56)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Ba-133		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	9.4	$2.6X10^{2}$
Ba-133m		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{4}$	$6.1X10^{5}$
Ba-140 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{-1}$	8.1	$2.7X10^{3}$	$7.3X10^{4}$
Be-7	Beryllium (4)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.3X10^{4}$	$3.5X10^{5}$
Be-10		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$8.3X10^{-4}$	$2.2X10^{-2}$
Bi-205	Bismuth (83)	$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{3}$	$4.2X10^{4}$
Bi-206		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.8X10^{3}$	$1.0X10^{5}$
Bi-207		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	1.9	$5.2X10^{1}$
Bi-210		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
Bi-210m (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.1X10^{-5}$	$5.7X10^{-4}$
Bi-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.4X10^{5}$	$1.5X10^{7}$
Bk-247	Berkelium (97)	8.0	$2.2X10^{2}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$3.8X10^{-2}$	1.0
Bk-249 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{-1}$	8.1	$6.1X10^{1}$	$1.6X10^{3}$
Br-76	Bromine (35)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$9.4X10^{4}$	$2.5X10^{6}$
Br-77		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$2.6X10^{4}$	$7.1X10^{5}$
Br-82		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{4}$	$1.1X10^{6}$
C-11	Carbon (6)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.1X10^{7}$	$8.4X10^{8}$
C-14		$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{-1}$	4.5
Ca-41	Calcium (20)	Unlimited	Unlimited	Unlimited	Unlimited	$3.1X10^{-3}$	$8.5X10^{-2}$
Ca-45		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Ca-47 (a)		3.0	$8.1X10^{1}$	$3.0X10^{-1}$	8.1	$2.3X10^{4}$	$6.1X10^{5}$
Cd-109	Cadmium (48)	$3.0X10^{1}$	$8.1X10^{2}$	2.0	$5.4X10^{1}$	$9.6X10^{1}$	$2.6X10^{3}$
Cd-113m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	8.3	$2.2X10^{2}$
Cd-115 (a)		3.0	$8.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.9X10^{4}$	$5.1X10^{5}$
Cd-115m		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.4X10^{2}$	$2.5X10^{4}$
Ce-139	Cerium (58)	7.0	$1.9X10^{2}$	2.0	$5.4X10^{1}$	$2.5X10^{2}$	$6.8X10^{3}$
Ce-141		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.8X10^{4}$
Ce-143		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.6X10^{5}$
Ce-144 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.2X10^{3}$

Cf-248	Californium (98)	$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$5.8X10^{1}$	$1.6X10^{3}$
Cf-249		3.0	$8.1X10^{1}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$1.5X10^{-1}$	4.1
Cf-250		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	4.0	$1.1X10^{2}$
Cf-251		7.0	$1.9X10^{2}$	$7.0X10^{-4}$	$1.9X10^{-2}$	$5.9X10^{-2}$	1.6
Cf-252		$1.0x10^{-1}$	2.7	$3.0x10^{-3}$	$8.1x10^{-2}$	$2.0x10^{1}$	$5.4x10^{2}$
Cf-253 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-2}$	1.1	$1.1X10^{3}$	$2.9X10^{4}$
Cf-254		$1.0X10^{-3}$	$2.7X10^{-2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.1X10^{2}$	$8.5X10^{3}$
Cl-36	Chlorine (17)	$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{-3}$	$3.3X10^{-2}$
Cl-38		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$4.9X10^{6}$	$1.3X10^{8}$
Cm-240	Curium (96)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$7.5X10^{2}$	$2.0X10^{4}$
Cm-241		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$6.1X10^{2}$	$1.7X10^{4}$
Cm-242		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$1.2X10^{2}$	$3.3X10^{3}$
Cm-243		9.0	$2.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.9X10^{-3}$	$5.2X10^{1}$
Cm-244		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	3.0	$8.1X10^{1}$
Cm-245		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$6.4X10^{-3}$	$1.7X10^{-1}$
Cm-246		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$1.1X10^{-2}$	$3.1X10^{-1}$
Cm-247 (a)		3.0	$8.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.4X10^{-6}$	$9.3X10^{-5}$
Cm-248		$2.0X10^{-2}$	$5.4X10^{-1}$	$3.0X10^{-4}$	$8.1X10^{-3}$	$1.6X10^{-4}$	$4.2X10^{-3}$
Co-55	Cobalt (27)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Co-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{3}$	$3.0X10^{4}$
Co-57		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$3.1X10^{2}$	$8.4X10^{3}$
Co-58		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Co-58m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.2X10^{5}$	$5.9X10^{6}$
Co-60		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.2X10^{1}$	$1.1X10^{3}$
Cr-51	Chromium (24)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.4X10^{3}$	$9.2X10^{4}$
Cs-129	Cesium (55)	4.0	$1.1X10^{2}$	4.0	$1.1X10^{2}$	$2.8X10^{4}$	$7.6X10^{5}$
Cs-131		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.8X10^{3}$	$1.0X10^{5}$
Cs-132		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.7X10^{3}$	$1.5X10^{5}$
Cs-134		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.8X10^{1}$	$1.3X10^{3}$
Cs-134m		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.0X10^{6}$
Cs-135		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$4.3X10^{-5}$	$1.2X10^{-3}$
Cs-136		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.7X10^{3}$	$7.3X10^{4}$
Cs-137 (a)		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	3.2	$8.7X10^{1}$
Cu-64	Copper (29)	6.0	$1.6X10^{2}$	1.0	$2.7X10^{1}$	$1.4X10^{5}$	$3.9X10^{6}$
Cu-67		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.8X10^{4}$	$7.6X10^{5}$
Dy-159	Dysprosium (66)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$2.1X10^{2}$	$5.7X10^{3}$
Dy-165		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Dy-166 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$3.0X10^{-1}$	8.1	$8.6X10^{3}$	$2.3X10^{5}$
Er-169	Erbium (68)	$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$3.1X10^{3}$	$8.3X10^{4}$

Er-171		$8.0X10^{-1}$	$2.2X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.0X10^{4}$	$2.4X10^{6}$
Eu-147	Europium (63)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.4X10^{3}$	$3.7X10^{4}$
Eu-148		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.0X10^{2}$	$1.6X10^{4}$
Eu-149		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$3.5X10^{2}$	$9.4X10^{3}$
Eu-150 (short lived)		2.0	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-150 (long lived)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-152		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	6.5	$1.8X10^{2}$
Eu-152m		$8.0X10^{-1}$	$2.2X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$8.2X10^{4}$	$2.2X10^{6}$
Eu-154		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	9.8	$2.6X10^{2}$
Eu-155		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$1.8X10^{1}$	$4.9X10^{2}$
Eu-156		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{3}$	$5.5X10^{4}$
F-18	Fluorine (9)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.5X10^{6}$	$9.5X10^{7}$
Fe-52 (a)	Iron (26)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.7X10^{5}$	$7.3X10^{6}$
Fe-55		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.8X10^{1}$	$2.4X10^{3}$
Fe-59		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$1.8X10^{3}$	$5.0X10^{4}$
Fe-60 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-1}$	5.4	$7.4X10^{-4}$	$2.0X10^{-2}$
Ga-67	Gallium (31)	7.0	$1.9X10^{2}$	3.0	$8.1X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Ga-68		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.5X10^{6}$	$4.1X10^{7}$
Ga-72		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Gd-146 (a)	Gadolinium (64)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Gd-148		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	1.2	$3.2X10^{1}$
Gd-153		$1.0X10^{1}$	$2.7X10^{2}$	9.0	$2.4X10^{2}$	$1.3X10^{2}$	$3.5X10^{3}$
Gd-159		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.9X10^{4}$	$1.1X10^{6}$
Ge-68 (a)	Germanium (32)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.6X10^{2}$	$7.1X10^{3}$
Ge-71		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.8X10^{3}$	$1.6X10^{5}$
Ge-77		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Hf-172 (a)	Hafnium (72)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Hf-175		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$3.9X10^{2}$	$1.1X10^{4}$
Hf-181		2.0	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.3X10^{2}$	$1.7X10^{4}$
Hf-182		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-6}$	$2.2X10^{-4}$
Hg-194 (a)	Mercury (80)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.3X10^{-1}$	3.5
Hg-195m (a)		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Hg-197		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.2X10^{3}$	$2.5X10^{5}$
Hg-197m		$1.0X10^{1}$	$2.7X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.5X10^{4}$	$6.7X10^{5}$
Hg-203		5.0	$1.4X10^{2}$	1.0	$2.7X10^{1}$	$5.1X10^{2}$	$1.4X10^{4}$
Ho-166	Holmium (67)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
Ho-166m		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.6X10^{-2}$	1.8
I-123	Iodine (53)	6.0	$1.6X10^{2}$	3.0	$8.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$

I-124		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$9.3X10^{3}$	$2.5X10^{5}$
I-125		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$6.4X10^{2}$	$1.7X10^{4}$
I-126		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$2.9X10^{3}$	$8.0X10^{4}$
I-129		Unlimited	Unlimited	Unlimited	Unlimited	$6.5X10^{-6}$	$1.8X10^{-4}$
I-131		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
I-132		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.8X10^{5}$	$1.0X10^{7}$
I-133		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{4}$	$1.1X10^{6}$
I-134		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$9.9X10^{5}$	$2.7X10^{7}$
I-135 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.3X10^{5}$	$3.5X10^{6}$
In-111	Indium (49)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$1.5X10^{4}$	$4.2X10^{5}$
In-113m		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$6.2X10^{5}$	$1.7X10^{7}$
In-114m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.6X10^{2}$	$2.3X10^{4}$
In-115m		7.0	$1.9X10^{2}$	1.0	$2.7X10^{1}$	$2.2X10^{5}$	$6.1X10^{6}$
Ir-189 (a)	Iridium (77)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.9X10^{3}$	$5.2X10^{4}$
Ir-190		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.3X10^{3}$	$6.2X10^{4}$
Ir-192		[c]1.0	[c]$2.7x10^{1}$	$6.0x10^{-1}$	$1.6x10^{1}$	$3.4x10^{2}$	$9.2x10^{3}$
Ir-194		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.1X10^{4}$	$8.4X10^{5}$
K-40	Potassium (19)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.4X10^{-7}$	$6.4X10^{-6}$
K-42		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.2X10^{5}$	$6.0X10^{6}$
K-43		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Kr-79	Krypton (36)	4.0	$1.1x10^{2}$	2.0	$5.4x10^{1}$	$4.2x10^{4}$	$1.1x10^{6}$
Kr-81		$4.0x10^{1}$	$1.1x10^{3}$	$4.0x10^{1}$	$1.1x10^{3}$	$7.8x10^{-4}$	$2.1x10^{-2}$
Kr-85		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.5X10^{1}$	$3.9X10^{2}$
Kr-85m		8.0	$2.2X10^{2}$	3.0	$8.1X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Kr-87		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.0X10^{6}$	$2.8X10^{7}$
La-137	Lanthanum (57)	$3.0X10^{1}$	$8.1X10^{2}$	6.0	$1.6X10^{2}$	$1.6X10^{-3}$	$4.4X10^{-2}$
La-140		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.1X10^{4}$	$5.6X10^{5}$
Lu-172	Lutetium (71)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{3}$	$1.1X10^{5}$
Lu-173		8.0	$2.2X10^{2}$	8.0	$2.2X10^{2}$	$5.6X10^{1}$	$1.5X10^{3}$
Lu-174		9.0	$2.4X10^{2}$	9.0	$2.4X10^{2}$	$2.3X10^{1}$	$6.2X10^{2}$
Lu-174m		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$2.0X10^{2}$	$5.3X10^{3}$
Lu-177		$3.0X10^{1}$	$8.1X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.1X10^{3}$	$1.1X10^{5}$
Mg-28 (a)	Magnesium (12)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^{5}$	$5.4X10^{6}$
Mn-52	Manganese (25)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.6X10^{4}$	$4.4X10^{5}$
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	$6.8X10^{-5}$	$1.8X10^{-3}$
Mn-54		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$2.9X10^{2}$	$7.7X10^{3}$
Mn-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.0X10^{5}$	$2.2X10^{7}$
Mo-93	Molybdenum (42)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.1X10^{-2}$	1.1
Mo-99 [a h]		1.0	$2.7x10^{1}$	$6.0x10^{-1}$	$1.6x10^{1}$	$1.8x10^{4}$	$4.8x10^{5}$

N-13	Nitrogen (7)	$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.4X10^{7}$	$1.5X10^{9}$
Na-22	Sodium (11)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.3X10^{3}$
Na-24		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.2X10^{5}$	$8.7X10^{6}$
Nb-93m	Niobium (41)	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	8.8	$2.4X10^{2}$
Nb-94		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.9X10^{-3}$	$1.9X10^{-1}$
Nb-95		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.5X10^{3}$	$3.9X10^{4}$
Nb-97		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.9X10^{5}$	$2.7X10^{7}$
Nd-147	Neodymium (60)	6.0	$1.6X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Nd-149		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{5}$	$1.2X10^{7}$
Ni-59	Nickel (28)	Unlimited	Unlimited	Unlimited	Unlimited	$3.0X10^{-3}$	$8.0X10^{-2}$
Ni-63		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	2.1	$5.7X10^{1}$
Ni-65		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{5}$	$1.9X10^{7}$
Np-235	Neptunium (93)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.2X10^{1}$	$1.4X10^{3}$
Np-236 (short-lived)		$2.0X10^{1}$	$5.4X10^{2}$	2.0	$5.4X10^{1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-236 (long-lived)		$9.0X10^{0}$	$2.4X10^{2}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	$2.6X10^{-5}$	$7.1X10^{-4}$
Np-239		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$8.6X10^{3}$	$2.3X10^{5}$
Os-185	Osmium (76)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$2.8X10^{2}$	$7.5X10^{3}$
Os-191		$1.0X10^{1}$	$2.7X10^{2}$	2.0	$5.4X10^{1}$	$1.6X10^{3}$	$4.4X10^{4}$
Os-191m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.6X10^{4}$	$1.3X10^{6}$
Os-193		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{4}$	$5.3X10^{5}$
Os-194 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{1}$	$3.1X10^{2}$
P-32	Phosphorus (15)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{4}$	$2.9X10^{5}$
P-33		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pa-230 (a)	Protactinium (91)	2.0	$5.4X10^{1}$	$7.0X10^{-2}$	1.9	$1.2X10^{3}$	$3.3X10^{4}$
Pa-231		4.0	$1.1X10^{2}$	$4.0X10^{-4}$	$1.1X10^{-2}$	$1.7X10^{-3}$	$4.7X10^{-2}$
Pa-233		5.0	$1.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.7X10^{2}$	$2.1X10^{4}$
Pb-201	Lead (82)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.2X10^{4}$	$1.7X10^{6}$
Pb-202		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.2X10^{-4}$	$3.4X10^{-3}$
Pb-203		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	$4.5X10^{-6}$	$1.2X10^{-4}$
Pb-210 (a)		1.0	$2.7X10^{1}$	$5.0X10^{-2}$	1.4	2.8	$7.6X10^{1}$
Pb-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{-1}$	5.4	$5.1X10^{4}$	$1.4X10^{6}$
Pd-103 (a)	Palladium (46)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.8X10^{3}$	$7.5X10^{4}$
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	$1.9X10^{-5}$	$5.1X10^{-4}$
Pd-109		2.0	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.9X10^{4}$	$2.1X10^{6}$
Pm-143	Promethium (61)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$1.3X10^{2}$	$3.4X10^{3}$
Pm-144		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.2X10^{1}$	$2.5X10^{3}$

Pm-145		$3.0X10^{1}$	$8.1X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	5.2	$1.4X10^{2}$
Pm-147		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$3.4X10^{1}$	$9.3X10^{2}$
Pm-148m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Pm-149		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Pm-151		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.7X10^{4}$	$7.3X10^{5}$
Po-210	Polonium (84)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.7X10^{2}$	$4.5X10^{3}$
Pr-142	Praseodymium (59)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.3X10^{4}$	$1.2X10^{6}$
Pr-143		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{3}$	$6.7X10^{4}$
Pt-188 (a)	Platinum (78)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$2.5X10^{3}$	$6.8X10^{4}$
Pt-191		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$8.7X10^{3}$	$2.4X10^{5}$
Pt-193		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	1.4	$3.7X10^{1}$
Pt-193m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pt-195m		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.2X10^{3}$	$1.7X10^{5}$
Pt-197		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.2X10^{4}$	$8.7X10^{5}$
Pt-197m		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.7X10^{5}$	$1.0X10^{7}$
Pu-236	Plutonium (94)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.3X10^{2}$
Pu-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.5X10^{2}$	$1.2X10^{4}$
Pu-238		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.3X10^{-1}$	$1.7X10^{1}$
Pu-239		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$2.3X10^{-3}$	$6.2X10^{-2}$
Pu-240		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.4X10^{-3}$	$2.3X10^{-1}$
Pu-241 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-2}$	1.6	3.8	$1.0X10^{2}$
Pu-242		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.5X10^{-4}$	$3.9X10^{-3}$
Pu-244 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.7X10^{-7}$	$1.8X10^{-5}$
Ra-223 (a)	Radium (88)	$4.0X10^{-1}$	$1.1X10^{1}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$1.9X10^{3}$	$5.1X10^{4}$
Ra-224 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$5.9X10^{3}$	$1.6X10^{5}$
Ra-225 (a)		$2.0X10^{-1}$	5.4	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.5X10^{3}$	$3.9X10^{4}$
Ra-226 (a)		$2.0X10^{-1}$	5.4	$3.0X10^{-3}$	$8.1X10^{-2}$	$3.7X10^{-2}$	1.0
Ra-228 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.0X10^{1}$	$2.7X10^{2}$
Rb-81	Rubidium (37)	2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{5}$	$8.4X10^{6}$
Rb-83 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$6.8X10^{2}$	$1.8X10^{4}$
Rb-84		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.8X10^{3}$	$4.7X10^{4}$
Rb-86		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	$3.2X10^{-9}$	$8.6X10^{-8}$
Rb(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$6.7X10^{6}$	$1.8X10^{8}$
Re-184	Rhenium (75)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Re-184m		3.0	$8.1X10^{1}$	1.0	$2.7X10^{1}$	$1.6X10^{2}$	$4.3X10^{3}$
Re-186		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.9X10^{3}$	$1.9X10^{5}$
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	$1.4X10^{-9}$	$3.8X10^{-8}$
Re-188		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.6X10^{4}$	$9.8X10^{5}$

Re-189 (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.8X10^{5}$
Re(nat)		Unlimited	Unlimited	Unlimited	Unlimited	0.0	$2.4X10^{-8}$
Rh-99	Rhodium (45)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Rh-101		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Rh-102		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{1}$	$1.2X10^{3}$
Rh-102m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Rh-103m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$1.2X10^{6}$	$3.3X10^{7}$
Rh-105		$1.0X10^{1}$	$2.7X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{4}$	$8.4X10^{5}$
Rn-222 (a)	Radon (86)	$3.0X10^{-1}$	8.1	$4.0X10^{-3}$	$1.1X10^{-1}$	$5.7X10^{3}$	$1.5X10^{5}$
Ru-97	Ruthenium (44)	5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.7X10^{4}$	$4.6X10^{5}$
Ru-103 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Ru-105		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{5}$	$6.7X10^{6}$
Ru-106 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.3X10^{3}$
S-35	Sulphur (16)	$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{3}$	$4.3X10^{4}$
Sb-122	Antimony (51)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Sb-124		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.5X10^{2}$	$1.7X10^{4}$
Sb-125		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$3.9X10^{1}$	$1.0X10^{3}$
Sb-126		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Sc-44	Scandium (21)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.7X10^{5}$	$1.8X10^{7}$
Sc-46		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.3X10^{3}$	$3.4X10^{4}$
Sc-47		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.1X10^{4}$	$8.3X10^{5}$
Sc-48		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.5X10^{4}$	$1.5X10^{6}$
Se-75	Selenium (34)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$5.4X10^{2}$	$1.5X10^{4}$
Se-79		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$2.6X10^{-3}$	$7.0X10^{-2}$
Si-31	Silicon (14)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.4X10^{6}$	$3.9X10^{7}$
Si-32		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	3.9	$1.1X10^{2}$
Sm-145	Samarium (62)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.8X10^{1}$	$2.6X10^{3}$
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5X10^{-10}$	$2.3X10^{-8}$
Sm-151		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.7X10^{-1}$	$2.6X10^{1}$
Sm-153		9.0	$2.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.6X10^{4}$	$4.4X10^{5}$
Sn-113 (a)	Tin (50)	4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$3.7X10^{2}$	$1.0X10^{4}$
Sn-117m		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Sn-119m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Sn-121m (a)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	2.0	$5.4X10^{1}$
Sn-123		$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Sn-125		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{3}$	$1.1X10^{5}$
Sn-126 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.8X10^{-2}$
Sr-82 (a)	Strontium (38)	$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.3X10^{3}$	$6.2X10^{4}$
Sr-85		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.8X10^{2}$	$2.4X10^{4}$

Sr-85m		5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.2X10^{6}$	$3.3X10^{7}$
Sr-87m		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$4.8X10^{5}$	$1.3X10^{7}$
Sr-89		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.9X10^{4}$
Sr-90 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	5.1	$1.4X10^{2}$
Sr-91 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Sr-92 (a)		1.0	$2.7X10^{1}$	$3.0X10^{-1}$	8.1	$4.7X10^{5}$	$1.3X10^{7}$
T(H-3)	Tritium (1)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.6X10^{2}$	$9.7X10^{3}$
Ta-178 (long-lived)	Tantalum (73)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$4.2X10^{6}$	$1.1X10^{8}$
Ta-179		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.1X10^{1}$	$1.1X10^{3}$
Ta-182		$9.0X10^{-1}$	$2.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Tb-157	Terbium (65)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-158		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-160		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{2}$	$1.1X10^{4}$
Tc-95m (a)	Technetium (43)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.3X10^{2}$	$2.2X10^{4}$
Tc-96		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.2X10^{4}$	$3.2X10^{5}$
Tc-96m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.4X10^{6}$	$3.8X10^{7}$
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	$5.2X10^{-5}$	$1.4X10^{-3}$
Tc-97m		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.6X10^{2}$	$1.5X10^{4}$
Tc-98		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.2X10^{-5}$	$8.7X10^{-4}$
Tc-99		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.3X10^{-4}$	$1.7X10^{-2}$
Tc-99m		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$1.9X10^{5}$	$5.3X10^{6}$
Te-121	Tellurium (52)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.4X10^{3}$	$6.4X10^{4}$
Te-121m		5.0	$1.4X10^{2}$	3.0	$8.1X10^{1}$	$2.6X10^{2}$	$7.0X10^{3}$
Te-123m		8.0	$2.2X10^{2}$	1.0	$2.7X10^{1}$	$3.3X10^{2}$	$8.9X10^{3}$
Te-125m		$2.0X10^{1}$	$5.4X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.7X10^{2}$	$1.8X10^{4}$
Te-127		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.8X10^{4}$	$2.6X10^{6}$
Te-127m (a)		$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
Te-129		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{5}$	$2.1X10^{7}$
Te-129m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Te-131m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{4}$	$8.0X10^{5}$
Te-132 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-3}$	$1.4X10^{-1}$	$1.1X10^{3}$	$3.1X10^{4}$
Th-228 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.0X10^{1}$	$8.2X10^{2}$
Th-229		5.0	$1.4X10^{2}$	$5.0X10^{-4}$	$1.4X10^{-2}$	$7.9X10^{-3}$	$2.1X10^{-1}$
Th-230		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.6X10^{-4}$	$2.1X10^{-2}$
Th-231		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.0X10^{4}$	$5.3X10^{5}$
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	$4.0X10^{-9}$	$1.1X10^{-7}$
Th-234 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.6X10^{2}$	$2.3X10^{4}$

Th(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-9}$	$2.2X10^{-7}$
Ti-44 (a)	Titanium (22)	$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	6.4	$1.7X10^{2}$
Tl-200	Thallium (81)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Tl-201		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$7.9X10^{3}$	$2.1X10^{5}$
Tl-202		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.0X10^{3}$	$5.3X10^{4}$
Tl-204		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.7X10^{1}$	$4.6X10^{2}$
Tm-167	Thulium (69)	7.0	$1.9X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{3}$	$8.5X10^{4}$
Tm-170		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{2}$	$6.0X10^{3}$
Tm-171		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$
U-230 (fast lung absorption) (a)(d)	Uranium (92)	$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-1}$	2.7	$1.0X10^{3}$	$2.7X10^{4}$
U-230 (medium lung absorption) (a)(e)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.0X10^{3}$	$2.7X10^{4}$
U-230 (slow lung absorption) (a)(f)		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$1.0X10^{3}$	$2.7X10^{4}$
U-232 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-233 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-234 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (medium lung absorption)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$

(e)							
U-234 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-235 (all lung absorption types) (a),(d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	$8.0X10^{-8}$	$2.2X10^{-6}$
U-236 (fast lung absorption) (d)		Unlimited	Unlimited	Unlimited	Unlimited	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-238 (all lung absorption types) (d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	$1.2X10^{-8}$	$3.4X10^{-7}$
U (nat)		Unlimited	Unlimited	Unlimited	Unlimited	$2.6X10^{-8}$	$7.1X10^{-7}$
U (enriched to 20% or less) (g)		Unlimited	Unlimited	Unlimited	Unlimited	See Table A-4	See Table A-4
U (dep)		Unlimited	Unlimited	Unlimited	Unlimited	See Table A-4	(See Table A-3)
V-48	Vanadium (23)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$6.3X10^{3}$	$1.7X10^{5}$
V-49		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{2}$	$8.1X10^{3}$
W-178 (a)	Tungsten (74)	9.0	$2.4X10^{2}$	5.0	$1.4X10^{2}$	$1.3X10^{3}$	$3.4X10^{4}$
W-181		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$2.2X10^{2}$	$6.0X10^{3}$
W-185		$4.0X10^{1}$	$1.1X10^{3}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
W-187		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
W-188 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{-1}$	8.1	$3.7X10^{2}$	$1.0X10^{4}$
Xe-122 (a)	Xenon (54)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.8X10^{4}$	$1.3X10^{6}$
Xe-123		2.0	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.4X10^{5}$	$1.2X10^{7}$
Xe-127		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$1.0X10^{3}$	$2.8X10^{4}$
Xe-131m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.1X10^{3}$	$8.4X10^{4}$
Xe-133		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$6.9X10^{3}$	$1.9X10^{5}$
Xe-135		3.0	$8.1X10^{1}$	2.0	$5.4X10^{1}$	$9.5X10^{4}$	$2.6X10^{6}$
Y-87 (a)	Yttrium (39)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.7X10^{4}$	$4.5X10^{5}$
Y-88		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$5.2X10^{2}$	$1.4X10^{4}$
Y-90		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^{4}$	$5.4X10^{5}$

Y-91		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.1X10^{2}$	$2.5X10^{4}$
Y-91m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.5X10^{6}$	$4.2X10^{7}$
Y-92		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.6X10^{5}$	$9.6X10^{6}$
Y-93		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.2X10^{5}$	$3.3X10^{6}$
Yb-169	Ytterbium (70)	4.0	$1.1X10^{2}$	1.0	$2.7X10^{1}$	$8.9X10^{2}$	$2.4X10^{4}$
Yb-175		$3.0X10^{1}$	$8.1X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.6X10^{3}$	$1.8X10^{5}$
Zn-65	Zinc (30)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Zn-69		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{6}$	$4.9X10^{7}$
Zn-69m (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Zr-88	Zirconium (40)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Zr-93		Unlimited	Unlimited	Unlimited	Unlimited	$9.3X10^{-5}$	$2.5X10^{-3}$
Zr-95 (a)		2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Zr-97 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$

[a] A_1 and/or A_2 values include contributions from daughter nuclides with half-lives less than 10 days, as listed in the following:

Mg-28	Al-28
Ca-47	Sc-47
Ti-44	Sc-44
Fe-52	Mn-52m
Fe-60	Co-60m
Zn-69m	Zn-69
Ge-68	Ga-68
Rb-83	Kr-83m
Sr-82	Rb-82
Sr-90	Y-90
Sr-91	Y-91m
Sr-92	Y-92
Y-87	Sr-87m
Zr-95	Nb-95m
Zr-97	Nb-97m, Nb-97
Mo-99	Tc-99m
Tc-95m	Tc-95
Tc-96m	Tc-96
Ru-103	Rh-103m
Ru-106	Rh-106
Pd-103	Rh-103m
Ag-108m	Ag-108
Ag-110m	Ag-110
Cd-115	In-115m
In-114m	In-114
Sn-113	In-113m
Sn-121m	Sn-121

Sn-126	Sb-126m
Te-127m	Te-127
Te-129m	Te-129
Te-131m	Te-131
Te-132	I-132
I-135	Xe-135m
Xe-122	I-122
Cs-137	Ba-137m
Ba-131	Cs-131
Ba-140	La-140
Ce-144	Pr-144m, Pr-144
Pm-148m	Pm-148
Gd-146	Eu-146
Dy-166	Ho-166
Hf-172	Lu-172
W-178	Ta-178
W-188	Re-188
Re-189	Os-189m
Os-194	Ir-194
Ir-189	Os-189m
Pt-188	Ir-188
Hg-194	Au-194
Hg-195m	Hg-195
Pb-210	Bi-210
Pb-212	Bi-212, Tl-208, Po-212
Bi-210m	Tl-206
Bi-212	Tl-208, Po-212
At-211	Po-211
Rn-222	Po-218, Pb-214, At-218, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Po-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212
Ra-225	Ac-225, Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209
Ra-226	Rn-222, Po-218, Pb-214, At-218, Bi-214, Po-214
Ra-228	Ac-228
Ac-225	Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209
Ac-227	Fr-223
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212
Th-234	Pa-234m, Pa-234
Pa-230	Ac-226, Th-226, Fr-222, Ra-222, Rn-218, Po-214
U-230	Th-226, Ra-222, Rn-218, Po-214
U-235	Th-231
Pu-241	U-237
Pu-244	U-240, Np-240m
Am-242m	Am-242, Np-238
Am-243	Np-239
Cm-247	Pu-243

Bk-249 Am-245
Cf-253 Cm-249

[b] The values of A_1 and A_2 in Curies (Ci) are approximate and for information only; the regulatory standard units are Terabecquerels (TBq) (see Appendix A to Part 71 - Determination of A_1 and A_2, Section I).
[c] The activity of Ir-192 in special form may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.
[d] These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.
[e] These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.
[f] These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.
[g] These values apply to unirradiated uranium only.
[h] A_2 = 0.74 TBq (20 Ci) for Mo-99 for domestic use.

Table A-2—EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ac-225	Actinium (89)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ac-227		$1.0X10^{-1}$	$2.7X10^{-12}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ac-228		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-105	Silver (47)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-108m (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-110m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-111		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Al-26	Aluminum (13)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Am-241	Americium (95)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-242m (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-243 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ar-37	Argon (18)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ar-39		$1.0X10^{7}$	$2.7X10^{-4}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ar-41		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
As-72	Arsenic (33)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-73		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
As-74		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

As-76		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-77		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
At-211	Astatine (85)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-193	Gold (79)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-194		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-195		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-198		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-199		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-131	Barium (56)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-140 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Be-7	Beryllium (4)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Be-10		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-205	Bismuth (83)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-206		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-207		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bk-247	Berkelium (97)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Bk-249		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-76	Bromine (35)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Br-77		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-82		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-11	Carbon (6)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-14		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-41	Calcium (20)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-45		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-47		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-109	Cadmium (48)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-113m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-139	Cerium (58)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-141		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$

Ce-143		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-144 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-248	Californium (98)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-249		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-250		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-251		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-252		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-253		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-254		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cl-36	Chlorine (17)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cl-38		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-240	Curium (96)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cm-242		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-243		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-244		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-245		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-246		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-247		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-248		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Co-55	Cobalt (27)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Co-57		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Co-60		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cr-51	Chromium (24)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-129	Cesium (55)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-131		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cs-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cs-134m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-135		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-136		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-137 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cu-64	Copper (29)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Cu-67		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-159	Dysprosium (66)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Dy-165		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-166		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Er-169	Erbium (68)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Er-171		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-147	Europium (63)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-150 (short lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-150 (long lived)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-154		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-155		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-156		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
F-18	Fluorine (9)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-52	Iron (26)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-55		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-59		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-60		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-67	Gallium (31)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ga-68		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-72		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Gd-146	Gadolinium (64)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Gd-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Gd-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Gd-159		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ge-68	Germanium (32)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ge-71		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ge-77		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Hf-172	Hafnium (72)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-175		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-181		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-182		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-194	Mercury (80)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Hg-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-197		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Hg-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166	Holmium (67)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-123	Iodine (53)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
I-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-125		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-126		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-131		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-133		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-135		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-111	Indium (49)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-113m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-114m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-115m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-189	Iridium (77)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ir-190		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-192		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ir-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
K-40	Potassium (19)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-42		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-43		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Kr-79	Krypton (36)	$1.0x10^{3}$	$2.7x10^{-8}$	$1.0x10^{5}$	$2.7x10^{-6}$
Kr-81		$1.0x10^{4}$	$2.7x10^{-7}$	$1.0x10^{7}$	$2.7x10^{-4}$
Kr-85		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{4}$	$2.7X10^{-7}$
Kr-85m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Kr-87		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
La-137	Lanthanum (57)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
La-140		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Lu-172	Lutetium (71)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Lu-173		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$

Lu-174		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-177		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Mg-28	Magnesium (12)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-52	Manganese (25)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-53		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{9}$	$2.7X10^{-2}$
Mn-54		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Mn-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mo-93	Molybdenum (42)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Mo-99		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
N-13	Nitrogen (7)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Na-22	Sodium (11)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Na-24		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Nb-93m	Niobium (41)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Nb-94		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-97		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-147	Neodymium (60)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ni-59	Nickel (28)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-63		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-65		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Np-235	Neptunium (93)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (short-lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (long-lived)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Np-237 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Np-239		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-185	Osmium (76)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-191m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-193		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-32	Phosphorus (15)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-33		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pa-230	Protactinium (91)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pa-231		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$

Pa-233		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-201	Lead (82)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-202		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-205		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-210 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pb-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pd-103	Palladium (46)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-107		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-109		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-143	Promethium (61)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-144		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-145		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-147		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-148m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-149		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-151		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Po-210	Polonium (84)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pr-142	Praseodymium (59)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pr-143		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-188	Platinum (78)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-193		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-193m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pu-236	Plutonium (94)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-237		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pu-238		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-239		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-240		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pu-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pu-242		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-244		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-223 (b)	Radium (88)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$

Ra-224 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-225		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-226 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-228 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-81	Rubidium (37)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-83		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-84		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-86		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-87		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rb(nat)		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Re-184	Rhenium (75)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-184m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-186		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-187		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Re-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Re-189		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re(nat)		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Rh-99	Rhodium (45)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-101		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rh-102		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-102m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-103m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Rh-105		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rn-222 (b)	Radon (86)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ru-97	Ruthenium (44)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ru-103		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-105		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-106 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
S-35	Sulphur (16)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sb-122	Antimony (51)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sb-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-44	Scandium (21)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-46		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-47		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Sc-48		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Se-75	Selenium (34)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Se-79		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Si-31	Silicon (14)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Si-32		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sm-145	Samarium (62)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sm-147		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sm-151		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sm-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-113	Tin (50)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-117m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-119m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-121m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-123		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sn-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-82	Strontium (38)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-85		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-85m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sr-87m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-89		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-90 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sr-91		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-92		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
T(H-3)	Tritium (1)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Ta-178 (long-lived)	Tantalum (73)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ta-179		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ta-182		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tb-157	Terbium (65)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tb-158		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tb-160		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-95m	Technetium (43)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-97		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Tc-97m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$

Tc-98		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-99		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-99m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-121	Tellurium (52)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-121m		$1.0x10^{2}$	$2.7x10^{-9}$	$1.0x10^{6}$	$2.7x10^{-5}$
Te-123m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-125m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-127m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-129m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-131m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-132		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-228 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-229 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Th-230		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-231		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-232		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-234 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Th (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ti-44	Titanium (22)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Tl-200	Thallium (81)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-201		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-202		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-204		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tm-167	Thulium (69)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-170		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-171		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
U-230 (fast lung absorption) (b),(d)	Uranium (92)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-230 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-230 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (fast lung absorption) (b),(d)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U-232 (medium		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$

lung absorption) (e)					
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-233 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-234 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-235 (all lung absorption types) (b),(d),(e),(f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-236 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-238 (all lung absorption types) (b),(d),(e),(f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (enriched to 20% or less) (g)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (dep)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
V-48	Vanadium (23)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
V-49		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-178	Tungsten (74)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-181		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-185		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-187		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-122	Xenon (54)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-123		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-131m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$

Xe-133		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-135		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Y-87	Yttrium (39)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-88		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-90		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-91		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-91m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-92		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-93		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Yb-169	Ytterbium (70)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Yb-175		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zn-65	Zinc (30)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-88	Zirconium (40)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-93 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zr-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-97 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

[a] [Reserved]
[b] Parent nuclides and their progeny included in secular equilibrium are listed as follows:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Ag-108m	Ag-108
Cs-137	Ba-137m
Ce-144	Pr-144
Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212(0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212,

	Tl-208 (0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

[c] [Reserved]
[d] These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.
[e] These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.
[f] These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.
[g] These values apply to unirradiated uranium only.

TABLE A-3—GENERAL VALUES FOR A_1 AND A_2

Contents	A_1		A_2		Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limits for exempt consignments (Bq)	Activity limits for exempt consignments (Ci)
	(TBq)	(Ci)	(TBq)	(Ci)				
Only beta or gamma emitting radionuclides are known to be present	1×10^{-1}	2.7×10^{0}	2×10^{-2}	5.4×10^{-1}	1×10^{1}	2.7×10^{-10}	1×10^{4}	2.7×10^{-7}
Alpha emitting nuclides, but no neutron emitters, are known to be present [a]	2×10^{-1}	5.4×10^{0}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}
Neutron emitting nuclides are known to be present or no	1×10^{-3}	2.7×10^{-2}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}

relevant data are available								

[a] If beta or gamma emitting nuclides are known to be present, the A_1 value of 0.1 TBq (2.7 Ci) should be used.

TABLE A-4—ACTIVITY-MASS RELATIONSHIPS FOR URANIUM

Uranium Enrichment[1] wt % U-235 present	Specific Activity	
	TBq/g	Ci/g
0.45	1.8×10^{-8}	5.0×10^{-7}
0.72	2.6×10^{-8}	7.1×10^{-7}
1	2.8×10^{-8}	7.6×10^{-7}
1.5	3.7×10^{-8}	1.0×10^{-6}
5	1.0×10^{-7}	2.7×10^{-6}
10	1.8×10^{-7}	4.8×10^{-6}
20	3.7×10^{-7}	1.0×10^{-5}
35	7.4×10^{-7}	2.0×10^{-5}
50	9.3×10^{-7}	2.5×10^{-5}
90	2.2×10^{-6}	5.8×10^{-5}
93	2.6×10^{-6}	7.0×10^{-5}
95	3.4×10^{-6}	9.1×10^{-5}

[1] The figures for uranium include representative values for the activity of the uranium-234 that is concentrated during the enrichment process.

[60 FR 50264, Sept. 28, 1995 as amended at 61 FR 28724, June 6, 1996; 69 FR 3800, Jan. 26, 2004; 77 FR 39908, Jul. 6, 2012; 80 FR 34014, Jun. 12, 2015; 85 FR 65656, Oct. 16, 2020]

CHAPTER 33.1-10-14.1
LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

Section
33.1-10-14.1-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 36

33.1-10-14.1-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 36.

10 Code of Federal Regulations 36.1, 36.2, 36.11, 36.13, 36.15, 36.17, 36.19, 36.21, 36.23, 36.25, 36.27, 36.29, 36.31, 36.33, 36.35, 36.37, 36.39, 36.41, 36.51, 36.53, 36.55, 36.57, 36.59, 36.61, 36.63, 36.65, 36.67, 36.69, 36.81, and 36.83 are adopted by reference as they exist on June 16, 2020~~October 1, 2015~~, with the following exceptions:

1. Not adopted by reference is paragraph (2) of the definition of "commencement of construction", and paragraph (9)(ii) of the definition "construction".

2. Requirements in 10 Code of Federal Regulations part 36 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", or "NRC regional office" appear in 10 Code of Federal Regulations part 36, substitute the words "department of environmental quality".

4. "Act" includes North Dakota Century Code chapters 23.1-02 and 23.1-03.

5. North Dakota state form number 8418, "application for radioactive material license", must be used instead of NRC form 313 as specified in 10 Code of Federal Regulations part 36.

6. For references to 10 Code of Federal Regulations parts 170 and 171, see chapter 33.1-10-11 for applicable fee schedules.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03; S.L. 2017, ch. 199, § 18

PART 36--LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

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Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Source: 58 FR 7728, Feb. 9, 1993, unless otherwise noted.

Subpart A--General Provisions

§ 36.1 Purpose and scope.

(a) This part contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This part also contains radiation safety requirements for operating irradiators. The requirements of this part are in addition to other requirements of this chapter. In particular, the provisions of parts 19, 20, 21, 30, 71, 170, and 171 of this chapter apply to applications and licenses subject to this part. Nothing in this part relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(b) The regulations in this part apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this part.

(c) The regulations in this part do not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

§ 36.2 Definitions.

Annually means either (1) at intervals not to exceed 1 year or (2) once per year, at about the same time each year (plus or minus 1 month).

Doubly encapsulated sealed source means a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

Irradiator means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

Irradiator operator means an individual who has successfully completed the training and testing described in § 36.51 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

Panoramic dry-source-storage irradiator means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

Panoramic irradiator means an irradiator in which the irradiations are done in air in areas

potentially accessible to personnel. The term includes beam-type irradiators.

Panoramic wet-source-storage irradiator means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

Pool irradiator means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

Product conveyor system means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

Radiation room means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

Radiation safety officer means an individual with responsibility for the overall radiation safety program at the facility.

Sealed source means any byproduct material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Seismic area means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. Geological Survey.

Underwater irradiator means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

§ 36.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission, other than a written interpretation by the General Counsel, will be recognized to be binding upon the Commission.

§ 36.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0158.

(b) The approved information collection requirements contained in this part appear in §§ 36.11, 36.13, 36.17, 36.19, 36.21, 36.53, 36.69, 36.81, and 36.83.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 36.11, NRC Form 313 is approved under control number 3150-0120.

(2) [Reserved]

[58 FR 7728, Feb. 9, 1993, as amended at 62 FR 52187, Oct. 6, 1997]

Subpart B--Specific Licensing Requirements

§ 36.11 Application for a specific license.

A person, as defined in § 30.4 of this chapter, may file an application for a specific license authorizing the use of sealed sources in an irradiator on Form NRC 313, "Application for Material License." Each application for a license, other than a license exempted from part 170 of this chapter, must be accompanied by the fee prescribed in § 170.31 of this chapter. The application and one copy must be sent to the appropriate NRC Regional Office listed in appendix D to part 20 of this chapter.

§ 36.13 Specific licenses for irradiators.

The Commission will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

(a) The applicant shall satisfy the general requirements specified in §§ 30.33(a)(1)–(4) and 30.33(b) of this chapter and the requirements contained in this part.

(b) The application must describe the training provided to irradiator operators including--

(1) Classroom training;

(2) On-the-job or simulator training;

(3) Safety reviews;

(4) Means employed by the applicant to test each operator's understanding of the Commission's regulations and licensing requirements and the irradiator operating and emergency procedures; and

(5) Minimum training and experience of personnel who may provide training.

(c) The application must include an outline of the written operating and emergency procedures listed in § 36.53 that describes the radiation safety aspects of the procedures.

(d) The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

(e) The application must include a description of the access control systems required by § 36.23, the radiation monitors required by § 36.29, the method of detecting leaking sources required by § 36.59 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

(f) If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Commission. The description must include the--

(1) Instruments to be used;

(2) Methods of performing the analysis; and

(3) Pertinent experience of the individual who analyzes the samples.

(g) If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by an organization specifically authorized by the Commission or an Agreement State to load or unload irradiator sources.

(h) The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by § 36.61.

§ 36.15 Start of construction.

The applicant may not begin construction of a new irradiator prior to the submission to NRC of both an application for a license for the irradiator and the fee required by § 170.31. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: Engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Atomic Energy Act of 1954, as amended, and rules, regulations, and orders issued under the Act.

§ 36.17 Applications for exemptions.

(a) The Commission may, upon application of any interested person or upon its own initiative,

grant any exemptions from the requirements in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

(b) Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this part. The Commission will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

§ 36.19 Request for written statements.

(a) After the filing of the original application, the Commission may request further information necessary to enable the Commission to determine whether the application should be granted or denied.

(b) Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Commission's request, submit written statements to enable the Commission to determine whether the license should be modified, suspended, or revoked.

Subpart C--Design and Performance Requirements for Irradiators

§ 36.21 Performance criteria for sealed sources.

(a) *Requirements*. Sealed sources installed after July 1, 1993:

(1) Must have a certificate of registration issued under 10 CFR 32.210;

(2) Must be doubly encapsulated;

(3) Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

(4) Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

(5) In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in paragraphs (b) through (g) of this section.

(b) *Temperature*. The test source must be held at -40ºC for 20 minutes, 600ºC for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600ºC to 20ºC within 15 seconds.

(c) *Pressure*. The test source must be twice subjected for at least 5 minutes to an external pressure (absolute) of 2 million newtons per square meter.

(d) *Impact*. A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

(e) *Vibration*. The test source must be subjected 3 times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of 5 times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.

(f) *Puncture*. A 50-gram weight and pin, 0.3-centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.

(g) *Bend*. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

§ 36.23 Access control.

(a) Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.

(b) In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is onsite of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

(c) A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in paragraph (b) of this section. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

(d) Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

(e) Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

(f) Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

(g) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must be posted as required by 10 CFR 20.1902. Radiation postings for panoramic irradiators must comply with the posting requirements of 10 CFR 20.1902, except that signs may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

(h) If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

(i) Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

§ 36.25 Shielding.

(a) The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (2 millirems) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. Areas where the radiation dose rate exceeds 0.02 millisievert (2 millirems) per hour must be locked, roped off, or posted.

(b) The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (2 millirems) per hour when the sources are in the fully shielded position.

(c) The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 millirems) per hour and at 5 centimeters from the shield may not exceed 0.2 millisievert (20 millirems) per hour.

§ 36.27 Fire protection.

(a) The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is

prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

(b) The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

§ 36.29 Radiation monitors.

(a) Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

(b) Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

§ 36.31 Control of source movement.

(a) The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

(b) The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

(c) The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

(d) Each control for a panoramic irradiator must be clearly marked as to its function.

§ 36.33 Irradiator pools.

(a) For licenses initially issued after July 1, 1993, irradiator pools must either:

(1) Have a water-tight stainless steel liner or a liner metallurgically compatible with other

components in the pool; or

(2) Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

(b) For licenses initially issued after July 1, 1993, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

(c) A means must be provided to replenish water losses from the pool.

(d) A visible indicator must be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

(e) Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

(f) A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

(g) If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 0.02 millisievert (2 millirems) per hour.

§ 36.35 Source rack protection.

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

§ 36.37 Power failures.

(a) If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the shielded position.

(b) The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.

(c) During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

§ 36.39 Design requirements.

Irradiators whose construction begins after July 1, 1993, must meet the design requirements of this section.

(a) *Shielding*. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of § 36.25. If the irradiator will use more than 2×10^{17} becquerels (5 million curies) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

(b) *Foundations*. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

(c) *Pool integrity*. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of § 36.33(b), and that metal components are metallurgically compatible with other components in the pool.

(d) *Water handling system*. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of § 36.33(e). The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

(e) *Radiation monitors*. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by § 36.29(a). The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under § 36.59(b), the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

(f) *Source rack*. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

(g) *Access control*. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of § 36.23.

(h) *Fire protection*. For panoramic irradiators, the licensee shall verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors

are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

(i) *Source return*. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

(j) *Seismic*. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

(k) *Wiring*. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

§ 36.41 Construction monitoring and acceptance testing.

The requirements of this section must be met for irradiators whose construction begins after July 1, 1993. The requirements must be met prior to loading sources.

(a) *Shielding*. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

(b) *Foundations*. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

(c) *Pool integrity*. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of § 36.33(b).

(d) *Water handling system*. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

(e) *Radiation monitors*. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by § 36.29(a). For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet § 36.59(b). For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by § 36.29(b).

(f) *Source rack*. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to

simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in § 36.35 are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

(g) *Access control*. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

(h) *Fire protection*. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.

(i) *Source return*. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

(j) *Computer systems*. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

(k) *Wiring*. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

Subpart D--Operation of Irradiators

§ 36.51 Training.

(a) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

(1) The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, NRC dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator);

(2) The requirements of parts 19 and 36 of NRC regulations that are relevant to the irradiator;

(3) The operation of the irradiator;

(4) Those operating and emergency procedures listed in § 36.53 that the individual is responsible for performing; and

(5) Case histories of accidents or problems involving irradiators.

(b) Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

(c) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

(d) The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following--

(1) Changes in operating and emergency procedures since the last review, if any;

(2) Changes in regulations and license conditions since the last review, if any;

(3) Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

(4) Relevant results of inspections of operator safety performance;

(5) Relevant results of the facility's inspection and maintenance checks; and

(6) A drill to practice an emergency or abnormal event procedure.

(e) The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

(f) Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in § 36.53 that they are expected to perform or comply with, and their proper response to alarms required in this part. Tests may be oral.

(g) Individuals who must be prepared to respond to alarms required by §§ 36.23(b), 36.23(i), 36.27(a), 36.29(a), 36.29(b), and 36.59(b) shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

§ 36.53 Operating and emergency procedures.

(a) The licensee shall have and follow written operating procedures for--

(1) Operation of the irradiator, including entering and leaving the radiation room;

(2) Use of personnel dosimeters;

(3) Surveying the shielding of panoramic irradiators;

(4) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

(5) Leak testing of sources;

(6) Inspection and maintenance checks required by § 36.61;

(7) Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

(8) Inspection of movable shielding required by § 36.23(h), if applicable.

(b) The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for--

(1) Sources stuck in the unshielded position;

(2) Personnel overexposures;

(3) A radiation alarm from the product exit portal monitor or pool monitor;

(4) Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;

(5) A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

(6) A prolonged loss of electrical power;

(7) A fire alarm or explosion in the radiation room;

(8) An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;

(9) Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

(10) The jamming of automatic conveyor systems.

(c) The licensee may revise operating and emergency procedures without Commission approval only if all of the following conditions are met:

(1) The revisions do not reduce the safety of the facility,

(2) The revisions are consistent with the outline or summary of procedures submitted with the license application,

(3) The revisions have been reviewed and approved by the radiation safety officer, and

(4) The users or operators are instructed and tested on the revised procedures before they are put into use.

§ 36.55 Personnel monitoring.

(a) Irradiator operators shall wear a personnel dosimeter while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter must be capable of detecting high energy photons in the normal and accident dose ranges. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and all other personnel dosimeters that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent. ~~Irradiator operators shall wear a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor must be accredited for high energy photons in the normal and accident dose ranges (see 10 CFR 20.1501(c)). Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and other personnel dosimeters must be processed at least quarterly~~.

(b) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose.

[85 FR 15347, Mar. 18, 2020]

§ 36.57 Radiation surveys.

(a) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed 3 years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might

increase dose rates.

(b) If the radiation levels specified in § 36.25 are exceeded, the facility must be modified to comply with the requirements in § 36.25.

(c) Portable radiation survey meters must be calibrated at least annually to an accuracy of ±20 percent for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

(d) Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in 10 CFR part 20, Table 2, Column 2 or Table 3 of appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

(e) Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.5 microsievert (0.05 millirem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.5 microsievert (0.05 millirem) per hour.

§ 36.59 Detection of leaking sources.

(a) Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed 6 months using a leak test kit or method approved by the Commission or an Agreement State. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the Commission or an Agreement State to perform the test.

(b) For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the 6 months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

(c) If a leaking source is detected, the licensee shall arrange to remove the leaking source from

service and have it decontaminated, repaired, or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, appendix B to part 20. (See 10 CFR 30.50 for reporting requirements.)

[58 FR 7728, Feb. 9, 1993, as amended at 58 FR 67660, Dec. 22, 1993]

§ 36.61 Inspection and maintenance.

(a) The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

(1) Operability of each aspect of the access control system required by § 36.23.

(2) Functioning of the source position indicator required by § 36.31(b).

(3) Operability of the radiation monitor for radioactive contamination in pool water required by § 36.59(b) using a radiation check source, if applicable.

(4) Operability of the over-pool radiation monitor at underwater irradiators as required by § 36.29(b).

(5) Operability of the product exit monitor required by § 36.29(a).

(6) Operability of the emergency source return control required by § 36.31(c).

(7) Leak-tightness of systems through which pool water circulates (visual inspection).

(8) Operability of the heat and smoke detectors and extinguisher system required by § 36.27 (but without turning extinguishers on).

(9) Operability of the means of pool water replenishment required by § 36.33(c).

(10) Operability of the indicators of high and low pool water levels required by § 36.33(d).

(11) Operability of the intrusion alarm required by § 36.23(i), if applicable.

(12) Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.

(13) Condition of the barrier to prevent products from hitting the sources or source mechanism as required by § 36.35.

(14) Amount of water added to the pool to determine if the pool is leaking.

(15) Electrical wiring on required safety systems for radiation damage.

(16) Pool water conductivity measurements and analysis as required by § 36.63(b).

(b) Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

§ 36.63 Pool water purity.

(a) Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

(b) The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

§ 36.65 Attendance during operation.

(a) Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite:

(1) Whenever the irradiator is operated using an automatic product conveyor system; and

(2) Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

(b) At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in § 36.51(g) must be onsite.

(c) At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in § 36.51 (f) and (g). Static irradiations may be performed without a person present at the facility.

§ 36.67 Entering and leaving the radiation room.

(a) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

(b) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

(1) Visually inspect the entire radiation room to verify that no one else is in it; and

(2) Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

(c) During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by § 36.29(b) is operating with backup power.

§ 36.69 Irradiation of explosive or flammable materials.

(a) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Commission. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

(b) Irradiation of more than small quantities of flammable material (flash point below 140 F) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Commission. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

Subpart E--Records

§ 36.81 Records and retention periods.

The licensee shall maintain the following records at the irradiator for the periods specified.

(a) A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Commission terminates the license for documents not superseded.

(b) Records of each individual's training, tests, and safety reviews provided to meet the requirements of § 36.51(a), (b), (c), (d), (f), and (g) until 3 years after the individual terminates work.

(c) Records of the annual evaluations of the safety performance of irradiator operators required by

§ 36.51(e) for 3 years after the evaluation.

(d) A copy of the current operating and emergency procedures required by § 36.53 until superseded or the Commission terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by § 36.53(c)(3) retained for 3 years from the date of the change.

(e) Evaluations of personnel dosimeters required by § 36.55 until the Commission terminates the license.

(f) Records of radiation surveys required by § 36.57 for 3 years from the date of the survey.

(g) Records of radiation survey meter calibrations required by § 36.57 and pool water conductivity meter calibrations required by § 36.63(b) until 3 years from the date of calibration.

(h) Records of the results of leak tests required by § 36.59(a) and the results of contamination checks required by § 36.59(b) for 3 years from the date of each test.

(i) Records of inspection and maintenance checks required by § 36.61 for 3 years.

(j) Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for 3 years after repairs are completed.

(k) Records of the receipt, transfer and disposal, of all licensed sealed sources as required by §§ 30.51 and 30.41.

(l) Records on the design checks required by § 36.39 and the construction control checks as required by § 36.41 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

(m) Records related to decommissioning of the irradiator as required by § 30.35(g).

[58 FR 7728, Feb. 9, 1993, as amended at 65 FR 63752, Oct. 24, 2000]

§ 36.83 Reports.

(a) In addition to the reporting requirements in other parts of NRC regulations, the licensee shall report the following events if not reported under other parts of NRC regulations:

(1) Source stuck in an unshielded position.

(2) Any fire or explosion in a radiation room.

(3) Damage to the source racks.

(4) Failure of the cable or drive mechanism used to move the source racks.

(5) Inoperability of the access control system.

(6) Detection of radiation source by the product exit monitor.

(7) Detection of radioactive contamination attributable to licensed radioactive material.

(8) Structural damage to the pool liner or walls.

(9) Abnormal water loss or leakage from the source storage pool.

(10) Pool water conductivity exceeding 100 microsiemens per centimeter.

(b) The report must include a telephone report within 24 hours as described in § 30.50(c)(1), and a written report within 30 days as described in § 30.50(c)(2).

Subpart F--Enforcement

§ 36.91 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

§ 36.93 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 36 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 36 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 36.1, 36.2, 36.5, 36.8, 36.11, 36.13, 36.17, 36.19, 36.91, and 36.93.

CHAPTER 33.1-10-16
DOMESTIC LICENSING OF SOURCE MATERIAL

Section
33.1-10-16-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 40

33.1-10-16-01. Adoption by reference of several sections in 10 Code of Federal Regulations, part 40.

10 Code of Federal Regulations 40.1, 40.2, 40.3, 40.4, 40.7, 40.9, 40.10, 40.11, 40.12, 40.13, 40.14, 40.20, 40.21, 40.22, 40.25, 40.26, 40.31, 40.32, 40.34, 40.35, 40.36, 40.41, 40.42, 40.43, 40.44, 40.45, 40.46, 40.51, 40.54, 40.55, 40.60, 40,61, 40.62, 40.63, 40.65, and 40.71 and appendix A to part 40 are adopted by reference as they exist on May 9, 2022~~December 30, 2019~~, with the following exceptions:

1. Not adopted by reference are 10 Code of Federal Regulations 40.12(b); 40.31(g),(j), (k), and (l); 40.32(d), (e), and (g); 40.41(d), (e)(1), (e)(3), and (g); 40.51(b)(6); appendix A, criterion 11A through F and criterion 12; paragraph (2) of the definition of "commencement of construction"; and paragraph (9)(ii) of the definition of "construction".

2. Requirements in 10 Code of Federal Regulations part 40 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States nuclear regulatory commission", "NRC regional administrator", or "administrator of the appropriate regional office" appear in 10 Code of Federal Regulations part 40, substitute the words "department of environmental quality" except when used in 10 Code of Federal Regulations 40.11.

4. 10 Code of Federal Regulations part 40 employee protection also applies to violations of North Dakota Century Code chapters 23.1-02 and 23.1-03.

5. "Act" includes North Dakota Century Code chapters 23.1-02 and 23.1-03.

6. North Dakota state form number 8414, "notice to employees", must be posted instead of NRC form 3 that is specified in 10 Code of Federal Regulations part 40.

7. North Dakota state form number 16092, "registration certificate: use of depleted uranium under general license", must be used instead of nuclear regulatory commission form 244 that is specified in 10 Code of Federal Regulations part 40.

8. North Dakota state form number 8418, "application for radioactive material license", must be used instead of NRC form 313 as specified in 10 Code of Federal Regulations part 40.

9. North Dakota state form number 18941, "certificate: disposition of radioactive material", must be used instead of NRC form 314 as specified in 10 Code of Federal Regulations part 40.

10. For references to 10 Code of Federal Regulations parts 170 and 171, see chapter 33.1-10-11 for applicable fee schedules.

History: Effective January 1, 2019; amended effective July 1, 2021.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

PART 40--DOMESTIC LICENSING OF SOURCE MATERIAL

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Appendix A to Part 40--Criteria Relating to the Operation of Uranium Mills and the Disposition of Tailings or Wastes Produced by the Extraction or Concentration of Source Material From Ores Processed Primarily for Their Source Material Content

Authority:

Atomic Energy Act of 1954, secs. 62, 63, 64, 65, 69, 81, 83, 84, 122, 161, 181, 182, 183, 184, 186, 187, 193, 223, 234, 274, 275 (42 U.S.C. 2092, 2093, 2094, 2095, 2099, 2111, 2113, 2114, 2152, 2201, 2231, 2232, 2233, 2234, 2236, 2237, 2243, 2273, 2282, 2021, 2022); Energy

Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Uranium Mill Tailings Radiation Control Act of 1978, sec. 104 (42 U.S.C. 7914); 44 U.S.C. 3504 note.

Source: 26 FR 284, Jan. 14, 1961, unless otherwise noted.

[72 FR 63973, Nov. 14, 2007; 73 FR 63570, Oct. 24, 2008; 76 FR 35568, Jun. 17, 2011; 76 FR 69122, Nov. 8, 2011; 76 FR 78805, Dec. 20, 2011; 77 FR 39906, Jul. 6, 2012; 78 FR 32340, May 29, 2013; 80 FR 54234, Sep. 9, 2015]

General Provisions

§ 40.1 Purpose.

(a) The regulations in this part establish procedures and criteria for the issuance of licenses to receive title to, receive, possess, use, transfer, or deliver source and byproduct materials, as defined in this part, and establish and provide for the terms and conditions upon which the Commission will issue such licenses. (Additional requirements applicable to natural and depleted uranium at enrichment facilities are set forth in § 70.22 of this chapter.) These regulations also provide for the disposal of byproduct material and for the long-term care and custody of byproduct material and residual radioactive material. The regulations in this part also establish certain requirements for the physical protection of import, export, and transient shipments of natural uranium. (Additional requirements applicable to the import and export of natural uranium are set forth in part 110 of this chapter.)

(b) The regulations contained in this part are issued under the Atomic Energy Act of 1954, as amended (68 Stat. 919), title II of the Energy Reorganization Act of 1974, as amended (88 Stat. 1242), and titles I and II of the Uranium Mill Tailings Radiation Control Act of 1978, as amended (42 U.S.C. 7901).

[55 FR 45597, Oct. 30, 1990, as amended at 56 FR 55997, Oct. 31, 1991]

§ 40.2 Scope.

Except as provided in §§ 40.11 to 40.14, inclusive, the regulations in this part apply to all persons in the United States. This part also gives notice to all persons who knowingly provide to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 40.10.

[56 FR 40689, Aug. 15, 1991]

§ 40.2a Coverage of inactive tailings sites.

(a) Prior to the completion of the remedial action, the Commission will not require a license pursuant to 10 CFR chapter I for possession of residual radioactive materials as defined in this part that are located at a site where milling operations are no longer active, if the site is covered by the remedial action program of title I of the Uranium Mill Tailings Radiation Control Act of 1978, as amended. The Commission will exert its regulatory role in remedial actions primarily through concurrence and consultation in the execution of the remedial action pursuant to title I of the Uranium Mill Tailings Radiation Control Act of 1978, as amended. After remedial actions are completed, the Commission will license the long-term care of sites, where residual radioactive materials are disposed, under the requirements set out in § 40.27.

(b) The Commission will regulate byproduct material as defined in this part that is located at a site where milling operations are no longer active, if such site is not covered by the remedial action program of title I of the Uranium Mill Tailings Radiation Control Act of 1978. The criteria in appendix A of this part will be applied to such sites.

[45 FR 65531, Oct. 3, 1980, as amended at 55 FR 45598, Oct. 30, 1990]

§ 40.3 License requirements.

A person subject to the regulations in this part may not receive title to, own, receive, possess, use, transfer, provide for long-term care, deliver or dispose of byproduct material or residual radioactive material as defined in this part or any source material after removal from its place of deposit in nature, unless authorized in a specific or general license issued by the Commission under the regulations in this part.

[55 FR 45598, Oct. 30, 1990]

§ 40.4 Definitions.

Act means the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto;

Agreement State means any State with which the Atomic Energy Commission or the Nuclear Regulatory Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended.

Alert means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

Byproduct Material means the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by such solution extraction operations do not constitute "byproduct material" within this definition.

With the exception of "byproduct material" as defined in section 11e. of the Act, other terms defined in section 11 of the Act shall have the same meaning when used in the regulations in this part.

Commencement of construction means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this part that has a reasonable nexus to:

(1) Radiological health and safety.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

Construction means the installation of wells associated with radiological operations (*e.g.*, production, injection, or monitoring well networks associated with in-situ recovery or other facilities), the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the regulations in this part that are related to radiological safety or security. The term "construction" does not include:

(1) Changes for temporary use of the land for public recreational purposes;

(2) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(3) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(4) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part;

(5) Excavation;

(6) Erection of support buildings (*e.g.*, construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(7) Building of service facilities (*e.g.*, paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

(8) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

(9) Taking any other action that has no reasonable nexus to:

(i) Radiological health and safety.

Corporation means the United States Enrichment Corporation (USEC), or its successor, a Corporation that is authorized by statute to lease the gaseous diffusion enrichment plants in Paducah, Kentucky, and Piketon, Ohio, from the Department of Energy, or any person authorized to operate one or both of the gaseous diffusion plants, or other facilities, pursuant to a plan for the privatization of USEC that is approved by the President.

Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits--

(1) Release of the property for unrestricted use and termination of the license; or

(2) Release of the property under restricted conditions and termination of the license.

Department and Department of Energy means the Department of Energy established by the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 et seq.) to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104 (b), (c) and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565 at 577-578, 42 U.S.C. 7151).

Depleted uranium means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

Effective kilogram means (1) for the source material uranium in which the uranium isotope uranium-235 is greater than 0.005 (0.5 weight percent) of the total uranium present: 10,000 kilograms, and (2) for any other source material: 20,000 kilograms.

Foreign obligations means the commitments entered into by the U.S. Government under Atomic Energy Act (AEA) section 123 agreements for cooperation in the peaceful uses of atomic energy. Imports and exports of material or equipment pursuant to such agreements are subject to these commitments, which in some cases involve an exchange of information on imports, exports, retransfers with foreign governments, peaceful end-use assurances, and other conditions placed on the transfer of the material or equipment. The U.S. Government informs the licensee of obligations attached to material.

Government agency means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

License, except where otherwise specified, means a license issued pursuant to the regulations in this part.

Persons means: (1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department of Energy except that the Department of Energy shall be considered a person within the meaning of the regulations in this part to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244) and the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), any State or any political subdivision of, or any political entity within a State, any foreign government or nation or any subdivision of any such government or nation, or other entity; and (2) any legal successor, representative, agent or agency of the foregoing.

Pharmacist means an individual registered by a state or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to compound and dispense drugs, prescriptions and poisons.

Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

Principal activities, as used in this part, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

Reconciliation means the process of evaluating and comparing licensee reports required under this part to the projected material balances generated by the Nuclear Materials Management and Safeguards System. This process is considered complete when the licensee resolves any differences between the reported and projected balances, including those listed for foreign obligated materials.

Residual radioactive material means: (1) Waste (which the Secretary of Energy determines to be radioactive) in the form of tailings resulting from the processing of ores for the extraction of uranium and other valuable constituents of the ores; and (2) other waste (which the Secretary of Energy determines to be radioactive) at a processing site which relates to such processing, including any residual stock of unprocessed ores or low-grade materials. This term is used only with respect to materials at sites subject to remediation under title I of the Uranium Mill Tailings

Radiation Control Act of 1978, as amended.

Site area emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

Source Material means: (1) Uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05%) or more of: (i) Uranium, (ii) thorium or (iii) any combination thereof. Source material does not include special nuclear material.

Special nuclear material means: (1) Plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material; or (2) any material artificially enriched by any of the foregoing.

Transient shipment means a shipment of nuclear material, originating and terminating in foreign countries, on a vessel or aircraft that stops at a United States port.

United States, when used in a geographical sense, includes Puerto Rico and all territories and possessions of the United States.

Unrefined and unprocessed ore means ore in its natural form prior to any processing, such as grinding, roasting or beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

Uranium enrichment facility means:

(1) Any facility used for separating the isotopes of uranium or enriching uranium in the isotope 235, except laboratory scale facilities designed or used for experimental or analytical purposes only; or

(2) Any equipment or device, or important component part especially designed for such equipment or device, capable of separating the isotopes of uranium or enriching uranium in the isotope 235.

Uranium Milling means any activity that results in the production of byproduct material as defined in this part.

[26 FR 284, Jan. 14, 1961; 73 FR 32461, Jun. 9, 2008; 76 FR 56963, Sep. 15, 2011; 78 FR 32338, May 29, 2013]Editorial Note: For Federal Register citations affecting § 40.4, see the List of CFR Sections Affected in the Finding Aids section.

§ 40.5 Communications.

(a) Unless otherwise specified or covered under the regional licensing program as provided in paragraph (b) of this section, any communication or report concerning the regulations in this part and any application filed under these regulations may be submitted to the Commission as follows:

(1) By mail addressed: ATTN: Document Control Desk, Director, Office of Nuclear Material Safety and Safeguards, or Director, Office of Nuclear Security, or Director, Office of Nuclear Security and Incident Response, as appropriate, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

(2) By hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland.

(3) Where practicable, by electronic submission, for example, via Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html*, by calling (301) 415-0439, by e-mail to *EIE@nrc.gov*, or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information.

(b) The Commission has delegated to the four Regional Administrators licensing authority for selected parts of its decentralized licensing program for nuclear materials as described in paragraph (b)(1) of this section. Any communication, report, or application covered under this licensing program must be submitted to the appropriate Regional Administrator. The administrators' jurisdictions and mailing addresses are listed in paragraph (b)(2) of this section.

(1) The delegated licensing program includes authority to issue, renew, amend, cancel, modify, suspend, or revoke licenses for nuclear materials issued pursuant to 10 CFR parts 30 through 36, 39, 40, and 70 to all persons for academic, medical, and industrial uses, with the following exceptions:

(i) Activities in the fuel cycle and special nuclear material in quantities sufficient to constitute a critical mass in any room or area. This exception does not apply to license modifications relating to termination of special nuclear material licenses that authorize possession of larger quantities when the case is referred for action from NRC's Headquarters to the Regional Administrators.

(ii) Health and safety design review of sealed sources and devices and approval, for licensing purposes, of sealed sources and devices.

(iii) Processing of source material for extracting of metallic compounds (including Zirconium, Hafnium, Tantalum, Titanium, Niobium, etc.).

(iv) Distribution of products containing radioactive material to persons exempt pursuant to 10 CFR 32.11 through 32.26.

(v) New uses or techniques for use of byproduct, source, or special nuclear material.

(vi) Uranium enrichment facilities.

(2) *Submission*--(i) *Region I*. The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region I non-Agreement States and the District of Columbia: Connecticut, Delaware, Maine, Massachusetts, New Jersey, Pennsylvania, and Vermont. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment or renewal of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region I, Nuclear Material Section B, 475 Allendale Road, Suite 102, King of Prussia, Pennsylvania 19406-1415; where e-mail is appropriate it should be addressed to *RidsRgn1MailCenter@nrc.gov*.

(ii) *Region II*. The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region II non-Agreement states and territories: Virginia, West Virginia, Puerto Rico, and the Virgin Islands. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment or renewal of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region I, Nuclear Material Section B, 475 Allendale Road, Suite 102, King of Prussia, PA 19406-1415~~U.S. Nuclear Regulatory Commission, Region II Material Licensing/Inspection Branch, Sam Nunn Atlanta Federal Center, Suite 23T85, 61 Forsyth Street, Atlanta, Georgia 30303-8931~~; where e-mail is appropriate it should be addressed to *RidsRgn2MailCenter@nrc.gov*.

(iii) *Region III.* The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region III non-Agreement States: Indiana, Michigan, Minnesota, Missouri, Ohio, and Wisconsin. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, or renewal of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region III, Material Licensing Section, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352; where e-mail is appropriate it should be addressed to *RidsRgn3MailCenter@nrc.gov*.

(iv) *Region IV*. The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region IV non-Agreement States and a territory: Alaska, Hawaii, Montana, Oklahoma, South Dakota, Wyoming, and Guam. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment or renewal of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region IV, Material Radiation Protection Section, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011-4005; where e-mail is appropriate it should be

addressed to *RidsRgn4MailCenter@nrc.gov*.

[48 FR 16031, Apr. 14, 1983, as amended at 49 FR 19631, May 9, 1984; 49 FR 47824, Dec. 7, 1984; 50 FR 14694, Apr. 15, 1985; 51 FR 36001, Oct. 8, 1986; 52 FR 8241, Mar. 17, 1987; 52 FR 38392, Oct. 16, 1987; 52 FR 48093, Dec. 18, 1987; 53 FR 3862, Feb. 10, 1988; 53 FR 43420, Oct. 27, 1988; 57 FR 18390, Apr. 30, 1992; 58 FR 7736, Feb. 9, 1993; 58 FR 64111, Dec. 6, 1993; 59 FR 17466, Apr. 13, 1994; 60 FR 24551, May 9, 1995; 62 FR 22880, Apr. 28, 1997; 68 FR 58806, Oct. 10, 2003; 70 FR 69421, Nov. 16, 2005; 71 FR 15011, Mar. 27, 2006; 72 FR 33386, Jun. 18, 2007; 73 FR 5720, Jan. 31, 2008; 74 FR 62681, Dec. 1, 2009; 75 FR 21980, Apr. 27, 2010; 75 FR 73943, Nov. 30, 2010; 76 FR 72085, Nov. 22, 2011; 77 FR 39906, Jul. 6, 2012; 77 FR 43696, Jul. 25, 2012; 78 FR 32338, May 29, 2013; 79 FR 75740, Dec. 19, 2014; 87 FR 20693, Apr. 8, 2022]

§ 40.6 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 40.7 Employee protection.

(a) Discrimination by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(1) The protected activities include but are not limited to:

(i) Providing the Commission or his or her employer information about alleged violations of either of the statutes named in paragraph (a) introductory text of this section or possible violations of requirements imposed under either of those statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) introductory text or under these requirements if the employee has identified the alleged illegality to the employer;

(iii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in

paragraph (a) introductory text.

(v) Assisting or participating in, or is about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraphs (a), (e), or (f) of this section by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant may be grounds for--

(1) Denial, revocation, or suspension of the license.

(2) Imposition of a civil penalty on the licensee, applicant, or a contractor or subcontractor of the licensee or applicant.

(3) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each specific licensee, each applicant for a specific license, and each general licensee subject to part 19 shall prominently post the revision of NRC Form 3, "Notice to Employees", referenced in 10 CFR 19.11(c).

(2) The posting of NRC Form 3 must be at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted

not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license termination.

(3) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of this chapter, by calling (301) 415-5877, via e-mail to *forms@nrc.gov*, or by visiting the NRC's Web site at *http://www.nrc.gov* and selecting forms from the index found on the home page.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to section 211 of the Energy Reorganization Act of 1974, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in paragraph (a)(1) of this section including, but not limited to, providing information to the NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

[58 FR 52409, Oct. 8, 1993, as amended at 60 FR 24551, May 9, 1995; 61 FR 6765, Feb. 22, 1996; 68 FR 58806, Oct. 10, 2003; 72 FR 63973, Nov. 14, 2007; 79 FR 66603, Nov. 10, 2014]

§ 40.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0020.

(b) The approved information collection requirements contained in this part appear in §§ 40.9, 40.14, 40.23, 40.25, 40.26, 40.27, 40.31, 40.35, 40.36, 40.41, 40.42, 40.43, 40.44, 40.51, 40.60, 40.61, 40.64, 40.65, 40.66, 40.67, and appendix A to this part.

(c) This Part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In §§ 40.31, 40.43, 40.44, and appendix A, NRC Form 313 is approved under control number 3150-0120.

(2) In § 40.31, DOC/NRC Forms AP–1, AP–A, and associated forms are approved under control numbers 0694–0135.

(3) In § 40.31, ~~Forms N–71 and associated forms~~IAEA Design Information Questionnaire forms are approved under control number 3150–0056.

(4) In § 40.42, NRC Form 314 is approved under control number 3150–0028.

(5) In § 40.64, DOE/NRC Form 741 is approved under control number 3150–0003.

[49 FR 19626, May 9, 1984, as amended at 56 FR 40768, Aug. 16, 1991; 58 FR 68731, Dec. 29, 1993; 62 FR 52187, Oct. 6, 1997; 73 FR 78604, Dec. 23, 2008; 77 FR 39906, Jul. 6, 2012; 78 FR 32338, May 29, 2013; 85 FR 65656, Oct. 16, 2020]

§ 40.9 Completeness and accuracy of information.

(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

(b) Each applicant or licensee shall notify the Commission of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or common defense and security. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Commission of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification shall be provided to the Administrator of the appropriate Regional Office within two working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or undating requirements.

[52 FR 49371, Dec. 31, 1987]

§ 40.10 Deliberate misconduct.

(a) Any licensee, applicant for a license, employee of a licensee or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or applicant for a license, who knowingly provides to any licensee, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities in this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or

(2) Deliberately submit to the NRC, a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be

incomplete or inaccurate in some respect material to the NRC.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

(c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

[63 FR 1896, Jan. 13, 1998]

Exemptions

§ 40.11 Persons using source material under certain Department of Energy and Nuclear Regulatory Commission contracts.

Except to the extent that Department facilities or activities of the types subject to licensing pursuant to section 202 of the Energy Reorganization Act of 1974 or the Uranium Mill Tailings Radiation Control Act of 1978 are involved, any prime contractor of the Department is exempt from the requirements for a license set forth in sections 62, 63, and 64 of the Act and from the regulations in this part to the extent that such contractor, under his prime contract with the Department, receives, possesses, uses, transfers or delivers source material for: (a) The performance of work for the Department at a United States Government-owned or controlled site, including the transportation of source material to or from such site and the performance of contract services during temporary interruptions of such transportation; (b) research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or (c) the use or operation of nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel. In addition to the foregoing exemptions, and subject to the requirement for licensing of Department facilities and activities pursuant to section 202 of the Energy Reorganization Act of 1974 or the Uranium Mill Tailings Radiation Control Act of 1980, any prime contractor or subcontractor of the Department or the Commission is exempt from the requirements for a license set forth in sections 62, 63, and 64 of the Act and from the regulations in this part to the extent that such prime contractor or subcontractor receives, possesses, uses, transfers or delivers source material under his prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

[40 FR 8787, Mar. 3, 1975, as amended at 43 FR 6923, Feb. 17, 1978; 45 FR 65531, Oct. 3,

1980]

§ 40.12 Carriers.

(a) Except as specified in paragraph (b) of this section, common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the regulations in this part and the requirements for a license set forth in section 62 of the Act to the extent that they transport or store source material in the regular course of the carriage for another or storage incident thereto.

(b) The exemption in paragraph (a) of this section does not apply to a person who possesses a transient shipment (as defined in § 40.4(r)), an import shipment, or an export shipment of natural uranium in an amount exceeding 500 kilograms, unless the shipment is in the form of ore or ore residue.

[52 FR 9651, Mar. 26, 1987]

§ 40.13 Unimportant quantities of source material.

(a) Any person is exempt from the regulations in this part and from the requirements for a license set forth in section 62 of the Act to the extent that such person receives, possesses, uses, transfers or delivers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than one-twentieth of 1 percent (0.05 percent) of the mixture, compound, solution or alloy. The exemption contained in this paragraph does not include byproduct material as defined in this part.

(b) Any person is exempt from the regulations in this part and from the requirements for a license set forth in section 62 of the act to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided, that, except as authorized in a specific license, such person shall not refine or process such ore.

(c) Any person is exempt from the requirements for a license set forth in section 62 of the Act and from the regulations in this part and parts 19, 20, and 21 of this chapter to the extent that such person receives, possesses, uses, or transfers: (1) Any quantities of thorium contained in (i) incandescent gas mantles, (ii) vacuum tubes, (iii) welding rods, (iv) electric lamps for illuminating purposes: *Provided*, That each lamp does not contain more than 50 milligrams of thorium, (v) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting: *Provided*, That each lamp does not contain more than 2 grams of thorium, (vi) rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or (vii) personnel neutron dosimeters: *Provided*, That each dosimeter does not contain more than 50 milligrams of thorium.

(2) Source material contained in the following products:

(i) Glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20 percent by weight source material;

(ii) Piezoelectric ceramic containing not more than 2 percent by weight source material;

(iii) Glassware containing not more than 2 percent by weight source material or, for glassware manufactured before August 27, 2013, 10 percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction;

(iv) Glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983.[1]

(3) Photographic film, negatives, and prints containing uranium or thorium;

(4) Any finished product or part fabricated of, or containing tungsten or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that the exemption contained in this subparagraph shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such product or part; and

(5) Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights: *Provided*, That:

(i) Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";[2]

(ii) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer, and the statement: "Unauthorized Alterations Prohibited";[2] and

(iii) The exemption contained in this paragraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

(6) Natural or depleted uranium metal used as shielding constituting part of any shipping container: *Provided*, That:

(i) The shipping container is conspicuously and legibly impressed with the legend "CAUTION--RADIOACTIVE SHIELDING--URANIUM"; and

(ii) The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of one-eighth inch (3.2 mm).

(7) Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than 10 percent by weight thorium or uranium or, for lenses manufactured before August 27, 2013, 30 percent by weight of thorium; and that the exemption contained in this paragraph does not authorize either:

(i) The shaping, grinding or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

(ii) The receipt, possession, use, or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

(8) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, *Provided*, That:

(i) The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

(ii) The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

(9) The exemptions in this paragraph (c) do not authorize the manufacture of any of the products described.

(10) No person may initially transfer for sale or distribution a product containing source material to persons exempt under this paragraph (c), or equivalent regulations of an Agreement State, unless authorized by a license issued under § 40.52 to initially transfer such products for sale or distribution.

(i) Persons initially distributing source material in products covered by the exemptions in this paragraph (c) before August 27, 2013, without specific authorization may continue such distribution for 1 year beyond this date. Initial distribution may also be continued until the Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than 1 year beyond this date.

(ii) Persons authorized to manufacture, process, or produce these materials or products containing source material by an Agreement State, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under § 40.52 for distribution only and are exempt from the requirements of parts 19 and 20 of this chapter, and § 40.32(b) and (c).

[26 FR 284, Jan. 14, 1961; 76 FR 69122, Nov. 8, 2011; 76 FR 78805, Dec. 20, 2011; 78 FR 32338, May 29, 2013]

Editorial Note: For Federal Register citations affecting § 40.13, see the List of CFR Sections

Affected in the Finding Aids section.

[1] On July 25, 1983, the exemption of glass enamel or glass enamel frit was suspended. The exemption was eliminated on September 11, 1984.

[2] The requirements specified in paragraphs (c)(5) (i) and (ii) of this section need not be met by counterweights manufactured prior to Dec. 31, 1969: provided that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were impressed with the legend required by § 40.13(c)(5)(ii) in effect on June 30, 1969.

§ 40.14 Specific exemptions.

(a) The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulation in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

(b) [Reserved]

(c) The Department of Energy is exempt from the requirements of this part to the extent that its activities are subject to the requirements of part 60 or 63 of this chapter.

(d) Except as specifically provided in part 61 of this chapter any licensee is exempt from the requirements of this part to the extent that its activities are subject to the requirements of part 61 of this chapter.

[37 FR 5747, Mar. 21, 1972, as amended at 39 FR 26279, July 18, 1974; 40 FR 8787, Mar. 3, 1975; 45 FR 65531, Oct. 3, 1980; 46 FR 13979, Feb. 25, 1981; 47 FR 57481, Dec. 27, 1982; 66 FR 55790, Nov. 2, 2001]

General Licenses

§ 40.20 Types of licenses.

(a) Licenses for source material and byproduct material are of two types: general and specific. Licenses for long-term care and custody of residual radioactive material at disposal sites are general licenses. The general licenses provided in this part are effective without the filing of applications with the Commission or the issuance of licensing documents to particular persons. Specific licenses are issued to named persons upon applications filed pursuant to the regulations in this part.

(b) Section 40.27 contains a general license applicable for custody and long-term care of residual radioactive material at uranium mill tailings disposal sites remediated under title I of the Uranium Mill Tailings Radiation Control Act of 1978, as amended.

(c) Section 40.28 contains a general license applicable for custody and long-term care of byproduct material at uranium or thorium mill tailings disposal sites under title II of the Uranium Mill Tailings Radiation Control Act of 1978, as amended.

[55 FR 45598, Oct. 30, 1990]

§ 40.21 General license to receive title to source or byproduct material.

A general license is hereby issued authorizing the receipt of title to source or byproduct material, as defined in this part, without regard to quantity. This general license does not authorize any person to receive, possess, deliver, use, or transfer source or byproduct material.

[45 FR 65531, Oct. 3, 1980]

§ 40.22 Small quantities of source material.

(a) A general license is hereby issued authorizing commercial and industrial firms; research, educational, and medical institutions; and Federal, State, and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

(1) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of August 27, 2013, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the Commission takes final action on a pending application submitted on or before August 27, 2014, for a specific license for such material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2014, or until the Commission takes final action on a pending application submitted on or before August 27, 2014, for a specific license for such material; and

(2) No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this paragraph unless it is accounted for under the limits of paragraph (a)(1) of this section; or

(3) No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this paragraph; or

(4) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

(b) Any person who receives, possesses, uses, or transfers source material in accordance with the general license in paragraph (a) of this section:

(1) Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the NRC in a specific license.

(2) Shall not abandon such source material. Source material may be disposed of as follows:

(i) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this paragraph is exempt from the requirements to obtain a license under this part to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under this chapter; or

(ii) In accordance with § 20.2001 of this chapter.

(3) Is subject to the provisions in §§ 40.1 through 40.10, 40.41(a) through (e), 40.46, 40.51, 40.56, 40.60 through 40.63, 40.71, and 40.81.

(4) Shall respond to written requests from the NRC to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the person cannot provide the requested information within the allotted time, the person shall, within that same time period, request a longer period to supply the information by providing the Director of the Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in § 40.5(a), a written justification for the request;

(5) Shall not export such source material except in accordance with part 110 of this chapter.

(c) Any person who receives, possesses, uses, or transfers source material in accordance with paragraph (a) of this section shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in § 40.5(a) about such contamination and may consult with the NRC as to the

appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in § 20.1402 of this chapter.

(d) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in paragraph (a) of this section is exempt from the provisions of parts 19, 20, and 21 of this chapter to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of §§ 20.1402 and 20.2001 of this chapter to the extent necessary to meet the provisions of paragraphs (b)(2) and (c) of this section. However, this exemption does not apply to any person who also holds a specific license issued under this chapter.

(e) No person may initially transfer or distribute source material to persons generally licensed under paragraph (a)(1) or (2) of this section, or equivalent regulations of an Agreement State, unless authorized by a specific license issued in accordance with § 40.54 or equivalent provisions of an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by paragraph (a) of this section before August 27, 2013, without specific authorization may continue for 1 year beyond this date. Distribution may also be continued until the Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before August 27, 2014.

[26 FR 284, Jan. 14, 1961, as amended at 38 FR 22221, Aug. 17, 1973; 42 FR 28896, June 6, 1977; 45 FR 55420, Aug. 20, 1980; 78 FR 32339, May 29, 2013; 79 FR 75740, Dec. 19, 2014]

§ 40.23 General license for carriers of transient shipments of natural uranium other than in the form of ore or ore residue.

(a) A general license is hereby issued to any person to possess a transient shipment of natural uranium, other than in the form of ore or ore residue, in amounts exceeding 500 kilograms.

(b)(1) Persons generally licensed under paragraph (a) of this section, who plan to carry a transient shipment with scheduled stops at a United States port, shall notify the Director Office of Nuclear Security and Incident Response, by email (preferred method) to AdvanceNotifications.Resource@nrc.gov or using an appropriate method listed in § 40.5. The notification must be in writing and must be received at least 10 days before transport of the shipment commences at the shipping facility. ~~Persons generally licensed under paragraph (a) of this section, who plan to carry a transient shipment with scheduled stops at a United States port, shall notify the Director, Office of Nuclear Security and Incident Response, using an appropriate method listed in § 40.5. The notification must be in writing and must be received at least 10 days before transport of the shipment commences at the shipping facility.~~

(2) The notification must include the following information:

(i) Location of all scheduled stops in United States territory;

(ii) Arrival and departure times for all scheduled stops in United States territory;

(iii) The type of transport vehicle;

(iv) A physical description of the shipment;

(v) The numbers and types of containers;

(vi) The name and telephone number of the carrier's representatives at each stopover location in the United States territory;

(vii) A listing of the modes of shipments, transfer points, and routes to be used;

(viii) The estimated date and time that shipment will commence and that each nation (other than the United States) along the route is scheduled to be entered;

(ix) For shipment between countries that are not party to the Convention on the Physical Protection of Nuclear Material (i.e., not listed in appendix F to part 73 of this chapter), a certification that arrangements have been made to notify the Director, Office of Nuclear Security and Incident Response when the shipment is received at the destination facility.

(c) Persons generally licensed under this section making unscheduled stops at United States ports, immediately after the decision to make an unscheduled stop, shall provide to the Director, Division of Physical and Cyber Security Policy the information required under paragraph (b) of this section.

(d) A licensee who needs to amend a notification may do so by telephoning the Division of Physical and Cyber Security Policy at 301-287-3598.

[52 FR 9651, Mar. 26, 1987, as amended at 53 FR 4110, Feb. 12, 1988; 60 FR 24551, May 9, 1995; 68 FR 58807, Oct. 10, 2003; 74 FR 62681, Dec. 1, 2009; 83 FR 57231, Nov. 21, 2018; 86 FR 67839, Nov. 30, 2021]

§ 40.24 [Reserved]

§ 40.25 General license for use of certain industrial products or devices.

(a) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of paragraphs (b), (c), (d), and (e) of this section, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(b) The general license in paragraph (a) of this section applies only to industrial products or devices which have been manufactured or initially transferred in accordance with a specific license issued pursuant to § 40.34 (a) of this part or in accordance with a specific license issued by an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the Agreement State.

(c)(1) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by paragraph (a) of this section shall file NRC Form 244, "Registration Certificate—Use of Depleted Uranium Under General License," with the Director, Office of Federal and State Materials and Environmental Management Programs, by an appropriate method listed in § 40.5, with a copy to the appropriate NRC Regional Administrator. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on NRC Form 244 the following information and such other information as may be required by that form:

(i) Name and address of the registrant;

(ii) A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in paragraph (a) of this section and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(iii) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in paragraph (c)(1)(ii) of this section.

(2) The registrant possessing or using depleted uranium under the general license established by paragraph (a) of this section shall report in writing to the Director, Office of Federal and State Materials and Environmental Management Programs, with a copy to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D of part 20 of this chapter, any changes in information furnished by him in the NRC Form 244 "Registration Certificate—Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

(d) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by paragraph (a) of this section:

(1) Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.

(2) Shall not abandon such depleted uranium.

(3) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the

provisions of § 40.51 of this part. In the case where the transferee receives the depleted uranium pursuant to the general license established by paragraph (a) of this section, the transferor shall furnish the transferee a copy of this section and a copy of Form NRC 244. In the case where the transferee receives the depleted uranium pursuant to a general license contained in an Agreement State's regulation equivalent to this section, the transferor shall furnish the transferee a copy of this section and a copy of Form NRC 244 accompanied by a note explaining that use of the product or device is regulated by the Agreement State under requirements substantially the same as those in this section.

(4) Within 30 days of any transfer, shall report in writing to the Director, Office of Federal and State Materials and Environmental Management Programs, with a copy to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D of part 20 of this chapter, the name and address of the person receiving the source material pursuant to such transfer.

(e) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by paragraph (a) of this section is exempt from the requirements of parts 19, 20 and 21 of this chapter with respect to the depleted uranium covered by that general license.

[41 FR 53331, Dec. 6, 1976, as amended at 42 FR 28896, June 6, 1977; 43 FR 6923, Feb. 17, 1978; 43 FR 52202, Nov. 9, 1978; 52 FR 31611, Aug. 21, 1987; 60 FR 24551, May 9, 1995; 68 FR 58807, Oct. 10, 2003; 73 FR 5720, Jan. 31, 2008; 79 FR 75740, Dec. 19, 2014]

§ 40.26 General license for possession and storage of byproduct material as defined in this part.

(a) A general license is hereby issued to receive title to, own, or possess byproduct material as defined in this part without regard to form or quantity.

(b) The general license in paragraph (a) of this section applies only: In the case of licensees of the Commission, where activities that result in the production of byproduct material are authorized under a specific license issued by the Commission pursuant to this part, to byproduct material possessed or stored at an authorized disposal containment area or transported incident to such authorized activity: Provided, That authority to receive title to, own, or possess byproduct material under this general license shall terminate when the specific license for source material expires, is renewed, or is amended to include a specific license for byproduct material as defined in this part.

(c) The general license in paragraph (a) of this section is subject to:

(1) The provisions of parts 19, 20, 21, and §§ 40.1, 40.2a, 40.3, 40.4, 40.5, 40.6, 40.41, 40.46, 40.60, 40.61, 40.62, 40.63, 40.65, 40.71, and 40.81 of part 40 of this chapter; and

(2) The documentation of daily inspections of tailings or waste retention systems and the immediate notification of the appropriate NRC regional office as indicated in appendix D to part 20 of this chapter, or the Director, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, of any failure in a tailings or waste retention system that results in a release of tailings or waste into unrestricted areas, or of any unusual conditions (conditions not contemplated in the design of the retention system) that if not corrected could lead to failure of the system and result in a release of tailings or waste into unrestricted areas; and any additional requirements the Commission may by order deem necessary. The licensee shall retain this documentation of each daily inspection as a record for three years after each inspection is documented.

(d) The general license in paragraph (a) of this section shall expire nine months from the effective date of this subparagraph unless an applicable licensee has submitted, pursuant to the provisions of § 40.31 of this part, an application for license renewal or amendment which includes a detailed program for meeting the technical and financial criteria contained in appendix A of this part.

[44 FR 50014, Aug. 24, 1979, as amended at 45 FR 12377, Feb. 26, 1980; 45 FR 65531, Oct. 3, 1980; 53 FR 19248, May 27, 1988; 56 FR 40768, Aug. 16, 1991; 73 FR 5720, Jan. 31, 2008; 79 FR 75740, Dec. 19, 2014]

§ 40.27 General license for custody and long-term care of residual radioactive material disposal sites.

(a) A general license is issued for the custody of and long-term care, including monitoring, maintenance, and emergency measures necessary to protect public health and safety and other actions necessary to comply with the standards promulgated under section 275(a) of the Atomic Energy Act of 1954, as amended, for disposal sites under title I of the Uranium Mill Tailings Radiation Control Act of 1978, as amended. The license is available only to the Department of Energy, or another Federal agency designated by the President to provide long-term care. The purpose of this general license is to ensure that uranium mill tailings disposal sites will be cared for in such a manner as to protect the public health, safety, and the environment after remedial action has been completed.

(b) The general license in paragraph (a) of this section becomes effective when the Commission accepts a site Long-Term Surveillance Plan (LTSP) that meets the requirements of this section, and when the Commission concurs with the Department of Energy's determination of completion of remedial action at each disposal site. There is no termination of this general license. The LTSP may incorporate by reference information contained in documents previously submitted to the Commission if the references to the individual incorporated documents are clear and specific. Each LTSP must include--

(1) A legal description of the disposal site to be licensed, including documentation on whether

land and interests are owned by the United States or an Indian tribe. If the site is on Indian land, then, as specified in the Uranium Mill Tailings Radiation Control Act of 1978, as amended, the Indian tribe and any person holding any interest in the land shall execute a waiver releasing the United States of any liability or claim by the Tribe or person concerning or arising from the remedial action and holding the United States harmless against any claim arising out of the performance of the remedial action;

(2) A detailed description, which can be in the form of a reference, of the final disposal site conditions, including existing ground water characterization and any necessary ground water protection activities or strategies. This description must be detailed enough so that future inspectors will have a baseline to determine changes to the site and when these changes are serious enough to require maintenance or repairs. If the disposal site has continuing aquifer restoration requirements, then the licensing process will be completed in two steps. The first step includes all items other than ground water restoration. Ground water monitoring, which would be addressed in the LTSP, may still be required in this first step to assess performance of the tailings disposal units. When the Commission concurs with the completion of ground water restoration, the licensee shall assess the need to modify the LTSP and report results to the Commission. If the proposed modifications meet the requirements of this section, the LTSP will be considered suitable to accommodate the second step.

(3) A description of the long-term surveillance program, including proposed inspection frequency and reporting to the Commission (as specified in appendix A, criterion 12 of this part), frequency and extent of ground water monitoring if required, appropriate constituent concentration limits for ground water, inspection personnel qualifications, inspection procedures, recordkeeping and quality assurance procedures;

(4) The criteria for follow-up inspections in response to observations from routine inspections or extreme natural events; and

(5) The criteria for instituting maintenance or emergency measures.

(c) The long-term care agency under the general license established by paragraph (a) of this section shall--

(1) Implement the LTSP as described in paragraph (b) of this section;

(2) Care for the disposal site in accordance with the provisions of the LTSP;

(3) Notify the Commission of any changes to the LTSP; the changes may not conflict with the requirements of this section;

(4) Guarantee permanent right-of-entry to Commission representatives for the purpose of periodic site inspections; and

(5) Notify the Commission prior to undertaking any significant construction, actions, or repairs related to the disposal site, even if the action is required by a State or another Federal agency.

(d) As specified in the Uranium Mill Tailings Radiation Control Act of 1978, as amended, the Secretary of the Interior, with the concurrence of the Secretary of Energy and the Commission, may sell or lease any subsurface mineral rights associated with land on which residual radioactive materials are disposed. In such cases, the Commission shall grant a license permitting use of the land if it finds that the use will not disturb the residual radioactive materials or that the residual radioactive materials will be restored to a safe and environmentally sound condition if they are disturbed by the use.

(e) The general license in paragraph (a) of this section is exempt from parts 19, 20, and 21 of this chapter, unless significant construction, actions, or repairs are required. If these types of actions are to be undertaken, the licensee shall explain to the Commission which requirements from these parts apply for the actions and comply with the appropriate requirements.

[55 FR 45598, Oct. 30, 1990]

§ 40.28 General license for custody and long-term care of uranium or thorium byproduct materials disposal sites.

(a) A general license is issued for the custody of and long-term care, including monitoring, maintenance, and emergency measures necessary to protect the public health and safety and other actions necessary to comply with the standards in this part for uranium or thorium mill tailings sites closed under title II of the Uranium Mill Tailings Radiation Control Act of 1978, as amended. The licensee will be the Department of Energy, another Federal agency designated by the President, or a State where the disposal site is located. The purpose of this general license is to ensure that uranium and thorium mill tailings disposal sites will be cared for in such a manner as to protect the public health, safety, and the environment after closure.

(b) The general license in paragraph (a) of this section becomes effective when the Commission terminates, or concurs in an Agreement State's termination of, the current specific license and a site Long-Term Surveillance Plan (LTSP) meeting the requirements of this section has been accepted by the Commission. There is no termination of this general license. If the LTSP has not been formally received by the NRC prior to termination of the current specific license, the Commission may issue a specific order to the intended custodial agency to ensure continued control and surveillance of the disposal site to protect the public health, safety, and the environment. The Commission will not unnecessarily delay the termination of the specific license solely on the basis that an acceptable LTSP has not been received. The LTSP may incorporate by reference information contained in documents previously submitted to the Commission if the references to the individual incorporated documents are clear and specific. Each LTSP must include--

(1) A legal description of the disposal site to be transferred (unless transfer is exempted under

provisions of the Atomic Energy Act, § 83(b)(1)(A)) and licensed;

(2) A detailed description, which can be in the form of a reference of the final disposal site conditions, including existing ground water characterization. This description must be detailed enough so that future inspectors will have a baseline to determine changes to the site and when these changes are serious enough to require maintenance or repairs;

(3) A description of the long-term surveillance program, including proposed inspection frequency and reporting to the Commission (as specified in appendix A, Criterion 12 of this part), frequency and extent of ground water monitoring if required, appropriate constituent concentration limits for ground water, inspection personnel qualifications, inspection procedures, recordkeeping and quality assurance procedures;

(4) The criteria for follow-up inspections in response to observations from routine inspections or extreme natural events; and

(5) The criteria for instituting maintenance or emergency measures.

(c) The long-term care agency who has a general license established by paragraph (a) of this section shall--

(1) Implement the LTSP as described in paragraph (b) of this section;

(2) Care for the disposal site in accordance with the provisions of the LTSP;

(3) Notify the Commission of any changes to the LTSP; the changes may not conflict with the requirements of this section;

(4) Guarantee permanent right-of-entry to Commission representatives for the purpose of periodic site inspections; and

(5) Notify the Commission prior to undertaking any significant construction, actions, or repairs related to the disposal site, even if the action is required by a State or another Federal agency.

(d) Upon application, the Commission may issue a specific license, as specified in the Uranium Mill Tailings Radiation Control Act of 1978, as amended, permitting the use of surface and/or subsurface estates transferred to the United States or a State. Although an application may be received from any person, if permission is granted, the person who transferred the land to DOE or the State shall receive the right of first refusal with respect to this use of the land. The application must demonstrate that--

(1) The proposed action does not endanger the public health, safety, welfare, or the environment;

(2) Whether the proposed action is of a temporary or permanent nature, the site would be

maintained and/or restored to meet requirements in appendix A of this part for closed sites; and

(3) Adequate financial arrangements are in place to ensure that the byproduct materials will not be disturbed, or if disturbed that the applicant is able to restore the site to a safe and environmentally sound condition.

(e) The general license in paragraph (a) of this section is exempt from parts 19, 20, and 21 of this chapter, unless significant construction, actions, or repairs are required. If these types of actions are to be undertaken, the licensee shall explain to the Commission which requirements from these parts apply for the actions and comply with the appropriate requirements.

(f) In cases where the Commission determines that transfer of title of land used for disposal of any byproduct materials to the United States or any appropriate State is not necessary to protect the public health, safety or welfare or to minimize or eliminate danger to life or property (Atomic Energy Act, § 83(b)(1)(A)), the Commission will consider specific modifications of the custodial agency's LTSP provisions on a case-by-case basis.

[55 FR 45599, Oct. 30, 1990]

License Applications

§ 40.31 Application for specific licenses.

(a) A person may file an application for specific license on NRC Form 313, "Application for Material License," in accordance with the instructions in § 40.5 of this chapter. Information contained in previous applications, statements or reports filed with the Commission may be incorporated by reference provided that the reference is clear and specific.

(b) The Commission may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Commission to determine whether the application should be granted or denied or whether a license should be modified or revoked. All applications and statements shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(c) Applications and documents submitted to the Commission in connection with applications will be made available for public inspection in accordance with the provisions of the regulations contained in parts 2 and 9 of this chapter.

(d) An application for a license filed pursuant to the regulations in this part will be considered also as an application for licenses authorizing other activities for which licenses are required by the Act: *Provided*, That the application specifies the additional activities for which licenses are requested and complies with regulations of the Commission as to applications for such licenses.

(e) Each application for a source material license, other than a license exempted from part 170 of

this chapter, shall be accompanied by the fee prescribed in § 170.31 of this chapter. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in § 170.31 of this chapter.

(f) An application for a license to possess and use source material for uranium milling, production of uranium hexafluoride, or for the conduct of any other activity which the Commission has determined pursuant to subpart A of part 51 of this chapter will significantly affect the quality of the environment shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by any Environmental Report required pursuant to subpart A of part 51 of this chapter.

(g) An applicant for a license to possess and use source material, or the recipient of such a license shall report information to the Commission as follows:

(1) In response to a written request by the Commission, a uranium or thorium processing plant, and any other applicant for a license to possess and use source material, shall submit facility information described in § 75.10 of this chapter on ~~Form N–71 and associated forms~~IAEA Design Information Questionnaire forms and site information on DOC/NRC Form AP–A, and associated forms;

(2) As required by the Additional Protocol, a uranium or thorium processing plant, and any other applicant for a license to possess and use source material, shall submit location information described in § 75.11 of this chapter on DOC/NRC Form AP–1 and associated forms; shall permit verification of this information by the International Atomic Energy Agency (IAEA); and shall take other actions as may be necessary to implement the US/IAEA Safeguards Agreement, as described in Part 75 of this chapter; or

(3) As required by the Additional Protocol, an ore processing plant or a facility using or storing ore concentrates or other impure source materials shall submit the information described in § 75.11 of this chapter, as appropriate, on DOC/NRC Form AP–1 and associated forms; shall permit verification of this information by the International Atomic Energy Agency (IAEA); and shall take other actions as may be necessary to implement the US/IAEA Safeguards Agreement, as described in Part 75 of this chapter.

(h) An application for a license to receive, possess, and use source material for uranium or thorium milling or byproduct material, as defined in this part, at sites formerly associated with such milling shall contain proposed written specifications relating to milling operations and the disposition of the byproduct material to achieve the requirements and objectives set forth in appendix A of this part. Each application must clearly demonstrate how the requirements and objectives set forth in appendix A of this part have been addressed. Failure to clearly demonstrate how the requirements and objectives in appendix A have been addressed shall be grounds for refusing to accept an application.

(i) As provided by § 40.36, certain applications for specific licenses filed under this part must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. In the case of renewal applications submitted before July 27, 1990, this submittal may follow the renewal application but must be submitted on or before July 27, 1990.

(j)(1) Each application to possess uranium hexafluoride in excess of 50 kilograms in a single container or 1000 kilograms total must contain either:

(i) An evaluation showing that the maximum intake of uranium by a member of the public due to a release would not exceed 2 milligrams; or

(ii) An emergency plan for responding to the radiological hazards of an accidental release of source material and to any associated chemical hazards directly incident thereto.

(2) One or more of the following factors may be used to support an evaluation submitted under paragraph (j)(1)(i) of this section:

(i) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(ii) Facility design or engineered safety features in the facility would reduce the amount of the release; or

(iii) Other factors appropriate for the specific facility.

(3) An emergency plan submitted under paragraph (j)(1)(ii) of this section must include the following:

(i) Facility description. A brief description of the licensee's facility and area near the site.

(ii) Types of accidents. An identification of each type of accident for which protective actions may be needed.

(iii) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(iv) Detection of accidents. Identification of the means of detecting each type of radioactive materials accident in a timely manner.

(v) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(vi) Assessment of releases. A brief description of the methods and equipment to assess releases

of radioactive materials.

(vii) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the NRC; also responsibilities for developing, maintaining, and updating the plan.

(viii) Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the NRC operations center immediately after notification of the offsite response organizations and not later than one hour after the licensee declares an emergency.[1]

(ix) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the NRC.

(x) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(xi) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(xii) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(xiii) Hazardous chemicals. A certification that the application has met its responsibilities under

the Emergency Planning and Community Right-to-Know Act of 1986, title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of the use of the source material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the NRC. The licensee shall provide any comments received within the 60 days to the NRC with the emergency plan.

(k) A license application for a uranium enrichment facility must be accompanied by an Environmental Report required under subpart A of part 51 of this chapter.

(l) A license application that involves the use of source material in a uranium enrichment facility must include the applicant's provisions for liability insurance.

(m) Each applicant for a license for the possession of source material at a facility for the production or conversion of uranium hexafluoride shall protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable. Each applicant for a license for source material shall protect Safeguards Information against unauthorized disclosure in accordance with the requirements in § 73.21 and the requirements of § 73.22 or § 73.23 of this chapter, as applicable.

[26 FR 284, Jan. 14, 1961, as amended at 31 FR 4669, Mar. 19, 1966; 34 FR 19546, Dec. 11, 1969; 36 FR 145, Jan. 6, 1971; 37 FR 5748, Mar. 21, 1972; 46 FR 13497, Feb. 23, 1981; 49 FR 9403, Mar. 12, 1984; 49 FR 19626, May 9, 1984; 49 FR 21699, May 23, 1984; 49 FR 27924, July 9, 1984; 53 FR 24047, June 27, 1988; 54 FR 14061, Apr. 7, 1989; 57 FR 18390, Apr. 30, 1992; 68 FR 58807, Oct. 10, 2003; 73 FR 78604, Dec. 23, 2008; 73 FR 63570, Oct. 24, 2008; 85 FR 65656, Oct. 16, 2020]

[1] These reporting requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III. Pub. L. 99-499 or other state or federal reporting requirements.

§ 40.32 General requirements for issuance of specific licenses.

An application for a specific license will be approved if:

(a) The application is for a purpose authorized by the Act; and

(b) The applicant is qualified by reason of training and experience to use the source material for the purpose requested in such manner as to protect health and minimize danger to life or property; and

(c) The applicant's proposed equipment, facilities and procedures are adequate to protect health and minimize danger to life or property; and

(d) The issuance of the license will not be inimical to the common defense and security or to the health and safety of the public; and

(e) In the case of an application for a license for a uranium enrichment facility, or for a license to possess and use source and byproduct material for uranium milling, production of uranium hexafluoride, or for the conduct of any other activity which the NRC determines will significantly affect the quality of the environment, the Director, Office of Federal and State Materials and Environmental Management Programs or his/her designee, before commencement of construction, on the basis of information filed and evaluations made pursuant to subpart A of part 51 of this chapter, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to this conclusion is grounds for denial of a license to possess and use source and byproduct material in the plant or facility. Commencement of construction as defined in section 40.4 may include non-construction activities if the activity has a reasonable nexus to radiological safety and security.

(f) The applicant satisfies any applicable special requirements contained in § 40.34.

(g) If the proposed activity involves use of source material in a uranium enrichment facility, the applicant has satisfied the applicable provisions of part 140 of this chapter.

[26 FR 284, Jan. 14, 1961, as amended at 36 FR 12731, July 7, 1971; 40 FR 8787, Mar. 3, 1975; 41 FR 53332, Dec. 6, 1976; 43 FR 6924, Feb. 17, 1978; 49 FR 9403, Mar. 12, 1984; 57 FR 18390, Apr. 30, 1992; 73 FR 5721, Jan. 31, 2008; 76 FR 56964, Sep. 15, 2011; 78 FR 32340, May 29, 2013; 79 FR 75740, Dec. 19, 2014]

§ 40.33 Issuance of a license for a uranium enrichment facility.

(a) The Commission will hold a hearing pursuant to 10 CFR part 2, subparts A, G, and I, on each application with regard to the licensing of the construction and operation of a uranium enrichment facility. The Commission will publish public notice of the hearing in the Federal Register at least 30 days before the hearing.

(b) A license for a uranium enrichment facility may not be issued before the hearing is completed and a decision issued on the application.

[57 FR 18391, Apr. 30, 1992]

§ 40.34 Special requirements for issuance of specific licenses.

(a) An application for a specific license to manufacture industrial products and devices containing depleted uranium, or to initially transfer such products or devices, for use pursuant to § 40.25 of this part or equivalent regulations of an Agreement State, will be approved if:

(1) The applicant satisfies the general requirements specified in § 40.32;

(2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in 1 year a radiation dose in excess of 10 percent of the annual limits specified in § 20.1201(a) of this chapter; and

(3) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(b) In the case of an industrial product or device whose unique benefits are questionable, the Commission will approve an application for a specific license under this paragraph only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(c) The Commission may deny an applicant for a specific license under this paragraph if the end uses of the industrial product or device cannot be reasonably foreseen.

[41 FR 53332, Dec. 6, 1976, as amended at 43 FR 6924, Feb. 17, 1978; 58 FR 67661, Dec. 22, 1993; 59 FR 41643, Aug. 15, 1994]

§ 40.35 Conditions of specific licenses issued pursuant to § 40.34.

Each person licensed pursuant to § 40.34 shall:

(a) Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(b) Label or mark each unit to: (1) Identify the manufacturer or initial transferor of the product or device and the number of the license under which the product or device was manufactured or initially transferred, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and (2) state that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. NRC or of an Agreement State;

(c) Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(d)(1) Furnish a copy of the general license contained in § 40.25 and a copy of Form NRC 244 to each person to whom he transfers source material in a product or device for use pursuant to the general license contained in § 40.25; or

(2) Furnish a copy of the general license contained in the Agreement State's regulation equivalent to § 40.25 and a copy of the Agreement State's certificate, or alternately, furnish a copy of the general license contained in § 40.25 and a copy of Form NRC 244 to each person to whom he transfers source material in a product or device for use pursuant to the general license of an Agreement State. If a copy of the general license in § 40.25 and a copy of Form NRC 244 are furnished to such person, they shall be accompanied by a note explaining that use of the product or device is regulated by the Agreement State under requirements substantially the same as those in § 40.25; and

(e)(1) Report to the Director, Office of Federal and State Materials and Environmental Management Programs, by an appropriate method listed in § 40.5, all transfers of industrial products or devices to persons for use under the general license in § 40.25. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Commission and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under § 40.25 during the reporting period, the report shall so indicate;

(2) Report to the responsible Agreement State Agency all transfers of industrial products or devices to persons for use under the general license in the Agreement State's regulation equivalent to § 40.25. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person. If no transfers have been made to a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State Agency;

(3) Keep records showing the name, address, and a point of contact for each general license to whom he or she transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in § 40.25 or equivalent regulations of an Agreement State. The records must be retained for three years from the date of transfer and must show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

(f) Licensees required to submit emergency plans by § 40.31(i) shall follow the emergency plan approved by the Commission. The licensee may change the plan without Commission approval if

the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the Director, Office of Federal and State Materials and Environmental Management Programs, by an appropriate method listed in § 40.5, and to affected offsite response organizations, within six months after the change is made. Proposed changes that decrease the effectiveness of the approved emergency plan may not be implemented without application to and prior approval by the Commission.

[41 FR 53332, Dec. 6, 1976, as amended at 43 FR 6924, Feb. 17, 1978; 52 FR 31611, Aug. 21, 1987; 53 FR 19248, May 27, 1988; 54 FR 14062, Apr. 7, 1989; 68 FR 58807, Oct. 10, 2003; 73 FR 5721, Jan. 31, 2008; 79 FR 75740, Dec. 19, 2014]

§ 40.36 Financial assurance and recordkeeping for decommissioning.

Except for licenses authorizing the receipt, possession, and use of source material for uranium or thorium milling, or byproduct material at sites formerly associated with such milling, for which financial assurance requirements are set forth in appendix A of this part, criteria for providing financial assurance for decommissioning are as follows:

(a) Each applicant for a specific license authorizing the possession and use of more than 100 mCi of source material in a readily dispersible form shall submit a decommissioning funding plan as described in paragraph (d) of this section.

(b) Each applicant for a specific license authorizing possession and use of quantities of source material greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form shall either--

(1) Submit a decommissioning funding plan as described in paragraph (d) of this section; or

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount of $225,000 by June 2, 2005 using one of the methods described in paragraph (e) of this section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section must be submitted to NRC prior to receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to NRC, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section.

(c)(1) Each holder of a specific license issued on or after July 27, 1990, which is covered by paragraph (a) or (b) of this section, shall provide financial assurance for decommissioning in accordance with the criteria set forth in this section.

(2) Each holder of a specific license issued before July 27, 1990, and of a type described in

paragraph (a) of this section shall submit a decommissioning funding plan as described in paragraph (d) of this section or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000 in accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal. Licensees required to submit the $1,125,000 amount must do so by December 2, 2004.

(3) Each holder of a specific license issued before July 27, 1990, and of a type described in paragraph (b) of this section shall submit, on or before July 27, 1990, a decommissioning funding plan, as described in paragraph (d) of this section, or a certification of financial assurance for decommissioning in accordance with the criteria set forth in this section.

(4) Any licensee who has submitted an application before July 27, 1990, for renewal of license in accordance with § 40.43 shall provide financial assurance for decommissioning in accordance with paragraphs (a) and (b) of this section. This assurance must be submitted when this rule becomes effective November 24, 1995.

(d)(1) Each decommissioning funding plan must be submitted for review and approval and must contain –

(i) A detailed cost estimate for decommissioning, in the amount reflecting:

(A) The cost of an independent contractor to perform all decommissioning activities;

(B) The cost of meeting the 10 CFR 20.1402 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 10 CFR 20.1403, the cost estimate may be based on meeting the 10 CFR 20.1403 criteria;

(C) The volume of onsite subsurface material containing residual radioactivity that will require remediation; and

(D) An adequate contingency factor.

(ii) Identification of and justification for using the key assumptions contained in the DCE;

(iii) A description of the method of assuring funds for decommissioning from paragraph (e) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(v) A signed original, or if permitted, a copy, of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section (unless a previously submitted and accepted

financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

(i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(ii) Waste inventory increasing above the amount previously estimated;

(iii) Waste disposal costs increasing above the amount previously estimated;

(iv) Facility modifications;

(v) Changes in authorized possession limits;

(vi) Actual remediation costs that exceed the previous cost estimate;

(vii) Onsite disposal; and

(viii) Use of a settling pond. (e) Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A to part 30. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix C to part 30. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in appendix D

to part 30. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in appendix E to part 30. A guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Commission, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Commission within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(iii) The surety method or insurance must remain in effect until the Commission has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provision must be as stated in paragraph (e)(2) of this section.

(4) In the case of Federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on paragraph (b) of this section, and indicating that funds for decommissioning will be obtained when necessary.

(5) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(f) Each person licensed under this part shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted

use. Before licensed activities are transferred or assigned in accordance with § 40.41(b) licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Commission considers important to decommissioning consists of--

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) Except for areas containing depleted uranium used only for shielding or as penetrators in unused munitions, a list contained in a single document and updated every 2 years, of the following:

(i) All areas designated and formerly designated as restricted areas as defined under 10 CFR 20.1003;

(ii) All areas outside of restricted areas that require documentation under § 40.36(f)(1);

(iii) All areas outside of restricted areas where current and previous wastes have been buried as documented under 10 CFR 20.2108; and

(iv) All areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 10 CFR part 20, subpart E, or apply for approval for disposal under 10 CFR 20.2002.

(4) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

[53 FR 24047, June 27, 1988, as amended at 58 FR 39633, July 26, 1993; 58 FR 67661, Dec. 22, 1993; 58 FR 68731, Dec. 29, 1993; 59 FR 1618, Jan. 12, 1994; 60 FR 38238, July 26, 1995; 61

FR 24674, May 16, 1996; 62 FR 39090, July 21, 1997; 63 FR 29543, June 1, 1998; 68 FR 57336, Oct. 3, 2003; 76 FR 35568 Jun. 17, 2011; 78 FR 34247, Jun. 7, 2013; 78 FR 75450, Dec. 12, 2013; 79 FR 75740, Dec. 19, 2014]

§ 40.38 Ineligibility of certain applicants.

A license may not be issued to the Corporation if the Commission determines that:

(a) The Corporation is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government; or

(b) The issuance of such a license would be inimical to--

(1) The common defense and security of the United States; or

(2) The maintenance of a reliable and economical domestic source of enrichment services.

[62 FR 6669, Feb. 12, 1997]

Licenses

§ 40.41 Terms and conditions of licenses.

(a) Each license issued pursuant to the regulations in this part shall be subject to all the provisions of the act, now or hereafter in effect, and to all rules, regulations and orders of the Commission.

(b) Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of the Act.

(c) Each person licensed by the Commission pursuant to the regulations in this part shall confine his possession and use of source or byproduct material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations in this part shall carry with it the right to receive, possess, and use source or byproduct material. Preparation for shipment and transport of source or byproduct material shall be in accordance with the provisions of part 71 of this chapter.

(d) Each license issued pursuant to the regulations in this part shall be deemed to contain the provisions set forth in sections 183b.-d., of the Act, whether or not said provisions are expressly set forth in the license.

(e) The Commission may incorporate in any license at the time of issuance, or thereafter, by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of source or byproduct material as it deems

appropriate or necessary in order to:

(1) Promote the common defense and security;

(2) Protect health or to minimize danger of life or property;

(3) Protect restricted data;

(4) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the act and regulations thereunder.

(f)(1) Each licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code by or against:

(i) The licensee;

(ii) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(iii) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(2) This notification must indicate:

(i) The bankruptcy court in which the petition for bankruptcy was filed; and

(ii) The date of the filing of the petition.

(g) No person may commence operation of a uranium enrichment facility until the Commission verifies through inspection that the facility has been constructed in accordance with the requirements of the license. The Commission shall publish notice of the inspection results in the Federal Register.

(h) Each licensee shall ensure that Safeguards Information is protected against unauthorized disclosure in accordance with the requirements in § 73.21 and the requirements of § 73.22 or § 73.23 of this chapter, as applicable.

[26 FR 284, Jan. 14, 1961, as amended at 31 FR 15145, Dec. 2, 1966; 45 FR 65531, Oct. 3, 1980; 48 FR 32328, July 15, 1983; 52 FR 1295, Jan. 12, 1987; 57 FR 18391, Apr. 30, 1992; 73 FR 63571, Oct. 24, 2008]

§ 40.42 Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

(a) Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under § 40.43 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days before the expiration date stated in the existing license, the existing license expires at the end of the day on which the Commission makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(b) Each specific license revoked by the Commission expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Commission Order.

(c) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of source material until the Commission notifies the licensee in writing that the license is terminated. During this time, the licensee shall--

(1) Limit actions involving source material to those related to decommissioning; and

(2) Continue to control entry to restricted areas until they are suitable for release in accordance with NRC requirements;

(d) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in § 40.5, each licensee shall provide notification to the NRC in writing and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity, so that the building or outdoor area is suitable for release in accordance with NRC requirements, or submit within 12 months of notification a decommissioning plan, if required by paragraph (g)(1) of this section, and begin decommissioning upon approval of that plan if--

(1) The license has expired pursuant to paragraph (a) or (b) of this section; or

(2) The licensee has decided to permanently cease principal activities, as defined in this part, at the entire site or in any separate building or outdoor area; or

(3) No principal activities under the license have been conducted for a period of 24 months; or

(4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.

(e) Coincident with the notification required by paragraph (d) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to § 40.36 in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph (g)(4)(v)

of this section.

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective November 24, 1995.

(2) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Commission.

(f) The Commission may grant a request to delay or postpone initiation of the decommissioning process if the Commission determines that such relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to paragraph (d) of this section. The schedule for decommissioning set forth in paragraph (d) of this section may not commence until the Commission has made a determination on the request.

(g)(1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Commission and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The Commission may approve an alternate schedule for submittal of a decommissioning plan required pursuant to paragraph (d) of this section if the Commission determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(3) The procedures listed in paragraph (g)(1) of this section may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(ii) A description of planned decommissioning activities;

(iii) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(iv) A description of the planned final radiation survey; and

(v) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(vi) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, a justification for the delay based on the criteria in paragraph (i) of this section.

(5) The proposed decommissioning plan will be approved by the Commission if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(h)(1) Except as provided in paragraph (i) of this section, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(2) Except as provided in paragraph (i) of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(i) The Commission may approve a request for an alternate schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Commission determines that the alternative is warranted by consideration of the following:

(1) Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(3) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(j) As the final step in decommissioning, the licensee shall--

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E or, for uranium milling (uranium and thorium recovery) facilities, Criterion 6(6) of Appendix A to this part. The licensee shall, as appropriate--

(i) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters removable and fixed for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(k) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Commission determines that:

(1) Source material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3)(i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E; or for uranium milling (uranium and thorium recovery) facilities, Criterion 6(6) of Appendix A to this part;

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E.

(4) Records required by § 40.61(d) and (f) have been received.

(l) Specific licenses for uranium and thorium milling are exempt from paragraphs (d)(4), (g) and (h) of this section with respect to reclamation of tailings impoundments and/or waste disposal areas.

[59 FR 36035, July 15, 1994, as amended at 60 FR 38239, July 26, 1995; 61 FR 1114, Jan. 16, 1996; 61 FR 24674, May 16, 1996; 61 FR 29637, June 12, 1996; 62 FR 39090, July 21, 1997; 66 FR 64738, Dec. 14, 2001; 68 FR 75390, Dec. 31, 2003; 73 FR 42673, Jul. 23, 2008]

§ 40.43 Renewal of licenses.

(a) Application for renewal of a specific license must be filed on NRC Form 313 and in accordance with § 40.31.

(b) If any licensee granted the extension described in 10 CFR 40.42(a)(2) has a currently pending renewal application for the extended license, that application will be considered to be withdrawn by the licensee and any renewal fees paid by the licensee for that application will be refunded.

[59 FR 36037, July 15, 1994, as amended at 61 FR 1114, Jan. 16, 1996; 62 FR 52187, Oct. 6, 1997; 75 FR 73943, Nov. 30, 2010]

§ 40.44 Amendment of licenses at request of licensee.

Applications for amendment of a license shall be filed on NRC Form 313 in accordance with § 40.31 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

[49 FR 19627, May 9, 1984, as amended at 56 FR 40768, Aug. 16, 1991]

§ 40.45 Commission action on applications to renew or amend.

In considering an application by a licensee to renew or amend his license the Commission will apply the applicable criteria set forth in § 40.32.

[26 FR 284, Jan. 14, 1961, as amended at 43 FR 6924, Feb. 17, 1978]

§ 40.46 Inalienability of licenses.

(a) No license issued or granted pursuant to the regulations in this part shall be transferred,

assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall after securing full information, find that the transfer is in accordance with the provisions of this act, and shall give its consent in writing.

(b) An application for transfer of license must include:

(1) The identity, technical and financial qualifications of the proposed transferee; and

(2) Financial assurance for decommissioning information required by § 40.36 or Appendix A to this part, as applicable.

[76 FR 35569, Jun. 17, 2011]

Transfer of Source Material

§ 40.51 Transfer of source or byproduct material.

(a) No licensee shall transfer source or byproduct material except as authorized pursuant to this section.

(b) Except as otherwise provided in his license and subject to the provisions of paragraphs (c) and (d) of this section, any licensee may transfer source or byproduct material:

(1) To the Department of Energy;

(2) To the agency in any Agreement State which regulates radioactive materials pursuant to an agreement with the Commission or the Atomic Energy Commission under section 274 of the Act;

(3) To any person exempt from the licensing requirements of the Act and regulations in this part, to the extent permitted under such exemption;

(4) To any person in an Agreement State subject to the jurisdiction of that State who has been exempted from the licensing requirements and regulations of that State, to the extent permitted under such exemptions;

(5) To any person authorized to receive such source or byproduct material under terms of a specific license or a general license or their equivalents issued by the Commission or an Agreement State;

(6) To any person abroad pursuant to an export license issued under part 110 of this chapter; or

(7) As otherwise authorized by the commission in writing.

(c) Before transferring source or byproduct material to a specific licensee of the Commission or an Agreement State or to a general licensee who is required to register with the Commission or with an Agreement State prior to receipt of the source or byproduct material, the licensee transferring the material shall verify that the transferee's license authorizes receipt of the type, form, and quantity of source or byproduct material to be transferred.

(d) The following methods for the verification required by paragraph (c) of this section are acceptable:

(1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

(2) The transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of source or byproduct material to be transferred, specifying the license or registration certification number, issuing agency and expiration date;

(3) For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of source or byproduct material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date: *Provided*, That the oral certification is confirmed in writing within 10 days;

(4) The transferor may obtain other sources of information compiled by a reporting service from official records of the Commission or the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registrations; or

(5) When none of the methods of verification described in paragraphs (d)(1) to (4) of this section are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Commission or the licensing agency of an Agreement State that the transferee is licensed to receive the source or byproduct material.

[45 FR 65532, Oct. 3, 1980]

§ 40.54 Requirements for license to initially transfer source material for use under the 'small quantities of source material' license.

An application for a specific license to initially transfer source material for use under § 40.22, or equivalent regulations of an Agreement State, will be approved if:

(a) The applicant satisfies the general requirements specified in § 40.32; and

(b) The applicant submits adequate information on, and the Commission approves the methods to

be used for quality control, labeling, and providing safety instructions to recipients.

[76 FR 78805, Dec. 20, 2011; 78 FR 32340, May 29, 2013]

§ 40.55 Conditions of licenses to initially transfer source material for use under the 'small quantities of source material' general license: Quality control, labeling, safety instructions, and records and reports.

(a) Each person licensed under § 40.54 shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "radioactive material."

(b) Each person licensed under § 40.54 shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(c) Each person licensed under § 40.54 shall provide the information specified in this paragraph to each person to whom source material is transferred for use under § 40.22 or equivalent provisions in Agreement State regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(1) A copy of §§ 40.22 and 40.51, or relevant equivalent regulations of the Agreement State.

(2) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

(d) Each person licensed under § 40.54 shall report transfers as follows:

(1) File a report with the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. The report shall include the following information:

(i) The name, address, and license number of the person who transferred the source material;

(ii) For each general licensee under § 40.22 or equivalent Agreement State provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(2) File a report with each responsible Agreement State agency that identifies all persons, operating under provisions equivalent to § 40.22, to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the Agreement State being reported to:

(i) The name, address, and license number of the person who transferred the source material; and

(ii) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.

(iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the Agreement State.

(3) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under § 40.22 or equivalent Agreement State provisions during the current period, a report shall be submitted to the Commission indicating so. If no transfers have been made to general licensees in a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency.

(e) Each person licensed under § 40.54 shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of 1 year after the event is included in a report to the Commission or to an Agreement State agency.

[76 FR 78805, Dec. 20, 2011; 78 FR 32340, May 29, 2013; 79 FR 75740, Dec. 19, 2014]

Records, Reports, and Inspections

§ 40.60 Reporting requirements.

(a) *Immediate report*. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(b) *Twenty-four hour report*. Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material:

(1) An unplanned contamination event that:

(i) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified in appendix B of §§ 20.1001-20.2401 of 10 CFR part 20 for the material; and

(iii) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

(i) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(ii) The equipment is required to be available and operable when it is disabled or fails to function; and

(iii) No redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(i) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of §§ 20.1001-20.2401 of 10 CFR part 20 for the material; and

(ii) The damage affects the integrity of the licensed material or its container.

(c) *Preparation and submission of reports*. Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees shall make reports required by paragraphs (a) and (b) of this section by telephone to the department of environmental quality~~NRC Operations Center~~.~~:~~ To the extent that the information is available at the time of notification, the information provided in these reports must include:

(i) The caller's name and call back telephone number;

(ii) A description of the event, including date and time;

(iii) The exact location of the event;

(iv) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(v) Any personnel radiation exposure data available.

(2) *Written report*. Each licensee who makes a report required by paragraph (a) or (b) of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the NRC's Document Control Desk by an appropriate method listed in § 40.5, with a copy to the appropriate NRC regional office listed in appendix D to part 20 of this chapter. The reports must include the following:

(i) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(ii) The exact location of the event;

(iii) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(iv) Date and time of the event;

(v) Corrective actions taken or planned and the results of any evaluations or assessments; and

(vi) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(3) The provisions of § 40.60 do not apply to licensees subject to the notification requirements in § 50.72. They do apply to those part 50 licensees possessing material licensed under part 40 who are not subject to the notification requirements in § 50.72.

[56 FR 40768, Aug. 16, 1991, as amended at 59 FR 14086, Mar. 25, 1994; 68 FR 58807, Oct. 10, 2003; 85 FR 65656, Oct. 16, 2020]

~~[1] The commercial telephone number for the NRC Operations Center is (301) 816-5100.~~

§ 40.61 Records.

(a) Each person who receives source or byproduct material pursuant to a license issued pursuant to the regulations in this part shall keep records showing the receipt, transfer, and disposal of this source or byproduct material as follows:

(1) The licensee shall retain each record of receipt of source or byproduct material as long as the material is possessed and for three years following transfer or disposition of the source or byproduct material.

(2) The licensee who transferred the material shall retain each record of transfer of source or

byproduct material until the Commission terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(3) The licensee shall retain each record of disposal of source or byproduct material until the Commission terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(4) If source or byproduct material is combined or mixed with other licensed material and subsequently treated in a manner that makes direct correlation of a receipt record with a transfer, export, or disposition record impossible, the licensee may use evaluative techniques (such as first-in-first-out), to make the records that are required by this Part account for 100 percent of the material received.

(b) The licensee shall retain each record that is required by the regulations in this part or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, each record must be maintained until the Commission terminates the license that authorizes the activity that is subject to the recordkeeping requirement.

(c)(1) Records which must be maintained pursuant to this part may be the original or reproduced copy or microform if the reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(2) If there is a conflict between the Commission's regulations in this part, license condition, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this part for such records shall apply unless the Commission, pursuant to § 40.14 of this part, has granted a specific exemption from the record retention requirements specified in the regulations in this part.

(d) Prior to license termination, each licensee authorized to possess source material, in an unsealed form, shall forward the following records to the appropriate NRC Regional Office:

(1) Records of disposal of licensed material made under § 20.2002 (including burials authorized before January 28, 1981[(1)]), 20.2003, 20.2004, 20.2005; and

(2) Records required by § 20.2103(b)(4).

(e) If licensed activities are transferred or assigned in accordance with § 40.41(b), each licensee authorized to possess source material, in an unsealed form, shall transfer the following records to

the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under § 20.2002 (including burials authorized before January 28, 1981[1]), 20.2003, 20.2004, 20.2005; and

(2) Records required by § 20.2103(b)(4).

(f) Prior to license termination, each licensee shall forward the records required by § 40.36(f) to the appropriate NRC Regional Office.

[45 FR 65532, Oct. 3, 1980, as amended at 53 FR 19248, May 27, 1988; 61 FR 24674, May 16, 1996; 80 FR 45843, Aug. 3, 2015]

[1] A previous § 20.304 permitted burial of small quantities of licensed materials in soil before January 28, 1981, without specific Commission authorization. See § 20.304 contained in the 10 CFR, parts 0 to 199, edition revised as of January 1, 1981.

§ 40.62 Inspections.

(a) Each licensee shall afford to the Commission at all reasonable times opportunity to inspect source or byproduct material and the premises and facilities wherein source or byproduct material is used or stored.

(b) Each licensee shall make available to the Commission for inspection, upon reasonable notice, records kept by him pursuant to the regulations in this chapter.

[45 FR 65532, Oct. 3, 1980]

§ 40.63 Tests.

Each licensee shall perform, or permit the Commission to perform, such tests as the Commission deems appropriate or necessary for the administration of the regulations in this part, including tests of:

(a) Source or byproduct material;

(b) Facilities wherein source or byproduct material is utilized or stored;

(c) Radiation detection and monitoring instruments; and

(d) Other equipment and devices used in connection with the utilization and storage of source or byproduct material.

[45 FR 65533, Oct. 3, 1980]

§ 40.64 Reports.

(a) Except as specified in paragraphs (d) and (e) of this section, each specific licensee who transfers, receives, or adjusts the inventory in any manner, of uranium or thorium source material with foreign obligations by one kilogram or more; or who imports or exports one kilogram or more of uranium or thorium source material; or who uses one kilogram or more of any uranium or thorium source material in enrichment services, downblending uranium that has an initial enrichment of the U^{235} isotope of 10 percent or more, or in the fabrication of mixed-oxide fuels, shall complete a Nuclear Material Transaction Report in computer-readable format as specified in the instructions in NUREG/BR–0006 and NMMSS Report D–24, ‘‘Personal Computer Data Input for NRC Licensees.’’ Each licensee who exports one kilogram or more of uranium or thorium source material shall complete in the format listed above the licensee’s portion of the Nuclear Material Transaction Report unless there is indication of loss, theft, or diversion as discussed under paragraph (d) of this section, in which case both the licensee’s and the foreign facility’s information must be reported. Licensees who import one kilogram or more of uranium or thorium source material shall complete the supplier’s and the licensee’s portion of the Nuclear Material Transaction Report. Copies of the instructions may be obtained either by writing the U.S. Nuclear Regulatory Commission, Division of Fuel Management, Washington, DC 20555–0001, or by e-mail to RidsNmssFcss@nrc.gov. Each licensee who transfers the material shall submit a Nuclear Material Transaction Report in computer-readable format as specified in the instructions no later than the close of business the next working day. Each licensee who receives the material shall submit a Nuclear Material Transaction Report in computer-readable format in accordance with instructions within ten (10) days after the material is received. The Commission’s copy of the report must be submitted to the address specified in the instructions. These prescribed computer-readable forms replace the DOE/NRC Form 741 previously submitted in paper form.

(b) Except as specified in paragraphs (d) and (e) of this section, each licensee who:

(1) Possesses, or had possessed in the previous reporting period, at any one time and location, one kilogram or more of uranium or thorium source material with foreign obligations as defined in this part, shall document holdings as of September 30 of each year and submit to the Commission within 30 days, a statement of its source material inventory with foreign obligations as defined in this part. Alternatively, this information may be submitted with the licensee’s material status reports on special nuclear material filed under part 72 or 74 of this chapter, as a statement of its source material inventory with foreign obligations as defined in this part. This statement must be submitted to the address specified in the reporting instructions in NUREG/BR–0007, and include the Reporting Identification Symbol (RIS) assigned by the Commission to the licensee.

(2) Possesses, or had possessed in the previous reporting period, one kilogram or more of uranium or thorium source material pursuant to the operation of enrichment services,

downblending uranium that has an initial enrichment of the U^{235} isotope of 10 percent or more, or in the fabrication of mixed-oxide fuels shall complete and submit, in computer-readable format, Material Balance and Physical Inventory Listing Reports concerning all source material that the licensee has received, produced, possessed, transferred, consumed, disposed of, or lost. Reports must be submitted for each Reporting Identification Symbol (RIS) account including all holding accounts. Each licensee shall prepare and submit these reports as specified in the instructions in NUREG/BR–0007 and NMMSS Report D–24, ‘‘Personal Computer Data Input for NRC Licensees.’’ These reports must document holdings as of September 30 of each year and must be
submitted to the Commission within 30 days. Alternatively, these reports may be submitted with the licensee's material status reports on special nuclear material filed under parts 72 or 74 of this chapter. Copies of the reporting instructions may be obtained either by writing to the U.S. Nuclear Regulatory Commission, Division of Fuel Management, Washington, DC 20555–0001, or by e-mail to *RidsNmssFcss@nrc.gov*. Each licensee required to report material balance, inventory, and/or foreign obligation information, as detailed in this part, shall resolve any discrepancies identified during the report review and reconciliation process within 30 calendar days of notification of a
discrepancy identified by the NRC.

(c)(1) Except as specified in paragraph (d) of this section, each licensee who is authorized to possess uranium or thorium pursuant to a specific license shall notify the NRC Headquarters Operations Center by telephone, at the numbers listed in appendix A of part 73 of this chapter, of any incident in which an attempt has been made or is believed to have been made to commit a theft or unlawful diversion of more than 6.8 kilograms (kg) [15 pounds] of such material at any one time or more than 68 kg [150 pounds] of such material in any one calendar year.

(2) The licensee shall notify the NRC as soon as possible, but within 4 hours, of discovery of any incident in which an attempt has been made or is believed to have been made to commit a theft or unlawful diversion of such material.

(3) The initial notification shall be followed within a period of sixty (60) days by a written follow-up notification submitted in accordance with § 40.5.

(4) Subsequent to the submission of the written follow-up notification required by this paragraph, the licensee shall promptly update the written follow-up notification, in accordance with this paragraph, with any substantive additional information, which becomes available to the licensee, concerning an attempted or apparent theft or unlawful diversion of source material.

(d) The reports described in paragraphs (a), (b), and (c) of this section are not required for:

(1) Processed ores containing less than five (5) percent of uranium or thorium, or any combination of uranium or thorium, by dry weight;

(2) Thorium contained in magnesium-thorium and tungsten-thorium alloys, if the thorium

content in the alloys does not exceed 4 percent by weight;

(3) Chemical catalysts containing uranium depleted in the U-235 isotope to 0.4 percent or less, if the uranium content of the catalyst does not exceed 15 percent by weight; or

(4) Any source material contained in non-nuclear end use devices or components, including but not limited to permanently installed shielding, teletherapy, radiography, X-ray, accelerator devices, or munitions.

(e) Any licensee who is required to submit inventory change reports and material status reports pursuant to part 75 of this chapter (pertaining to implementation of the US/IAEA Safeguards Agreement) shall prepare and submit such reports only as provided in §§ 75.34 and 75.35 of this chapter (instead of as provided in paragraphs (a) and (b) of this section).

[35 FR 12195, July 30, 1970, as amended at 36 FR 10938, June 5, 1971; 38 FR 1272, Jan. 11, 1973; 38 FR 2330, Jan. 24, 1973; 40 FR 8787, Mar. 3, 1975; 41 FR 16446, Apr. 19, 1976; 45 FR 50710, July 31, 1980; 49 FR 24707, June 15, 1984; 51 FR 9766, Mar. 21, 1986; 52 FR 31611, Aug. 21, 1987; 59 FR 35620, July 13, 1994; 68 FR 10364, Mar. 5, 2003; 68 FR 58807, Oct. 10, 2003; 73 FR 32461, Jun. 9, 2008; 74 FR 62681, Dec. 1, 2009; 79 FR 75740, Dec. 19, 2014; 83 FR 57231, Nov. 21, 2018; 84 FR 65639, Nov. 29, 2019; 84 FR 66561, Dec. 5, 2019]

§ 40.65 Effluent monitoring reporting requirements.

(a) Each licensee authorized to possess and use source material in uranium milling, in production of uranium hexafluoride, or in a uranium enrichment facility shall:

(1) Within 60 days after January 1, 1976 and July 1, 1976, and within 60 days after January 1 and July 1 of each year thereafter, submit a report to the Director, Office of Federal and State Materials and Environmental Management Programs, using an appropriate method listed in § 40.5, with a copy to the appropriate NRC Regional Office shown in appendix D to part 20 of this chapter; the report must specify the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents during the previous six months of operation, and such other information as the Commission may require to estimate maximum potential annual radiation doses to the public resulting from effluent releases. If quantities of radioactive materials released during the reporting period are significantly above the licensee's design objectives previously reviewed as part of the licensing action, the report shall cover this specifically. On the basis of such reports and any additional information the Commission may obtain from the licensee or others, the Commission may from time to time require the licensee to take such action as the Commission deems appropriate.

(2) [Reserved]

(b) [Reserved]

[40 FR 53230, Nov. 17, 1975, as amended at 41 FR 21627, May 27, 1976; 42 FR 25721, May 19, 1977; 52 FR 31611, Aug. 21, 1987; 57 FR 18391, Apr. 30, 1992; 68 FR 58807, Oct. 10, 2003; 73 FR 5721, Jan. 31, 2008; 79 FR 75740, Dec. 19, 2014]

§ 40.66 Requirements for advance notice of export shipments of natural uranium.

(a) Each licensee authorized to export natural uranium, other than in the form of ore or ore residue, in amounts exceeding 500 kilograms, shall notify the Director, Office of Nuclear Security and Incident Response, by email (preferred method) to AdvanceNotifications.Resource@nrc.gov or by an appropriate method listed in § 40.5. The notification must be in writing and must be received at least 10 days before transport of the shipment commences at the shipping facility.~~Each licensee authorized to export natural uranium, other than in the form of ore or ore residue, in amounts exceeding 500 kilograms, shall notify the Director, Office of Nuclear Security and Incident Response, by an appropriate method listed in § 40.5.~~

~~The notification must be in writing and must be received at least 10 days before transport of the shipment commences at the shipping facility.~~

(b) The notification must include the following information:

(1) The name(s), address(es), and telephone number(s) of the shipper, receiver, and carrier(s);

(2) A physical description of the shipment;

(3) A listing of the mode(s) of shipment, transfer points, and routes to be used;

(4) The estimated date and time that shipment will commence and that each nation (other than the United States) along the route is scheduled to be entered; and

(5) A certification that arrangements have been made to notify the Director, Office of Nuclear Security and Incident Response when the shipment is received at the receiving facility.

(c) A licensee who needs to amend a notification may do so by telephoning the Director, Office of Nuclear Security and Incident Response at (301) 816-5100.

[52 FR 9651, Mar. 26, 1987, as amended at 53 FR 4110, Feb. 12, 1988; 60 FR 24551, May 9, 1995; 68 FR 58808, Oct. 10, 2003; 69 FR 76600, Dec. 22, 2004; 74 FR 62681, Dec. 1, 2009; 83 FR 57231, Nov. 21, 2018; 86 FR 67839, Nov. 30, 2021]

§ 40.67 Requirement for advance notice for importation of natural uranium from countries that are not party to the Convention on the Physical Protection of Nuclear Material.

(a) Each licensee authorized to import natural uranium, other than in the form of ore or ore

residue, in amounts exceeding 500 kilograms, from countries not party to the Convention on the Physical Protection of Nuclear Material (see appendix F to part 73 of this chapter) shall notify the Director, Office of Nuclear Security and Incident Response, by email (preferred method) to AdvanceNotifications.Resource@nrc.gov or using an appropriate method listed in § 40.5. The notification must be in writing and must be received at least 10 days before transport of the shipment commences at the shipping facility. ~~Each licensee authorized to import natural uranium, other than in the form of ore or ore residue, in amounts exceeding 500 kilograms, from countries not party to the Convention on the Physical Protection of Nuclear Material (see appendix F to Part 73 of this chapter) shall notify the Director, Office of Nuclear Security and Incident Response, using an appropriate method listed in § 40.5. . The notification must be in writing and must be received at least 10 days before transport of the shipment commences at the shipping facility.~~

(b) The notification must include the following information:

(1) The name(s), address(es), and telephone number(s) of the shipper, receiver, and carrier(s);

(2) A physical description of the shipment;

(3) A listing of the mode(s) of shipment, transfer points, and routes to be used;

(4) The estimated date and time that shipment will commence and that each nation along the route is scheduled to be entered.

(c) The licensee shall notify the Director, Office of Nuclear Security and Incident Response, by telephone at the numbers for the NRC Headquarters Operations Center specified in appendix A to part 73 of this chapter when the shipment is received in the receiving facility.~~The licensee shall notify the Director, Office of Nuclear Security and Incident Response by telephone at (301) 816-5100 when the shipment is received in the receiving facility.~~

(d) A licensee who needs to amend a notification shall notify the Director, Office of Nuclear Security and Incident Response, by telephone at the numbers specified for the NRC Headquarters Operations Center in appendix A to part 73 of this chapter.~~A licensee who needs to amend a notification may do so by telephoning the Director, Office of Nuclear Security and Incident Response at (301) 816-5100.~~

[52 FR 9652, Mar. 26, 1987, as amended at 53 FR 4110, Feb. 12, 1988; 60 FR 24551, May 9, 1995; 68 FR 58808, Oct. 10, 2003; 69 FR 76600, Dec. 22, 2004; 74 FR 62681, Dec. 1, 2009; 83 FR 57231, Nov. 21, 2018; 85 FR 65656, Oct. 16, 2020; 86 FR 67839, Nov. 30, 2021]

Modification and Revocation of Licenses

§ 40.71 Modification and revocation of licenses.

(a) The terms and conditions of each license shall be subject to amendment, revision, or modification by reason of amendments to the Act, or by reason of rules, regulations, or orders issued in accordance with the Act.

(b) Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under section 182 of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Commission to refuse to grant a license on an original application, or for violation of, or failure to observe any of, the terms and conditions of the Act, or the license, or of any rule, regulation or order of the Commission.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded opportunity to demonstrate or achieve compliance with all lawful requirements.

[26 FR 284, Jan. 14, 1961, as amended at 35 FR 11460, July 17, 1970; 48 FR 32328, July 15, 1983]

Enforcement

§ 40.81 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i)

of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55074, Nov. 24, 1992]

§ 40.82 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 40 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 40 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 40.1, 40.2, 40.2a, 40.4, 40.5, 40.6, 40.8, 40.11, 40.12, 40.13, 40.14, 40.20, 40.21, 40.31, 40.32, 40.34, 40.43, 40.44, 40.45, 40.71, 40.81, and 40.82.

[57 FR 55075, Nov. 24, 1992; 78 FR 32341, May 29, 2013]

Appendix A to Part 40--Criteria Relating to the Operation of Uranium Mills and the Disposition of Tailings or Wastes Produced by the Extraction or Concentration of Source Material From Ores Processed Primarily for Their Source Material Content

Introduction. Every applicant for a license to possess and use source material in conjunction with uranium or thorium milling, or byproduct material at sites formerly associated with such milling, is required by the provisions of § 40.31(h) to include in a license application proposed specifications relating to milling operations and the disposition of tailings or wastes resulting from such milling activities. This appendix establishes technical, financial, ownership, and long-term site surveillance criteria relating to the siting, operation, decontamination, decommissioning, and reclamation of mills and tailings or waste systems and sites at which such mills and systems are located. As used in this appendix, the term "as low as is reasonably achievable" has the same meaning as in § 20.1003 of this chapter.

In many cases, flexibility is provided in the criteria to allow achieving an optimum tailings disposal program on a site-specific basis. However, in such cases the objectives, technical alternatives and concerns which must be taken into account in developing a tailings program are identified. As provided by the provisions of § 40.31(h) applications for licenses must clearly demonstrate how the criteria have been addressed.

The specifications must be developed considering the expected full capacity of tailings or waste systems and the lifetime of mill operations. Where later expansions of systems or operations may be likely (for example, where large quantities of ore now marginally uneconomical may be stockpiled), the amenability of the disposal system to accommodate increased capacities without degradation in long-term stability and other performance factors must be evaluated.

Licensees or applicants may propose alternatives to the specific requirements in this appendix. The alternative proposals may take into account local or regional conditions, including geology, topography, hydrology, and meterology. The Commission may find that the proposed alternatives meet the Commission's requirements if the alternatives will achieve a level of stabilization and containment of the sites concerned, and a level of protection for public health, safety, and the environment from radiological and nonradiological hazards associated with the sites, which is equivalent to, to the extent practicable, or more stringent than the level which would be achieved by the requirements of this Appendix and the standards promulgated by the Environmental Protection Agency in 40 CFR Part 192, Subparts D and E.

All site specific licensing decisions based on the criteria in this Appendix or alternatives proposed by licensees or applicants will take into account the risk to the public health and safety and the environment with due consideration to the economic costs involved and any other factors the Commission determines to be appropriate. In implementing this Appendix, the Commission will consider "practicable" and "reasonably achievable" as equivalent terms. Decisions involved these terms will take into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest.

The following definitions apply to the specified terms as used in this appendix:

Aquifer means a geologic formation, group of formations, or part of a formation capable of

yielding a significant amount of ground water to wells or springs. Any saturated zone created by uranium or thorium recovery operations would not be considered an aquifer unless the zone is or potentially is (1) hydraulically interconnected to a natural aquifer, (2) capable of discharge to surface water, or (3) reasonably accessible because of migration beyond the vertical projection of the boundary of the land transferred for long-term government ownership and care in accordance with Criterion 11 of this appendix.

As expeditiously as practicable considering technological feasibility, for the purposes of Criterion 6A, means as quickly as possible considering: the physical characteristics of the tailings and the site; the limits of *available technology*; the need for consistency with mandatory requirements of other regulatory programs; and *factors beyond the control of the licensee*. The phrase permits consideration of the cost of compliance only to the extent specifically provided for by use of the term *available technology*.

Available technology means technologies and methods for emplacing a final radon barrier on uranium mill tailings piles or impoundments. This term shall not be construed to include extraordinary measures or techniques that would impose costs that are grossly excessive as measured by practice within the industry (or one that is reasonably analogous), (such as, by way of illustration only, unreasonable overtime, staffing, or transportation requirements, etc., considering normal practice in the industry; laser fusion of soils, etc.), provided there is reasonable progress toward emplacement of the final radon barrier. To determine grossly excessive costs, the relevant baseline against which cost shall be compared is the cost estimate for tailings impoundment closure contained in the licensee's approved reclamation plan, but costs beyond these estimates shall not automatically be considered grossly excessive.

Closure means the activities following operations to decontaminate and decommission the buildings and site used to produce byproduct materials and reclaim the tailings and/or waste disposal area.

Closure plan means the Commission approved plan to accomplish closure.

Compliance period begins when the Commission sets secondary ground-water protection standards and ends when the owner or operator's license is terminated and the site is transferred to the State or Federal agency for long-term care.

Dike means an embankment or ridge of either natural or man-made materials used to prevent the movement of liquids, sludges, solids or other materials.

Disposal area means the area containing byproduct materials to which the requirements of Criterion 6 apply.

Existing portion means that land surface area of an existing surface impoundment on which significant quantities of uranium or thorium byproduct materials had been placed prior to September 30, 1983.

Factors beyond the control of the licensee means factors proximately causing delay in meeting the schedule in the applicable reclamation plan for the timely emplacement of the final radon barrier notwithstanding the good faith efforts of the licensee to complete the barrier in compliance with paragraph (1) of Criterion 6A. These factors may include, but are not limited to:

(1) Physical conditions at the site;

(2) Inclement weather or climatic conditions;

(3) An act of God;

(4) An act of war;

(5) A judicial or administrative order or decision, or change to the statutory, regulatory, or other legal requirements applicable to the licensee's facility that would preclude or delay the performance of activities required for compliance;

(6) Labor disturbances;

(7) Any modifications, cessation or delay ordered by State, Federal, or local agencies;

(8) Delays beyond the time reasonably required in obtaining necessary government permits, licenses, approvals, or consent for activities described in the reclamation plan proposed by the licensee that result from agency failure to take final action after the licensee has made a good faith, timely effort to submit legally sufficient applications, responses to requests (including relevant data requested by the agencies), or other information, including approval of the reclamation plan; and

(9) An act or omission of any third party over whom the licensee has no control.

Final radon barrier means the earthen cover (or approved alternative cover) over tailings or waste constructed to comply with Criterion 6 of this appendix (excluding erosion protection features).

Ground water means water below the land surface in a zone of saturation. For purposes of this appendix, ground water is the water contained within an aquifer as defined above.

Leachate means any liquid, including any suspended or dissolved components in the liquid, that has percolated through or drained from the byproduct material.

Licensed site means the area contained within the boundary of a location under the control of persons generating or storing byproduct materials under a Commission license.

Liner means a continuous layer of natural or man-made materials, beneath or on the sides of a

surface impoundment which restricts the downward or lateral escape of byproduct material, hazardous constituents, or leachate.

Milestone means an action or event that is required to occur by an enforceable date.

Operation means that a uranium or thorium mill tailings pile or impoundment is being used for the continued placement of byproduct material or is in standby status for such placement. A pile or impoundment is in operation from the day that byproduct material is first placed in the pile or impoundment until the day final closure begins.

Point of compliance is the site specific location in the uppermost aquifer where the ground-water protection standard must be met.

Reclamation plan, for the purposes of Criterion 6A, means the plan detailing activities to accomplish reclamation of the tailings or waste disposal area in accordance with the technical criteria of this appendix. The reclamation plan must include a schedule for reclamation milestones that are key to the completion of the final radon barrier including as appropriate, but not limited to, wind blown tailings retrieval and placement on the pile, interim stabilization (including dewatering or the removal of freestanding liquids and recontouring), and final radon barrier construction. (Reclamation of tailings must also be addressed in the closure plan; the detailed reclamation plan may be incorporated into the closure plan.)

Surface impoundment means a natural topographic depression, man-made excavation, or diked area, which is designed to hold an accumulation of liquid wastes or wastes containing free liquids, and which is not an injection well.

Uppermost aquifer means the geologic formation nearest the natural ground surface that is an aquifer, as well as lower aquifers that are hydraulically interconnected with this aquifer within the facility's property boundary.

I. Technical Criteria

Criterion 1--The general goal or broad objective in siting and design decisions is permanent isolation of tailings and associated contaminants by minimizing disturbance and dispersion by natural forces, and to do so without ongoing maintenance. For practical reasons, specific siting decisions and design standards must involve finite times (e.g., the longevity design standard in Criterion 6). The following site features which will contribute to such a goal or objective must be considered in selecting among alternative tailings disposal sites or judging the adequacy of existing tailings sites:

Remoteness from populated areas;

Hydrologic and other natural conditions as they contribute to continued immobilization and isolation of contaminants from ground-water sources; and

Potential for minimizing erosion, disturbance, and dispersion by natural forces over the long term.

The site selection process must be an optimization to the maximum extent reasonably achievable in terms of these features.

In the selection of disposal sites, primary emphasis must be given to isolation of tailings or wastes, a matter having long-term impacts, as opposed to consideration only of short-term convenience or benefits, such as minimization of transportation or land acquisition costs. While isolation of tailings will be a function of both site and engineering design, overriding consideration must be given to siting features given the long-term nature of the tailings hazards.

Tailings should be disposed of in a manner that no active maintenance is required to preserve conditions of the site.

Criterion 2--To avoid proliferation of small waste disposal sites and thereby reduce perpetual surveillance obligations, byproduct material from in situ extraction operations, such as residues from solution evaporation or contaminated control processes, and wastes from small remote above ground extraction operations must be disposed of at existing large mill tailings disposal sites; unless, considering the nature of the wastes, such as their volume and specific activity, and the costs and environmental impacts of transporting the wastes to a large disposal site, such offsite disposal is demonstrated to be impracticable or the advantages of onsite burial clearly outweigh the benefits of reducing the perpetual surveillance obligations.

Criterion 3--The "prime option" for disposal of tailings is placement below grade, either in mines or specially excavated pits (that is, where the need for any specially constructed retention structure is eliminated). The evaluation of alternative sites and disposal methods performed by mill operators in support of their proposed tailings disposal program (provided in applicants' environmental reports) must reflect serious consideration of this disposal mode. In some instances, below grade disposal may not be the most environmentally sound approach, such as might be the case if a ground-water formation is relatively close to the surface or not very well isolated by overlying soils and rock. Also, geologic and topographic conditions might make full below grade burial impracticable: For example, bedrock may be sufficiently near the surface that blasting would be required to excavate a disposal pit at excessive cost, and more suitable alternative sites are not available. Where full below grade burial is not practicable, the size of retention structures, and size and steepness of slopes associated exposed embankments must be minimized by excavation to the maximum extent reasonably achievable or appropriate given the geologic and hydrologic conditions at a site. In these cases, it must be demonstrated that an above grade disposal program will provide reasonably equivalent isolation of the tailings from natural erosional forces.

Criterion 4--The following site and design criteria must be adhered to whether tailings or wastes are disposed of above or below grade.

(a) Upstream rainfall catchment areas must be minimized to decrease erosion potential and the size of the floods which could erode or wash out sections of the tailings disposal area.

(b) Topographic features should provide good wind protection.

(c) Embankment and cover slopes must be relatively flat after final stabilization to minimize erosion potential and to provide conservative factors of safety assuring long-term stability. The broad objective should be to contour final slopes to grades which are as close as possible to those which would be provided if tailings were disposed of below grade; this could, for example, lead to slopes of about 10 horizontal to 1 vertical (10h:1v) or less steep. In general, slopes should not be steeper than about 5h:1v. Where steeper slopes are proposed, reasons why a slope less steep than 5h:1v would be impracticable should be provided, and compensating factors and conditions which make such slopes acceptable should be identified.

(d) A full self-sustaining vegetative cover must be established or rock cover employed to reduce wind and water erosion to negligible levels.

Where a full vegetative cover is not likely to be self-sustaining due to climatic or other conditions, such as in semi-arid and arid regions, rock cover must be employed on slopes of the impoundment system. The NRC will consider relaxing this requirement for extremely gentle slopes such as those which may exist on the top of the pile.

The following factors must be considered in establishing the final rock cover design to avoid displacement of rock particles by human and animal traffic or by natural process, and to preclude undercutting and piping:

Shape, size, composition, and gradation of rock particles (excepting bedding material average particles size must be at least cobble size or greater);

Rock cover thickness and zoning of particles by size; and

Steepness of underlying slopes.

Individual rock fragments must be dense, sound, and resistant to abrasion, and must be free from cracks, seams, and other defects that would tend to unduly increase their destruction by water and frost actions. Weak, friable, or laminated aggregate may not be used.

Rock covering of slopes may be unnecessary where top covers are very thick (on the order of 10 m or greater); impoundment slopes are very gentle (on the order of 10 h:1v or less); bulk cover materials have inherently favorable erosion resistance characteristics; and, there is negligible drainage catchment area upstream of the pile and good wind protection as described in points (a) and (b) of this Criterion.

Furthermore, all impoundment surfaces must be contoured to avoid areas of concentrated surface

runoff or abrupt or sharp changes in slope gradient. In addition to rock cover on slopes, areas toward which surface runoff might be directed must be well protected with substantial rock cover (rip rap). In addition to providing for stability of the impoundment system itself, overall stability, erosion potential, and geomorphology of surrounding terrain must be evaluated to assure that there are not ongoing or potential processes, such as gully erosion, which would lead to impoundment instability.

(e) The impoundment may not be located near a capable fault that could cause a maximum credible earthquake larger than that which the impoundment could reasonably be expected to withstand. As used in this criterion, the term "capable fault" has the same meaning as defined in section III(g) of Appendix A of 10 CFR Part 100. The term "maximum credible earthquake" means that earthquake which would cause the maximum vibratory ground motion based upon an evaluation of earthquake potential considering the regional and local geology and seismology and specific characteristics of local subsurface material.

(f) The impoundment, where feasible, should be designed to incorporate features which will promote deposition. For example, design features which promote deposition of sediment suspended in any runoff which flows into the impoundment area might be utilized; the object of such a design feature would be to enhance the thickness of cover over time.

Criterion 5--Criteria 5A-5D and new Criterion 13 incorporate the basic ground-water protection standards imposed by the Environmental Protection Agency in 40 CFR Part 192, Subparts D and E (48 FR 45926; October 7, 1983) which apply during operations and prior to the end of closure. Ground-water monitoring to comply with these standards is required by Criterion 7A.

5A(1)--The primary ground-water protection standard is a design standard for surface impoundments used to manage uranium and thorium byproduct material. Unless exempted under paragraph 5A(3) of this criterion, surface impoundments (except for an existing portion) must have a liner that is designed, constructed, and installed to prevent any migration of wastes out of the impoundment to the adjacent subsurface soil, ground water, or surface water at any time during the active life (including the closure period) of the impoundment. The liner may be constructed of materials that may allow wastes to migrate into the liner (but not into the adjacent subsurface soil, ground water, or surface water) during the active life of the facility, provided that impoundment closure includes removal or decontamination of all waste residues, contaminated containment system components (liners, etc.), contaminated subsoils, and structures and equipment contaminated with waste and leachate. For impoundments that will be closed with the liner material left in place, the liner must be constructed of materials that can prevent wastes from migrating into the liner during the active life of the facility.

5A(2)--The liner required by paragraph 5A(1) above must be--

(a) Constructed of materials that have appropriate chemical properties and sufficient strength and thickness to prevent failure due to pressure gradients (including static head and external hydrogeologic forces), physical contact with the waste or leachate to which they are exposed,

climatic conditions, the stress of installation, and the stress of daily operation;

(b) Placed upon a foundation or base capable of providing support to the liner and resistance to pressure gradients above and below the liner to prevent failure of the liner due to settlement, compression, or uplift; and

(c) Installed to cover all surrounding earth likely to be in contact with the wastes or leachate.

5A(3)--The applicant or licensee will be exempted from the requirements of paragraph 5A(1) of this criterion if the Commission finds, based on a demonstration by the applicant or licensee, that alternate design and operating practices, including the closure plan, together with site characteristics will prevent the migration of any hazardous constituents into ground water or surface water at any future time. In deciding whether to grant an exemption, the Commission will consider--

(a) The nature and quantity of the wastes;

(b) The proposed alternate design and operation;

(c) The hydrogeologic setting of the facility, including the attenuative capacity and thickness of the liners and soils present between the impoundment and ground water or surface water; and

(d) All other factors which would influence the quality and mobility of the leachate produced and the potential for it to migrate to ground water or surface water.

5A(4)--A surface impoundment must be designed, constructed, maintained, and operated to prevent overtopping resulting from normal or abnormal operations, overfilling, wind and wave actions, rainfall, or run-on; from malfunctions of level controllers, alarms, and other equipment; and from human error.

5A(5)--When dikes are used to form the surface impoundment, the dikes must be designed, constructed, and maintained with sufficient structural integrity to prevent massive failure of the dikes. In ensuring structural integrity, it must not be presumed that the liner system will function without leakage during the active life of the impoundment.

5B(1)--Uranium and thorium byproduct materials must be managed to conform to the following secondary ground-water protection standard: Hazardous constituents entering the ground water from a licensed site must not exceed the specified concentration limits in the uppermost aquifer beyond the point of compliance during the compliance period. Hazardous constituents are those constituents identified by the Commission pursuant to paragraph 5B(2) of this criterion. Specified concentration limits are those limits established by the Commission as indicated in paragraph 5B(5) of this criterion. The Commission will also establish the point of compliance and compliance period on a site specific basis through license conditions and orders. The objective in selecting the point of compliance is to provide the earliest practicable warning that

the impoundment is releasing hazardous constituents to the ground water. The point of compliance must be selected to provide prompt indication of ground-water contamination on the hydraulically downgradient edge of the disposal area. The Commission shall identify hazardous constituents, establish concentration limits, set the compliance period, and may adjust the point of compliance if needed to accord with developed data and site information as to the flow of ground water or contaminants, when the detection monitoring established under Criterion 7A indicates leakage of hazardous constituents from the disposal area.

5B(2)--A constituent becomes a hazardous constituent subject to paragraph 5B(5) only when the constituent meets all three of the following tests:

(a) The constituent is reasonably expected to be in or derived from the byproduct material in the disposal area;

(b) The constituent has been detected in the ground water in the uppermost aquifer; and

(c) The constituent is listed in Criterion 13 of this appendix.

5B(3)--Even when constituents meet all three tests in paragraph 5B(2) of this criterion, the Commission may exclude a detected constituent from the set of hazardous constituents on a site specific basis if it finds that the constituent is not capable of posing a substantial present or potential hazard to human health or the environment. In deciding whether to exclude constituents, the Commission will consider the following:

(a) Potential adverse effects on ground-water quality, considering--

(i) The physical and chemical characteristics of the waste in the licensed site, including its potential for migration;

(ii) The hydrogeological characteristics of the facility and surrounding land;

(iii) The quantity of ground water and the direction of ground-water flow;

(iv) The proximity and withdrawal rates of ground-water users;

(v) The current and future uses of ground water in the area;

(vi) The existing quality of ground water, including other sources of contamination and their cumulative impact on the ground-water quality;

(vii) The potential for health risks caused by human exposure to waste constituents;

(viii) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents;

(ix) The persistence and permanence of the potential adverse effects.

(b) Potential adverse effects on hydraulically-connected surface water quality, considering--

(i) The volume and physical and chemical characteristics of the waste in the licensed site;

(ii) The hydrogeological characteristics of the facility and surrounding land;

(iii) The quantity and quality of ground water, and the direction of ground-water flow;

(iv) The patterns of rainfall in the region;

(v) The proximity of the licensed site to surface waters;

(vi) The current and future uses of surface waters in the area and any water quality standards established for those surface waters;

(vii) The existing quality of surface water, including other sources of contamination and the cumulative impact on surface-water quality;

(viii) The potential for health risks caused by human exposure to waste constituents;

(ix) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents; and

(x) The persistence and permanence of the potential adverse effects.

5B(4)--In making any determinations under paragraphs 5B(3) and 5B(6) of this criterion about the use of ground water in the area around the facility, the Commission will consider any identification of underground sources of drinking water and exempted aquifers made by the Environmental Protection Agency.

5B(5)--At the point of compliance, the concentration of a hazardous constituent must not exceed--

(a) The Commission approved background concentration of that constituent in the ground water;

(b) The respective value given in the table in paragraph 5C if the constituent is listed in the table and if the background level of the constituent is below the value listed; or

(c) An alternate concentration limit established by the Commission.

5B(6)--Conceptually, background concentrations pose no incremental hazards and the drinking water limits in paragraph 5C state acceptable hazards but these two options may not be

practically achievable at a specific site. Alternate concentration limits that present no significant hazard may be proposed by licensees for Commission consideration. Licensees must provide the basis for any proposed limits including consideration of practicable corrective actions, that limits are as low as reasonably achievable, and information on the factors the Commission must consider. The Commission will establish a site specific alternate concentration limit for a hazardous constituent as provided in paragraph 5B(5) of this criterion if it finds that the proposed limit is as low as reasonably achievable, after considering practicable corrective actions, and that the constituent will not pose a substantial present or potential hazard to human health or the environment as long as the alternate concentration limit is not exceeded. In making the present and potential hazard finding, the Commission will consider the following factors:

(a) Potential adverse effects on ground-water quality, considering--

(i) The physical and chemical characteristics of the waste in the licensed site including its potential for migration;

(ii) The hydrogeological characteristics of the facility and surrounding land;

(iii) The quantity of ground water and the direction of ground-water flow;

(iv) The proximity and withdrawal rates of ground-water users;

(v) The current and future uses of ground water in the area;

(vi) The existing quality of ground water, including other sources of contamination and their cumulative impact on the ground-water quality;

(vii) The potential for health risks caused by human exposure to waste constituents;

(viii) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents;

(ix) The persistence and permanence of the potential adverse effects.

(b) Potential adverse effects on hydraulically-connected surface water quality, considering--

(i) The volume and physical and chemical characteristics of the waste in the licensed site;

(ii) The hydrogeological characteristics of the facility and surrounding land;

(iii) The quantity and quality of ground water, and the direction of ground-water flow;

(iv) The patterns of rainfall in the region;

(v) The proximity of the licensed site to surface waters; (vi) The current and future uses of surface waters in the area and any water quality standards established for those surface waters;

(vii) The existing quality of surface water including other sources of contamination and the cumulative impact on surface water quality;

(viii) The potential for health risks caused by human exposure to waste constituents;

(ix) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents; and

(x) The persistence and permanence of the potential adverse effects.

5C-Maximum Values for Ground-Water Protection

Constituent or property	Maximum concentration
Milligrams per liter:	
Arsenic	0.05
Barium	1.0
Cadmium	0.01
Chromium	0.05
Lead	0.05
Mercury	0.002
Selenium	0.01
Silver	0.05
Endrin (1,2,3,4,10,10-hexachloro-1,7 -expoxy-1,4,4a,5,6,7,8,9a-octahydro-1, 4-endo, endo-5, 8-dimethano napthalene)	0.0002
Lindane (1,2,3,4,5,6-hexachlorocyclohexane, gamma isomer)	0.004
Methoxychlor (1,1,1-Trichloro-2,2-bis (p-methoxyphenylethane)	0.1
Toxaphene (C_{10} H_{10} $C1_6$, Technical chlorinated camphene, 67-69 percent chlorine)	0.005
2, 4-D(2,4-Dichlorophenoxyacetic acid)	0.1
2, 4,5-TP Silvex (2,4,5-Trichlorophenoxypropionic acid)	
Picocuries per liter:	
Combined radium-226 and radium-228	5

Gross alpha-particle activity (excluding radon and uranium when producing uranium byproduct material or radon and thorium when producing thorium byproduct material)	15

5D-If the ground-water protection standards established under paragraph 5B(1) of this criterion are exceeded at a licensed site, a corrective action program must be put into operation as soon as is practicable, and in no event later than eighteen (18) months after the Commission finds that the standards have been exceeded. The licensee shall submit the proposed corrective action program and supporting rationale for Commission approval prior to putting the program into operation, unless otherwise agreed to by the Commission. The objective of the program is to return hazardous constituent concentration levels in ground water to the concentration levels set as standards. The licensee's proposed program must address removing hazardous constituents that have entered the ground water at the point of compliance or treating them in place. The program must also address removing or treating any hazardous constituents that exceed concentration limits in ground water between the point of compliance and the downgradient facility property boundary. The licensee shall continue corrective action measures to the extent necessary to achieve and maintain compliance with the groundwater standard. The Commission will determine when the licensee may terminate corrective action measures based on data from the ground-water monitoring program and other information that provide reasonable assurance that the ground-water protection standard will not be exceeded.

5E-In developing and conducting ground-water protection programs, applicants and licensees shall also consider the following:

(1) Installation of bottom liners(Where synthetic liners are used, a leakage detection system must be installed immediately below the liner to ensure major failures are detected if they occur. This is in addition to the ground-water monitoring program conducted as provided in Criterion 7. Where clay liners are proposed or relatively thin, in-situ clay soils are to be relied upon for seepage control, tests must be conducted with representative tailings solutions and clay materials to confirm that no significant deterioration of permeability or stability properties will occur with continuous exposure of clay to tailings solutions. Tests must be run for a sufficient period of time to reveal any effects if they are going to occur (in some cases deterioration has been observed to occur rather rapidly after about nine months of exposure)).

(2) Mill process designs which provide the maximum practicable recycle of solutions and conservation of water to reduce the net input of liquid to the tailings impoundment.

(3) Dewatering of tailings by process devices and/or in-situ drainage systems (At new sites, tailings must be dewatered by a drainage system installed at the bottom of the impoundment to lower the phreatic surface and reduce the driving head of seepage, unless tests show tailings are not amenable to such a system. Where in-situ dewatering is to be conducted, the impoundment bottom must be graded to assure that the drains are at a low point. The drains must be protected by suitable filter materials to assure that drains remain free running. The drainage system must also be adequately sized to assure good drainage).

(4) Neutralization to promote immobilization of hazardous constituents.

5F--Where ground-water impacts are occurring at an existing site due to seepage, action must be taken to alleviate conditions that lead to excessive seepage impacts and restore ground-water quality. The specific seepage control and ground-water protection method, or combination of methods, to be used must be worked out on a site-specific basis. Technical specifications must be prepared to control installation of seepage control systems. A quality assurance, testing, and inspection program, which includes supervision by a qualified engineer or scientist, must be established to assure the specifications are met.

5G--In support of a tailings disposal system proposal, the applicant/operator shall supply information concerning the following:

(1) The chemical and radioactive characteristics of the waste solutions.

(2) The characteristics of the underlying soil and geologic formations particularly as they will control transport of contaminants and solutions. This includes detailed information concerning extent, thickness, uniformity, shape, and orientation of underlying strata. Hydraulic gradients and conductivities of the various formations must be determined. This information must be gathered from borings and field survey methods taken within the proposed impoundment area and in surrounding areas where contaminants might migrate to ground water. The information gathered on boreholes must include both geologic and geophysical logs in sufficient number and degree of sophistication to allow determining significant discontinuities, fractures, and channeled deposits of high hydraulic conductivity. If field survey methods are used, they should be in addition to and calibrated with borehole logging. Hydrologic parameters such as permeability may not be determined on the basis of laboratory analysis of samples alone; a sufficient amount of field testing (e.g., pump tests) must be conducted to assure actual field properties are adequately understood. Testing must be conducted to allow estimating chemi-sorption attenuation properties of underlying soil and rock.

(3) Location, extent, quality, capacity and current uses of any ground water at and near the site.

5H--Steps must be taken during stockpiling of ore to minimize penetration of radionuclides into underlying soils; suitable methods include lining and/or compaction of ore storage areas.

Criterion 6--(1) In disposing of waste byproduct material, licensees shall place an earthen cover (or approved alternative) over tailings or wastes at the end of milling operations and shall close the waste disposal area in accordance with a design[1] which provides reasonable assurance of control of radiological hazards to (i) be effective for 1,000 years, to the extent reasonably achievable, and, in any case, for at least 200 years, and (ii) limit releases of radon-222 from uranium byproduct materials, and radon-220 from thorium byproduct materials, to the atmosphere so as not to exceed an average[2] release rate of 20 picocuries per square meter per second (pCi/m^2s) to the extent practicable throughout the effective design life determined pursuant to (1)(i) of this Criterion. In computing required tailings cover thicknesses, moisture in

soils in excess of amounts found normally in similar soils in similar circumstances may not be considered. Direct gamma exposure from the tailings or wastes should be reduced to background levels. The effects of any thin synthetic layer may not be taken into account in determining the calculated radon exhalation level. If non-soil materials are proposed as cover materials, it must be demonstrated that these materials will not crack or degrade by differential settlement, weathering, or other mechanism, over long-term intervals.

(2) As soon as reasonably achievable after emplacement of the final cover to limit releases of radon-222 from uranium byproduct material and prior to placement of erosion protection barriers or other features necessary for long-term control of the tailings, the licensee shall verify through appropriate testing and analysis that the design and construction of the final radon barrier is effective in limiting releases of radon-222 to a level not exceeding 20 pCi/m^2s averaged over the entire pile or impoundment using the procedures described in 40 CFR part 61, appendix B, Method 115, or another method of verification approved by the Commission as being at least as effective in demonstrating the effectiveness of the final radon barrier.

(3) When phased emplacement of the final radon barrier is included in the applicable reclamation plan, the verification of radon-222 release rates required in paragraph (2) of this criterion must be conducted for each portion of the pile or impoundment as the final radon barrier for that portion is emplaced.

(4) Within ninety days of the completion of all testing and analysis relevant to the required verification in paragraphs (2) and (3) of this criterion, the uranium mill licensee shall report to the Commission the results detailing the actions taken to verify that levels of release of radon-222 do not exceed 20 pCi/m^2s when averaged over the entire pile or impoundment. The licensee shall maintain records until termination of the license documenting the source of input parameters including the results of all measurements on which they are based, the calculations and/or analytical methods used to derive values for input parameters, and the procedure used to determine compliance. These records shall be kept in a form suitable for transfer to the custodial agency at the time of transfer of the site to DOE or a State for long-term care if requested.

(5) Near surface cover materials (i.e., within the top three meters) may not include waste or rock that contains elevated levels of radium; soils used for near surface cover must be essentially the same, as far as radioactivity is concerned, as that of surrounding surface soils. This is to ensure that surface radon exhalation is not significantly above background because of the cover material itself.

(6) The design requirements in this criterion for longevity and control of radon releases apply to any portion of a licensed and/or disposal site unless such portion contains a concentration of radium in land, averaged over areas of 100 square meters, which, as a result of byproduct material, does not exceed the background level by more than: (i) 5 picocuries per gram (pCi/g) of radium-226, or, in the case of thorium byproduct material, radium-228, averaged over the first 15 centimeters (cm) below the surface, and (ii) 15 pCi/g of radium-226, or, in the case of thorium byproduct material, radium-228, averaged over 15-cm thick layers more than 15 cm below the

surface.

Byproduct material containing concentrations of radionuclides other than radium in soil, and surface activity on remaining structures, must not result in a total effective dose equivalent (TEDE) exceeding the dose from cleanup of radium contaminated soil to the above standard (benchmark dose), and must be at levels which are as low as is reasonably achievable. If more than one residual radionuclide is present in the same 100-square-meter area, the sum of the ratios for each radionuclide of concentration present to the concentration limit will not exceed "1" (unity). A calculation of the potential peak annual TEDE within 1000 years to the average member of the critical group that would result from applying the radium standard (not including radon) on the site must be submitted for approval. The use of decommissioning plans with benchmark doses which exceed 100 mrem/yr, before application of ALARA, requires the approval of the Commission after consideration of the recommendation of the NRC staff. This requirement for dose criteria does not apply to sites that have decommissioning plans for soil and structures approved before June 11, 1999.

(7) The licensee shall also address the nonradiological hazards associated with the wastes in planning and implementing closure. The licensee shall ensure that disposal areas are closed in a manner that minimizes the need for further maintenance. To the extent necessary to prevent threats to human health and the environment, the licensee shall control, minimize, or eliminate post-closure escape of nonradiological hazardous constituents, leachate, contaminated rainwater, or waste decomposition products to the ground or surface waters or to the atmosphere.

Criterion 6A--(1) For impoundments containing uranium byproduct materials, the final radon barrier must be completed *as expeditiously as practicable considering technological feasibility* after the pile or impoundment ceases operation in accordance with a written, Commission-approved reclamation plan. (The term *as expeditiously as practicable considering technological feasibility* as specifically defined in the Introduction of this appendix includes factors beyond the control of the licensee.) Deadlines for completion of the final radon barrier and, if applicable, the following interim milestones must be established as a condition of the individual license: windblown tailings retrieval and placement on the pile and interim stabilization (including dewatering or the removal of freestanding liquids and recontouring). The placement of erosion protection barriers or other features necessary for long-term control of the tailings must also be completed in a timely manner in accordance with a written, Commission-approved reclamation plan.

(2) The Commission may approve a licensee's request to extend the time for performance of milestones related to emplacement of the final radon barrier if, after providing an opportunity for public participation, the Commission finds that the licensee has adequately demonstrated in the manner required in paragraph (2) of Criterion 6 that releases of radon-222 do not exceed an average of 20 pCi/m^2s. If the delay is approved on the basis that the radon releases do not exceed 20 pCi/m^2s, a verification of radon levels, as required by paragraph (2) of Criterion 6, must be made annually during the period of delay. In addition, once the Commission has established the date in the reclamation plan for the milestone for completion of the final radon barrier, the

Commission may extend that date based on cost if, after providing an opportunity for public participation, the Commission finds that the licensee is making good faith efforts to emplace the final radon barrier, the delay is consistent with the definition of available technology, and the radon releases caused by the delay will not result in a significant incremental risk to the public health.

(3) The Commission may authorize by license amendment, upon licensee request, a portion of the impoundment to accept uranium byproduct material or such materials that are similar in physical, chemical, and radiological characteristics to the uranium mill tailings and associated wastes already in the pile or impoundment, from other sources, during the closure process. No such authorization will be made if it results in a delay or impediment to emplacement of the final radon barrier over the remainder of the impoundment in a manner that will achieve levels of radon-222 releases not exceeding 20 pCi/m^2s averaged over the entire impoundment. The verification required in paragraph (2) of Criterion 6 may be completed with a portion of the impoundment being used for further disposal if the Commission makes a final finding that the impoundment will continue to achieve a level of radon-222 releases not exceeding 20 pCi/m^2s averaged over the entire impoundment. In this case, after the final radon barrier is complete except for the continuing disposal area, (a) only byproduct material will be authorized for disposal, (b) the disposal will be limited to the specified existing disposal area, and (c) this authorization will only be made after providing opportunity for public participation. Reclamation of the disposal area, as appropriate, must be completed in a timely manner after disposal operations cease in accordance with paragraph (1) of Criterion 6; however, these actions are not required to be complete as part of meeting the deadline for final radon barrier construction.

Criterion 7--At least one full year prior to any major site construction, a preoperational monitoring program must be conducted to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, an operational monitoring program must be conducted to measure or evaluate compliance with applicable standards and regulations; to evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential long-term effects.

7A--The licensee shall establish a detection monitoring program needed for the Commission to set the site-specific ground-water protection standards in paragraph 5B(1) of this appendix. For all monitoring under this paragraph the licensee or applicant will propose for Commission approval as license conditions which constituents are to be monitored on a site specific basis. A detection monitoring program has two purposes. The initial purpose of the program is to detect leakage of hazardous constituents from the disposal area so that the need to set ground-water protection standards is monitored. If leakage is detected, the second purpose of the program is to generate data and information needed for the Commission to establish the standards under Criterion 5B. The data and information must provide a sufficient basis to identify those hazardous constituents which require concentration limit standards and to enable the Commission to set the limits for those constituents and the compliance period. They may also need to provide the basis for adjustments to the point of compliance. For licenses in effect September 30, 1983, the detection monitoring programs must have been in place by October 1, 1984. For licenses issued after September 30, 1983, the detection monitoring programs must be

in place when specified by the Commission in orders or license conditions. Once ground-water protection standards have been established pursuant to paragraph 5B(1), the licensee shall establish and implement a compliance monitoring program. The purpose of the compliance monitoring program is to determine that the hazardous constituent concentrations in ground water continue to comply with the standards set by the Commission. In conjunction with a corrective action program, the licensee shall establish and implement a corrective action monitoring program. The purpose of the corrective action monitoring program is to demonstrate the effectiveness of the corrective actions. Any monitoring program required by this paragraph may be based on existing monitoring programs to the extent the existing programs can meet the stated objective for the program.

Criterion 8--Milling operations must be conducted so that all airborne effluent releases are reduced to levels as low as is reasonably achievable. The primary means of accomplishing this must be by means of emission controls. Institutional controls, such as extending the site boundary and exclusion area, may be employed to ensure that offsite exposure limits are met, but only after all practicable measures have been taken to control emissions at the source. Notwithstanding the existence of individual dose standards, strict control of emissions is necessary to assure that population exposures are reduced to the maximum extent reasonably achievable and to avoid site contamination. The greatest potential sources of offsite radiation exposure (aside from radon exposure) are dusting from dry surfaces of the tailings disposal area not covered by tailings solution and emissions from yellowcake drying and packaging operations. During operations and prior to closure, radiation doses from radon emissions from surface impoundments of uranium or thorium byproduct materials must be kept as low as is reasonably achievable.

Checks must be made and logged hourly of all parameters (e.g., differential pressures and scrubber water flow rates) that determine the efficiency of yellowcake stack emission control equipment operation. The licensee shall retain each log as a record for three years after the last entry in the log is made. It must be determined whether or not conditions are within a range prescribed to ensure that the equipment is operating consistently near peak efficiency; corrective action must be taken when performance is outside of prescribed ranges. Effluent control devices must be operative at all times during drying and packaging operations and whenever air is exhausting from the yellowcake stack. Drying and packaging operations must terminate when controls are inoperative. When checks indicate the equipment is not operating within the range prescribed for peak efficiency, actions must be taken to restore parameters to the prescribed range. When this cannot be done without shutdown and repairs, drying and packaging operations must cease as soon as practicable. Operations may not be restarted after cessation due to off-normal performance until needed corrective actions have been identified and implemented. All these cessations, corrective actions, and restarts must be reported to the appropriate NRC regional office as indicated in Criterion 8A, in writing, within ten days of the subsequent restart.

To control dusting from tailings, that portion not covered by standing liquids must be wetted or chemically stabilized to prevent or minimize blowing and dusting to the maximum extent reasonably achievable. This requirement may be relaxed if tailings are effectively sheltered from wind, such as may be the case where they are disposed of below grade and the tailings surface is

not exposed to wind. Consideration must be given in planning tailings disposal programs to methods which would allow phased covering and reclamation of tailings impoundments because this will help in controlling particulate and radon emissions during operation. To control dusting from diffuse sources, such as tailings and ore pads where automatic controls do not apply, operators shall develop written operating procedures specifying the methods of control which will be utilized.

Milling operations producing or involving thorium byproduct material must be conducted in such a manner as to provide reasonable assurance that the annual dose equivalent does not exceed 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ of any member of the public as a result of exposures to the planned discharge of radioactive materials, radon-220 and its daughters excepted, to the general environment.

Uranium and thorium byproduct materials must be managed so as to conform to the applicable provisions of Title 40 of the Code of Federal Regulations, Part 440, "Ore Mining and Dressing Point Source Category: Effluent Limitations Guidelines and New Source Performance Standards, Subpart C, Uranium, Radium, and Vanadium Ores Subcategory," as codified on January 1, 1983.

Criterion 8A--Daily inspections of tailings or waste retention systems must be conducted by a qualified engineer or scientist and documented. The licensee shall retain the documentation for each daily inspection as a record for three years after the documentation is made. The appropriate NRC regional office as indicated in Appendix D to 10 CFR Part 20 of this chapter, or the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001, must be immediately notified of any failure in a tailings or waste retention system that results in a release of tailings or waste into unrestricted areas, or of any unusual conditions (conditions not contemplated in the design of the retention system) that if not corrected could indicate the potential or lead to failure of the system and result in a release of tailings or waste into unrestricted areas.

II. Financial Criteria

Criterion 9--(a)Financial surety arrangements must be established by each mill operator before the commencement of operations to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the mill and site and for the reclamation of any tailings or waste disposal areas. The amount of funds to be ensured by such surety arrangements must be based on Commission-approved cost estimates in a Commission-approved plan, or a proposed revision to the plan submitted to the Commission for approval, if the proposed revision contains a higher cost estimate, for

(1) Decontamination and decommissioning of mill buildings and the milling site to levels which allow unrestricted use of these areas upon decommissioning, and

(2) The reclamation of tailings and/or waste areas in accordance with technical criteria delineated in Section I of this appendix.

(b) Each cost estimate must contain –

(1) A detailed cost estimate for decontamination, decommissioning, and reclamation, in the amount reflecting:

(i) The cost of an independent contractor to perform the decontamination, decommissioning and reclamation activities; and

(ii) An adequate contingency factor;

(2) An estimate of the amount of radioactive contamination in onsite subsurface material;

(3) Identification of and justification for using the key assumptions contained in the DCE; and

(4) A description of the method of assuring funds for decontamination, decommissioning, and reclamation.

(c) The licensee shall submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and evaluates alternatives for mitigating these impacts. The plan must include a signed original of the financial instrument obtained to satisfy the surety arrangement requirements of this criterion (unless a previously submitted and approved financial instrument continues to cover the cost estimate and the payment of the charge for for long-term surveillance and control required by Criterion 10 of this section.

(d) To avoid unnecessary duplication and expense, the Commission may accept financial sureties that have been consolidated with financial or surety arrangements established to meet requirements of other Federal or state agencies and/or local governing bodies for such decommissioning, decontamination, reclamation, and long-term site surveillance and control, provided such arrangements are considered adequate to satisfy these requirements and that the portion of the surety which covers the decommissioning and reclamation of the mill, mill tailings site and associated areas, and the long-term funding charge is clearly identified and committed for use in accomplishing these activities.

(e) The licensees' surety mechanism will be reviewed annually by the Commission to assure, that sufficient funds would be available for completion of the reclamation plan if the work had to be performed by an independent contractor.

(f) The amount of surety liability should be adjusted to recognize any increases or decreases resulting from

(1) Inflation;

(2) Changes in engineering plans;

(3) Activities performed;

(4) Spills, leakage or migration of radioactive material producing additional contamination in onsite subsurface material that must be remediated to meet applicable remediation criteria;

(5) Waste inventory increasing above the amount previously estimated;

(6) Waste disposal costs increasing above the amount previously estimated;

(7) Facility modifications;

(8) Changes in authorized possession limits;

(9) Actual remediation costs that exceed the previous cost estimate;

(10) Onsite disposal; and

(11) Any other conditions affecting costs.

(g) Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability must be retained until final compliance with the reclamation plan is determined.

(h) The appropriate portion of surety liability retained until final compliance with the reclamation plan is determined will be at least sufficient at all times to cover the costs of decommissioning and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance would be provided with a surety instrument which is written for a specified period of time (e.g., 5 years) and which must be automatically renewed unless the surety notifies the beneficiary (the Commission or the State regulatory agency) and the principal (the licensee) with reasonable time (e.g., 90 days) before the renewal date of their intention not to renew. In such a situation the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief time to allow at least 60 days for the regulatory agency to collect.

(i) Proof of forfeiture must not be necessary to collect the surety. In the event that the licensee cannot provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The surety instrument must provide for collection of the full face amount immediately on demand without reduction for any reason, except for trustee fees and expenses provided for in a trust agreement, and that the surety will not refuse to make full payment. The conditions described previously would have to be clearly stated on any surety instrument which is not open-ended, and must be agreed to by all parties. Financial surety arrangements generally acceptable to the Commission are:

(1) Trust funds;

(2) Surety bonds;

(3) Irrevocable letters or lines of credit; and

(4) Combinations of the financial surety arrangements or other types of arrangements as may be approved by the Commission. If a trust is not used, then a standby trust must be set up to receive funds in the event the Commission of State regulatory agency exercises its right to collect the surety. The surety arrangement and the surety or trustee, as applicable, must be acceptable to the Commission. Self insurance, or any arrangement which essentially constitutes self insurance (e.g., a contract with a State or Federal agency), will not satisfy the surety requirement because this provides no additional assurance other than that which already exists through license requirements.

Criterion 10--A minimum charge of $250,000 (1978 dollars) to cover the costs of long-term surveillance must be paid by each mill operator to the general treasury of the United States or to an appropriate State agency prior to the termination of a uranium or thorium mill license.

If site surveillance or control requirements at a particular site are determined, on the basis of a site-specific evaluation, to be significantly greater than those specified in Criterion 12 (e.g., if fencing is determined to be necessary), variance in funding requirements may be specified by the Commission. In any case, the total charge to cover the costs of long-term surveillance must be such that, with an assumed 1 percent annual real interest rate, the collected funds will yield interest in an amount sufficient to cover the annual costs of site surveillance. The total charge will be adjusted annually prior to actual payment to recognize inflation. The inflation rate to be used is that indicated by the change in the Consumer Price Index published by the U.S. Department of Labor, Bureau of Labor Statistics.

III. Site and Byproduct Material Ownership

Criterion 11--A. These criteria relating to ownership of tailings and their disposal sites become effective on November 8, 1981, and apply to all licenses terminated, issued, or renewed after that date.

B. Any uranium or thorium milling license or tailings license must contain such terms and conditions as the Commission determines necessary to assure that prior to termination of the license, the licensee will comply with ownership requirements of this criterion for sites used for tailings disposal.

C. Title to the byproduct material licensed under this Part and land, including any interests therein (other than land owned by the United States or by a State) which is used for the disposal of any such byproduct material, or is essential to ensure the long term stability of such disposal site, must be transferred to the United States or the State in which such land is located, at the

option of such State. In view of the fact that physical isolation must be the primary means of long-term control, and Government land ownership is a desirable supplementary measure, ownership of certain severable subsurface interests (for example, mineral rights) may be determined to be unnecessary to protect the public health and safety and the environment. In any case, however, the applicant/operator must demonstrate a serious effort to obtain such subsurface rights, and must, in the event that certain rights cannot be obtained, provide notification in local public land records of the fact that the land is being used for the disposal of radioactive material and is subject to either an NRC general or specific license prohibiting the disruption and disturbance of the tailings. In some rare cases, such as may occur with deep burial where no ongoing site surveillance will be required, surface land ownership transfer requirements may be waived. For licenses issued before November 8, 1981, the Commission may take into account the status of the ownership of such land, and interests therein, and the ability of a licensee to transfer title and custody thereof to the United States or a State.

D. If the Commission subsequent to title transfer determines that use of the surface or subsurface estates, or both, of the land transferred to the United States or to a State will not endanger the public health, safety, welfare, or environment, the Commission may permit the use of the surface or subsurface estates, or both, of such land in a manner consistent with the provisions provided in these criteria. If the Commission permits such use of such land, it will provide the person who transferred such land with the right of first refusal with respect to such use of such land.

E. Material and land transferred to the United States or a State in accordance with this Criterion must be transferred without cost to the United States or a State other than administrative and legal costs incurred in carrying out such transfer.

F. The provisions of this part respecting transfer of title and custody to land and tailings and wastes do not apply in the case of lands held in trust by the United States for any Indian tribe or lands owned by such Indian tribe subject to a restriction against alienation imposed by the United States. In the case of such lands which are used for the disposal of byproduct material, as defined in this Part, the licensee shall enter into arrangements with the Commission as may be appropriate to assure the long-term surveillance of such lands by the United States.

IV. Long-Term Site Surveillance

Criterion 12--The final disposition of tailings, residual radioactive material, or wastes at milling sites should be such that ongoing active maintenance is not necessary to preserve isolation. As a minimum, annual site inspections must be conducted by the government agency responsible for long-term care of the disposal site to confirm its integrity and to determine the need, if any, for maintenance and/or monitoring. Results of the inspections for all the sites under the licensee's jurisdiction will be reported to the Commission annually within 90 days of the last site inspection in that calendar year. Any site where unusual damage or disruption is discovered during the inspection, however, will require a preliminary site inspection report to be submitted within 60 days. On the basis of a site specific evaluation, the Commission may require more frequent site inspections if necessary due to the features of a particular disposal site. In this case, a preliminary

inspection report is required to be submitted within 60 days following each inspection.

V. Hazardous Constituents

Criterion 13--Secondary ground-water protection standards required by Criterion 5 of this appendix are concentration limits for individual hazardous constituents. The following list of constituents identifies the constituents for which standards must be set and complied with if the specific constituent is reasonably expected to be in or derived from the byproduct material and has been detected in ground water. For purposes of this appendix, the property of gross alpha activity will be treated as if it is a hazardous constituent. Thus, when setting standards under paragraph 5B(5) of Criterion 5, the Commission will also set a limit for gross alpha activity. The Commission does not consider the following list imposed by 40 CFR Part 192 to be exhaustive and may determine other constituents to be hazardous on a case-by-case basis, independent of those specified by the U.S. Environmental Protection Agency in Part 192.

Hazardous Constituents

Acetonitrile (Ethanenitrile)

Acetophenone (Ethanone, 1-phenyl)

3-(alpha-Acetonylbenzyl)-4-hydroxycoumarin and salts (Warfarin)

2-Acetylaminofluorene (Acetamide, N-(9H-fluoren-2-yl)-)

Acetyl chloride (Ethanoyl chloride)

1-Acetyl-2-thiourea (Acetamide, N-(aminothioxomethyl)-)

Acrolein (2-Propenal)

Acrylamide (2-Propenamide)

Acrylonitrile (2-Propenenitrile)

Aflatoxins

Aldrin (1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a,8b-hexahydro-endo, exo-1,4:5,8-Dimethanonaphthalene)

Allyl alcohol (2-Propen-1-ol)

Aluminum phosphide

4-Aminobiphenyl ([1,1'-Biphenyl]-4-amine)

6-Amino-1,1a,2,8,8a,8b-hexahydro-8-(hydroxymethyl)-8a-methoxy-5-methyl-carbamate azirino[2',3'3,4]pyrrolo[1,2-a]indole-4,7-dione, (ester) (Mitomycin C) (Azirino[2'3'3,4]pyrrolo(1,2-a)indole-4,7-dione, 6-amino-8-[((amino-cabonyl)oxy)methyl]-1,1a,2,8,8a,8b-hexa-hydro-8a methoxy-5-methy-)

5-(Aminomethyl)-3-isoxazolol (3(2H)-Isoxazolone, 5-(aminomethyl)-) 4-Aminopyridine (4-Pyridinamine)

Amitrole (1H-1,2,4-Triazol-3-amine)

Aniline (Benzenamine)

Antimony and compounds, N.O.S.[(3)]

Aramite (Sulfurous acid, 2-chloroethyl-, 2-[4-(1,1-dimethylethyl) phenoxy]-1-methylethyl ester)

Arsenic and compounds, N.O.S.[3]

Arsenic acid (Orthoarsenic acid)

Arsenic pentoxide (Arsenic (V) oxide)

Arsenic trioxide (Arsenic (III) oxide)

Auramine (Benzenamine, 4,4'-carbonimidoylbis[N,N-Dimethyl-, monohydrochloride)

Azaserine (L-Serine, diazoacetate (ester))

Barium and compounds, N.O.S.[3]

Barium cyanide

Benz[c]acridine (3,4-Benzacridine)

Benz[a]anthracene (1,2-Benzanthracene)

Benzene (Cyclohexatriene)

Benzenearsonic acid (Arsonic acid, phenyl-)

Benzene, dichloromethyl- (Benzal chloride)

Benzenethiol (Thiophenol)

Benzidine ([1,1'-Biphenyl]-4,4'diamine)

Benzo[b]fluoranthene (2,3-Benzofluoranthene)

Benzo[j]fluoranthene (7,8-Benzofluoranthene)

Benzo[a]pyrene (3,4-Benzopyrene)

p-Benzoquinone (1,4-Cyclohexadienedione)

Benzotrichloride (Benzene, trichloromethyl)

Benzyl chloride (Benzene, (chloromethyl)-)

Beryllium and compounds, N.O.S.[3]

Bis(2-chloroethoxy)methane (Ethane, 1,1'-[methylenebis(oxy)]bis[2-chloro-])

Bis(2-chloroethyl) ether (Ethane, 1,1'-oxybis[2-chloro-])

N,N-Bis(2-chloroethyl)-2-naphthylamine (Chlornaphazine)

Bis(2-chloroisopropyl) ether (Propane, 2,2'-oxybis[2-chloro-])

Bis(chloromethyl) ether (Methane, oxybis[chloro-])

Bis(2-ethylhexyl) phthalate (1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester)

Bromoacetone (2-Propanone, 1-bromo-)

Bromomethane (Methyl bromide)

4-Bromophenyl phenyl ether (Benzene, 1-bromo-4-phenoxy-)

Brucine (Strychnidin-10-one, 2,3-dimethoxy-)

2-Butanone peroxide (Methyl ethyl ketone, peroxide)

Butyl benzyl phthalate (1,2-Benzenedicarboxylic acid, butyl phenylmethyl ester)

2-sec-Butyl-4,6-dinitrophenol (DNBP) (Phenol, 2,4-dinitro-6-(1-methylpropyl)-)

Cadmium and compounds, N.O.S.[3]

Calcium chromate (Chromic acid, calcium salt)

Calcium cyanide

Carbon disulfide (Carbon bisulfide)

Carbon oxyfluoride (Carbonyl fluoride)

Chloral (Acetaldehyde, trichloro-)

Chlorambucil (Butanoic acid, 4-[bis(2-chloroethyl)amino]benzene-)

Chlordane (alpha and gamma isomers) (4,7-Methanoindan, 1,2,4,5,6,7,8,8-octachloro-3,4,7,7a-tetrahydro-) (alpha and gamma isomers)

Chlorinated benzenes, N.O.S.[3]

Chlorinated ethane, N.O.S.[3]

Chlorinated fluorocarbons, N.O.S.[3]

Chlorinated naphthalene, N.O.S.[3]

Chlorinated phenol, N.O.S.[3]

Chloroacetaldehyde (Acetaldehyde, chloro-)

Chloroalkyl ethers, N.O.S.[3]

p-Chloroaniline (Benzenamine, 4-chloro-)

Chlorobenzene (Benzene, chloro-)

Chlorobenzilate (Benzeneacetic acid, 4-chloro-alpha-(4-chlorophenyl)-alpha-hydroxy-,ethyl ester)

p-Chloro-m-cresol (Phenol, 4-chloro-3-methyl)

1-Chloro-2,3-epoxypropane (Oxirane, 2-(chloromethyl)-)

2-Chloroethyl vinyl ether (Ethene, (2-chloroethoxy)-)

Chloroform (Methane, trichloro-)

Chloromethane (Methyl chloride)

Chloromethyl methyl ether (Methane, chloromethoxy-)

2-Chloronaphthalene (Naphthalene, betachloro-)

2-Chlorophenol (Phenol, o-chloro-)

1-(o-Chlorophenyl)thiourea (Thiourea, (2-chlorophenyl)-)

3-Chloropropionitrile (Propanenitrile, 3-chloro-)

Chromium and compounds, N.O.S.[3]

Chrysene (1,2-Benzphenanthrene)

Citrus red No. 2 (2-Naphthol, 1-[(2,5-dimethoxyphenyl)azo]-)

Coal tars

Copper cyanide

Creosote (Creosote, wood)

Cresols (Cresylic acid) (Phenol, methyl-)

Crotonaldehyde (2-Butenal)

Cyanides (soluble salts and complexes), N.O.S.[3]

Cyanogen (Ethanedinitrile)

Cyanogen bromide (Bromine cyanide)

Cyanogen chloride (Chlorine cyanide)

Cycasin (beta-D-Glucopyranoside, (methyl-ONN-azoxy)methyl-)

2-Cyclohexyl-4,6-dinitrophenol (Phenol, 2-cyclohexyl-4,6-dinitro-)

Cyclophosphamide (2H-1,3,2,-Oxazaphosphorine, [bis(2-chloroethyl) amino]-tetrahydro-,2-oxide)

Daunomycin (5,12-Naphthacenedione, (8S-cis)-8-acetyl-10-[(3-amino-2,3,6-trideoxy)-alpha-L-lyxo-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-)

DDD (Dichlorodiphenyldichloroethane) (Ethane, 1,1-dichloro-2,2-bis(p-chlorophenyl)-)

DDE (Ethylene, 1,1-dichloro-2,2-bis(4-chlorophenyl)-)

DDT (Dichlorodiphenyltrichloroethane) (Ethane, 1,1,1-trichloro-2,2-bis (p-chlorophenyl)-)

Diallate (S-(2,3-dichloroallyl) diisopropylthiocarbamate)

Dibenz[a,h]acridine (1,2,5,6-Dibenzacridine)

Dibenz[a,j]acridine (1,2,7,8-Dibenzacridine)

Dibenz[a,h]anthracene (1,2,5,6-Dibenzanthracene)

7H-Dibenzo[c,g]carbazole (3,4,5,6-Dibenzcarbazole)

Dibenzo[a,e]pyrene (1,2,4,5-Dibenzpyrene)

Dibenzo[a,h]pyrene (1,2,5,6-Dibenzpyrene)

Dibenzo[a,i]pyrene (1,2,7,8-Dibenzpyrene)

1,2-Dibromo-3-chloropropane (Propane, 1,2-dibromo-3-chloro-)

1,2-Dibromoethane (Ethylene dibromide)

Dibromomethane (Methylene bromide)

Di-n-butyl phthalate (1,2-Benzenedicarboxylic acid, dibutyl ester)

o-Dichlorobenzene (Benzene, 1,2-dichloro-)

m-Dichlorobenzene (Benzene, 1,3-dichloro-)

p-Dichlorobenzene (Benzene, 1,4-dichlor-)

Dichlorobenzene, N.O.S.[3] (Benzene, dichloro-, N.O.S.[3])

3,3'-Dichlorobenzidine ([1,1'-Biphenyl]-4,4'-diamine, 3,3'-dichloro-)

1,4-Dichloro-2-butene (2-Butene, 1,4-dichloro-)

Dichlorodifluoromethane (Methane, dichlorodifluoro-)

1,1-Dichloroethane (Ethylidene dichloride)

1,2-Dichloroethane (Ethylene dichloride)

trans-1,2-Dichloroethene (1,2-Dichloroethylene)

Dichloroethylene, N.O.S.[3] (Ethene, dichloro-, N.O.S.[3])

1,1-Dichloroethylene (Ethene, 1,1-dichloro-)

Dichloromethane (Methylene chloride)

2,4-Dichlorophenol (Phenol, 2,4-dichloro-)

2,6-Dichlorophenol (Phenol, 2,6-dichloro-)

2,4-Dichlorophenoxyacetic acid (2,4-D), salts and esters (Acetic acid, 2,4-dichlorophenoxy-, salts and esters)

Dichlorophenylarsine (Phenyl dichloroarsine)

Dichloropropane, N.O.S.[3] (Propane, dichloro-, N.O.S.[3])

1,2-Dichloropropane (Propylene dichloride)

Dichloropropanol, N.O.S.[3] (Propanol, dichloro-, N.O.S.[3])

Dichloropropene, N.O.S.[3] (Propene, dichloro-, N.O.S.[3])

1,3-Dichloropropene (1-Propene, 1,3-dichloro-)

Dieldin (1,2,3,4,10.10-hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octa-hydro-endo, exo- 1,4:5,8-Dimethanonaphthalene)

1,2:3,4-Diepoxybutane (2,2'-Bioxirane)

Diethylarsine (Arsine, diethyl-)

N,N-Diethylhydrazine (Hydrazine, 1,2-diethyl)

O,O-Diethyl S-methyl ester of phosphorodithioic acid (Phosphorodithioic acid, O,O-diethyl S-methyl ester)

O,O-Diethylphosphoric acid, O-p-nitrophenyl ester (Phosphoric acid, diethyl p-nitrophenyl ester)

Diethyl phthalate (1,2-Benzenedicarboxylic acid, diethyl ester)

O,O-Diethyl O-2-pyrazinyl phosphorothioate (Phosphorothioic acid, O,O-diethyl O-pyrazinyl ester)

Diethylstilbesterol (4,4'-Stilbenediol,alpha,alpha-diethyl, bis(dihydrogen phosphate, (E)-)

Dihydrosafrole (Benzene, 1,2-methylenedioxy-4-propyl-)

3,4-Dihydroxy-alpha-(methylamino)methyl benzyl alcohol (1,2-Benzenediol, 4-[1-hydroxy-2-(methylamino)ethyl]-)

Dilsopropylfluorophosphate (DFP) (Phosphorofluoridic acid, bis(1-methylethyl) ester)

Dimethoate (Phosphorodithioic acid, O,O-dimethyl S-[2-(methylamino)-2-oxoethyl] ester)

3,3'-Dimethoxybenzidine ([1,1'-Biphenyl]- 4,4'-diamine, 3-3'-dimethoxy-)

p-Dimethylaminoazobenzene (Benzenamine, N,N-dimethyl-4-(phenylazo)-)

7,12-Dimethylbenz[a]anthracene (1,2-Benzanthracene, 7,12-dimethyl-)

3,3'-Dimethylbenzidine ([1,1'-Biphenyl]-4,4'-diamine, 3,3'-dimethyl-)

Dimethylcarbamoyl chloride (Carbamoyl chloride, dimethyl-)

1,1-Dimethylhydrazine (Hydrazine, 1,1-dimethyl-)

1,2-Dimethylhydrazine (Hydrazine, 1,2-dimethyl-)

3,3-Dimethyl-1-(methylthio)-2-butanone, O-[(methylamino) carbonyl] oxime (Thiofanox)

alpha,alpha-Dimethylphenethylamine (Ethanamine, 1,1-dimethyl-2-phenyl-)

2,4-Dimethylphenol (Phenol, 2,4-dimethyl-)

Dimethyl phthalate (1,2-Benzenedicarboxylic acid, dimethyl ester)

Dimethyl sulfate (Sulfuric acid, dimethyl ester)

Dinitrobenzene, N.O.S.[3] (Benzene, dinitro-, N.O.S.[3])

4,6-Dinitro-o-cresol and salts (Phenol, 2,4-dinitro-6-methyl-, and salts)

2,4-Dinitrophenol (Phenol, 2,4-dinitro-)

2,4-Dinitrotoluene (Benzene, 1-methyl-2,4-dinitro-)

2,6-Dinitrotoluene (Benzene, 1-methyl-2,6-dinitro-)

Di-n-octyl phthalate (1,2-Benzenedicarboxylic acid, dioctyl ester)

1,4-Dioxane (1,4-Diethylene oxide)

Diphenylamine (Benzenamine, N-phenyl-)

1,2-Diphenylhydrazine (Hydrazine, 1,2-diphenyl-)

Di-n-propylnitrosamine (N-Nitroso-di-n-propylamine)

Disulfoton (O,O-diethyl S-[2-(ethylthio)ethyl] phosphorodithioate)

2,4-Dithiobiuret (Thioimidodicarbonic diamide)

Endosulfan (5-Norbornene, 2,3-dimethanol, 1,4,5,6,7,7-hexachloro-, cyclic sulfite)

Endrin and metabolites (1,2,3,4,10,10-hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-endo,endo-1,4:5,8-dimethanonaphthalene, and metabolites)

Ethyl carbamate (Urethan) (Carbamic acid, ethyl ester)

Ethyl cyanide (propanenitrile)

Ethylenebisdithiocarbamic acid, salts and esters (1,2-Ethanediyl-biscarbamodithioic acid, salts and esters)

Ethyleneimine (Aziridine)

Ethylene oxide (Oxirane)

Ethylenethiourea (2-Imidazolidinethione)

Ethyl methacrylate (2-Propenoic acid, 2-methyl-, ethyl ester)

Ethyl methanesulfonate (Methanesulfonic acid, ethyl ester)

Fluoranthene (Benzo[j,k]fluorene)

Fluorine

2-Fluoroacetamide (Acetamide, 2-fluoro-)

Fluoroacetic acid, sodium salt (Acetic acid, fluoro-, sodium salt)

Formaldehyde (Methylene oxide)

Formic acid (Methanoic acid)

Glycidylaldehyde (1-Propanol-2,3-epoxy)

Halomethane, N.O.S.[3]

Heptachlor (4,7-Methano-1H-indene, 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-)

Heptachlor epoxide (alpha, beta, and gamma isomers) (4,7-Methano-1H-indene, 1,4,5,6,7,8,8-heptachloro-2,3-epoxy-3a,4,7,7-tetrahydro-, alpha, beta, and gamma isomers)

Hexachlorobenzene (Benzene, hexachloro-)

Hexachlorobutadiene (1,3-Butadiene, 1,1,2,3,4,4-hexachloro-)

Hexachlorocyclohexane (all isomers) (Lindane and isomers)

Hexachlorocyclopentadiene (1,3-Cyclopentadiene, 1,2,3,4,5,5-hexachloro-)

Hexachloroethane (Ethane, 1,1,1,2,2,2-hexachloro-)

1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-1,4:5,8-endo,endo-dimethanonaphthalene (Hexachlorohexa-hydro-endo,endo-dimethanonaphthalene)

Hexachlorophene (2,2'-Methylenebis(3,4,6-trichlorophenol)

Hexachloropropene (1-Propene, 1,1,2,3,3,3-hexachloro-)

Hexaethyl tetraphosphate (Tetraphosphoric acid, hexaethyl ester)

Hydrazine (Diamine)

Hydrocyanic acid (Hydrogen cyanide)

Hydrofluoric acid (Hydrogen fluoride)

Hydrogen sulfide (Sulfur hydride)

Hydroxydimethylarsine oxide (Cacodylic acid)

Indeno (1,2,3-cd)pyrene (1,10-(1,2-phenylene)pyrene)

Iodomethane (Methyl iodide)

Iron dextran (Ferric dextran)

Isocyanic acid, methyl ester (Methyl isocyanate)

Isobutyl alcohol (1-Propanol, 2-methyl-)

Isosafrole (Benzene, 1,2-methylenedioxy-4-allyl-)

Kepone (Decachlorooctahydro-1,3,4-Methano-2H-cyclobuta[cd]pentalen-2-one)

Lasiocarpine (2-Butenoic acid, 2-methyl-, 7-[(2,3-dihydroxy-2-(1-methoxyethyl)-3-methyl-1-oxobutoxy)methyl]-2,3,5,7a- tetrahydro-1H-pyrrolizin-1-yl ester)

Lead and compounds, N.O.S.[3]

Lead acetate (Acetic acid, lead salt)

Lead phosphate (Phosphoric acid, lead salt)

Lead subacetate (Lead, bis(acetato-0)tetrahydroxytri-)

Maleic anhydride (2,5-Furandione)

Maleic hydrazide (1,2-Dihydro-3,6-pyridazinedione)

Malononitrile (Propanedinitrile)

Melphalan (Alanine, 3-[p-bis(2-chloroethyl)amino]phenyl-,L-)

Mercury fulminate (Fulminic acid, mercury salt)

Mercury and compounds, N.O.S.[3]

Methacrylonitrile (2-Propenenitrile, 2-methyl-)

Methanethiol (Thiomethanol)

Methapyrilene (Pyridine. 2-[(2-dimethylamino)ethyl]-2-thenylamino-)

Metholmyl (Acetimidic acid, N-[(methylcarbamoyl)oxy]thio-, methyl ester)

Methoxychlor (Ethane, 1,1,1-trichloro-2,2-bis(p-methoxyphenyl)-)

2-Methylaziridine (1,2-Propylenimine)

3-Methylcholanthrene (Benz[j]aceanthrylene, 1,2-dihydro-3-methyl-)

Methyl chlorocarbonate (Carbonochloridic acid, methyl ester)

4,4-Methylenebis(2-chloroaniline) (Benzenamine, 4,4-methylenebis- (2-chloro-)

Methyl ethyl ketone (MEK) (2-Butanone)

Methyl hydrazine (Hydrazine, methyl-)

2-Methyllactonitrile (Propanenitrile, 2-hydroxy-2-methyl-)

Methyl methacrylate (2-Propenoic acid, 2-methyl-, methyl ester)

Methyl methanesulfonate (Methanesulfonic acid, methyl ester)

2-Methyl-2-(methylthio)propionaldehyde-o-(methylcarbonyl) oxime (Propanal, 2-methyl-2-(methylthio)-, 0-[(methylamino)carbonyl]oxime)

N-Methyl-N-nitro-N-nitrosoguanidine (Guanidine, N-nitroso-N-methyl-N- nitro-)

Methyl parathion (0,0-dimethyl 0-(4-nitrophenyl) phosphorothioate)

Methylthiouracil (4-IH-Pyrimidinone, 2,3-dihydro-6-methyl-2-thioxo-)

Molybdenum and compounds, N.O.S.[3]

Mustard gas (Sulfide, bis(2-chloroethyl)-)

Naphthalene

1,4-Naphthoquinone (1,4-Naphthalenedione)

1-Naphthylamine (alpha-Naphthylamine)

2-Naphthylamine (beta-Naphthylamine)

1-Naphthyl-2-thiourea (Thiourea, 1-naphthalenyl-)

Nickel and compounds, N.O.S.[3]

Nickel carbonyl (Nickel tetracarbonyl)

Nickel cyanide (Nickel (II) cyanide)

Nicotine and salts (Pyridine, (S)-3-(1-methyl-2-pyrrolidinyl)-, and salts)

Nitric oxide (Nitrogen (II) oxide)

p-Nitroaniline (Benzenamine, 4-nitro-)

Nitrobenzine (Benzene, nitro-)

Nitrogen dioxide (Nitrogen (IV) oxide)

Nitrogen mustard and hydrochloride salt (Ethanamine, 2-chloro-, N-(2-chloroethyl)- N-methyl-, and hydrochloride salt)

Nitrogen mustard N-Oxide and hydrochloride salt (Ethanamine, 2-chloro-, N-(2-chloroethyl)-N-methyl-, and hydrochloride salt)

Nitroglycerine (1,2,3-Propanetriol, trinitrate)

4-Nitrophenol (Phenol, 4-nitro-)

4-Nitroquinoline-1-oxide (Quinoline, 4-nitro-1-oxide-)

Nitrosamine, N.O.S.[3]

N-Nitrosodi-n-butylamine (1-Butanamine, N-butyl-N-nitroso-)

N-Nitrosodiethanolamine (Ethanol, 2,2-(nitrosoimino)bis-)

N-Nitrosodiethylamine (Ethanamine, N-ethyl-N-nitroso-)

N-Nitrosodimethylamine (Dimethylnitrosamine)

N-Nitroso-N-ethylurea (Carbamide, N-ethyl-N-nitroso-)

N-Nitrosomethylethylamine (Ethanamine, N-methyl-N-nitroso-)

N-Nitroso-N-methylurea (Carbamide, N-methyl-N-nitroso-)

N-Nitroso-N-methylurethane (Carbamic acid, methylnitroso-, ethyl ester)

N-Nitrosomethylvinylamine (Ethenamine, N-methyl-N-nitroso-)

N-Nitrosomorpholine (Morpholine, N-nitroso-)

N-Nitrosonornicotine (Nornicotine, N-nitroso-)

N-Nitrosopiperidine (Pyridine, hexahydro-, N-nitroso-)

Nitrosopyrrolidine (Pyrrole, tetrahydro-, N-nitroso-)

N-Nitrososarcosine (Sarcosine, N-nitroso-)

5-Nitro-o-toluidine (Benzenamine, 2-methyl-5-nitro-)

Octamethylpyrophosphoramide (Diphosphoramide, octamethyl-)

Osmium tetroxide (Osmium (VIII) oxide)

7-Oxabicyclo[2.2.1]heptane-2,3-dicarboxylic acid (Endothal)

Paraldehyde (1,3,5-Trioxane, 2,4,6-trimethyl-)

Parathion (Phosphorothioic acid, O,O-diethyl O-(p-nitrophenyl)ester)

Pentachlorobenzene (Benzene, pentachloro-)

Pentachloroethane (Ethane, pentachloro-)

Pentachloronitrobenzene (PCNB) (Benzene, pentachloronitro-)

Pentachlorophenol (Phenol, pentachloro-)

Phenacetin (Acetamide, N-(4-ethoxyphenyl)-)

Phenol (Benzene, hydroxy-)

Phenylenediamine (Benzenediamine)

Phenylmercury acetate (Mercury, acetatophenyl-)

N-Phenylthiourea (Thiourea, phenyl-)

Phosgene (Carbonyl chloride)

Phosphine (Hydrogen phosphide)

Phosphorodithioic acid, O,O-diethyl S-[(ethylthio)methyl] ester (Phorate)

Phosphorothioic acid, O,O-dimethyl O-[p-((dimethylamino)sulfonyl)phenyl] ester (Famphur)

Phthalic acid esters, N.O.S.[3] (Benzene, 1,2-dicarboxylic acid, esters, N.O.S.[3])

Phthalic anhydride (1,2-Benzenedicarboxylic acid anhydride)

2-Picoline (Pyridine, 2-methyl-)

Polychlorinated biphenyl, N.O.S.[3]

Potassium cyanide

Potassium silver cyanide (Argentate(1-), dicyano-, potassium)

Pronamide (3,5-Dichloro-N-(1,1-dimethyl-2-propynyl)benzamide)

1,3-Propane sultone (1,2-Oxathiolane, 2,2-dioxide)

n-Propylamine (1-Propanamine)

Propylthiouracil (Undecamethylenediamine, N,N'-bis(2-chlorobenzyl-), dihydrochloride)

2-Propyn-1-ol (Propargyl alcohol)

Pyridine

Radium -226 and -228

Reserpine (Yohimban-16-carboxylic acid, 11,17-dimethoxy-18-[3,4,5- trimethoxybenzoyl)oxy]-, methyl ester)

Resorcinol (1,3-Benzenediol)

Saccharin and salts (1,2-Benzoisothiazolin-3-one, 1,1-dioxide, and salts)

Safrole (Benzene, 1,2-methylenedioxy-4-allyl-)

Selenious acid (Selenium dioxide)

Selenium and compounds, N.O.S.[3]

Selenium sulfide (Sulfur selenide)

Selenourea (Carbamimidoselenoic acid)

Silver and compounds, N.O.S.[3]

Silver cyanide

Sodium cyanide

Streptozotocin (D-Glucopyranose, 2-deoxy-2-(3-methyl-3-nitrosoureido)-)

Strontium sulfide

Strychnine and salts (Strychnidin-10-one, and salts)

1,2,4,5-Tetrachlorobenzene (Benzene, 1,2,4,5-tetrachloro-)

2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) (Dibenzo-p-dioxin, 2,3,7,8-tetrachloro-)

Tetrachloroethane, N.O.S.[3] (Ethane, tetrachloro-, N.O.S.[3])

1,1,1,2-Tetrachlorethane (Ethane, 1,1,1,2-tetrachloro-)

1,1,2,2-Tetrachlorethane (Ethane, 1,1,2,2-tetrachloro-)

Tetrachloroethane (Ethene, 1,1,2,2-tetrachloro-)

Tetrachloromethane (Carbon tetrachloride)

2,3,4,6,-Tetrachlorophenol (Phenol, 2,3,4,6-tetrachloro-)

Tetraethyldithiopyrophosphate (Dithiopyrophosphoric acid, tetraethyl-ester)

Tetraethyl lead (Plumbane, tetraethyl-)

Tetraethylpyrophosphate (Pyrophosphoric acide, tetraethyl ester)

Tetranitromethane (Methane, tetranitro-)

Thallium and compounds, N.O.S.[3]

Thallic oxide (Thallium (III) oxide)

Thallium (I) acetate (Acetic acid, thallium (I) salt)

Thallium (I) carbonate (Carbonic acid, dithallium (I) salt)

Thallium (I) chloride

Thallium (I) nitrate (Nitric acid, thallium (I) salt)

Thallium selenite

Thallium (I) sulfate (Sulfuric acid, thallium (I) salt)

Thioacetamide (Ethanethioamide)

Thiosemicarbazide (Hydrazinecarbothioamide)

Thiourea (Carbamide thio-)

Thiuram (Bis(dimethylthiocarbamoyl) disulfide)

Thorium and compounds, N.O.S.,[3] when producing thorium byproduct material

Toluene (Benzene, methyl-)

Toluenediamine (Diaminotoluene)

o-Toluidine hydrochloride (Benzenamine, 2-methyl-, hydrochloride)

Tolylene diisocyanate (Benzene, l,3-diisocyanatomethyl-)

Toxaphene (Camphene, octachloro-)

Tribromomethane (Bromoform)

1,2,4-Trichlorobenzene (Benzene, 1,2,4-trichloro-)

1,1,1-Trichloroethane (Methyl chloroform)

1,1,2-Trichloroethane (Ethane, 1,1,2-trichloro-)

Trichloroethene (Trichloroethylene)

Trichloromethanethiol (Methanethiol, trichloro-)

Trichloromonofluoromethane (Methane, trichlorofluoro-)

2,4,5-Trichlorophenol (Phenol, 2,4,5-trichloro-)

2,4,6-Trichlorophenol (Phenol, 2,4,6-trichloro-)

2,4,5-Trichlorophenoxyacetic acid (2,4,5-T) (Acetic acid, 2,4,5-trichlorophenoxy-)

2,4,5-Trichlorophenoxypropionic acid (2,4,5-TP) (Silvex) (Propionoic acid, 2-(2,4,5-trichlorophenoxy)-)

Trichloropropane, N.O.S.[3] (Propane, trichloro-, N.O.S.[3])

1,2,3-Trichloropropane (Propane, 1,2,3-trichloro-)

O,O,O-Triethyl phosphorothioate (Phosphorothioic acid, O,O,O-triethyl ester)

sym-Trinitrobenzene (Benzene, 1,3,5-trinitro-)

Tris(1-azridinyl) phosphine sulfide (Phosphine sulfide, tris(1-aziridinyl-)

Tris(2,3-dibromopropyl) phosphate (1-Propanol, 2,3-dibromo-, phosphate)

Trypan blue (2,7-Naphthalenedisulfonic acid, 3,3'-[(3,3'-dimethyl (1,1'-biphenyl)- 4,4'-diyl)bis(azo)]bis(5-amino-4-hydroxy-, tetrasodium salt)

Uracil mustard (Uracil 5-[bis(2-chloroethyl)amino]-)

Uranium and compounds, N.O.S.[3]

Vanadic acid, ammonium salt (ammonium vanadate)

Vanadium pentoxide (Vanadium (V) oxide)

Vinyl chloride (Ethene, chloro-)

Zinc cyanide

Zinc phosphide

[50 FR 41862, Oct. 16, 1985, as amended at 52 FR 31611, Aug. 21, 1987; 52 FR 43562, Nov. 13, 1987; 53 FR 19248, May 27, 1988; 55 FR 45600, Oct. 30, 1990; 56 FR 23473, May 21, 1991; 58 FR 67661, Dec. 22, 1993; 59 FR 28229, June 1, 1994; 64 FR 17510, Apr. 12, 1999; 76 FR 35570, Jun. 17, 2011; 77 FR 39906, Jul. 6, 2012]

1. In the case of thorium byproduct materials, the standard applies only to design. Monitoring for radon emissions from thorium byproduct materials after installation of an appropriately designed cover is not required.

2. This average applies to the entire surface of each disposal area over a period of a least one year, but a period short compared to 100 years. Radon will come from both byproduct materials and from covering materials. Radon emissions from covering materials should be estimated as part of developing a closure plan for each site. The standard, however, applies only to emissions from byproduct materials to the atmosphere.

3. The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.

CHAPTER 33.1-10-17
DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

Section
33.1-10-17-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 70

33.1-10-17-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 70.

10 Code of Federal Regulations 70.1, 70.2, 70.3, 70.4, 70.7, 70.9, 70.10, 70.11, 70.12, 70.17, 70.18, 70.19, 70.20, 70.21, 70.22, 70.23, 70.25, 70.31, 70.32, 70.33, 70.34, 70.35, 70.36, 70.38, 70.39, 70.41, 70.42, 70.50, 70.51, 70.56, and 70.81 are adopted by reference as they exist on May 9, 2022~~December 21, 2018~~, with the following exceptions:

1. The following are not adopted by reference: 10 Code of Federal Regulations 70.1(c), (d), and (e); 70.20a; 70.20b; 70.21(a)(1), (c), (f), (g), and (h); 70.22(b), (c), (f), (g), (h), (i), (j), (k), (l), (m), and (n); 70.23(a)(6), (a)(7), (a)(8), (a)(9), (a)(10), (a)(11), (a)(12), and (b); 70.23a; 70.25(a)(1); 70.31(c), (d), and (e); 70.32(a)(1), (a)(4), (a)(5), (a)(6), (a)(7), (b)(1), (b)(3), (b)(4), (c), (d), (e), (f), (g), (h), (i), (j), and (k); 70.42(b)(6); 70.51(c); paragraph (2) of the definition of "commencement of construction"; and paragraph (9)(ii) of the definition of "construction".

2. Requirements in 10 Code of Federal Regulations part 70 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States nuclear regulatory commission", "NRC regional administrator", "NRC regional office", "administrator of the appropriate nuclear regulatory commission's regional office", "administrator of the appropriate regional office", or "nuclear regulatory commission's office of nuclear material safety and safeguards, division of industrial and medical nuclear safety" appear in 10 Code of Federal Regulations part 70, substitute the words "department of environmental quality".

4. 10 Code of Federal Regulations 70.7 employee protection also applies to violations of North Dakota Century Code chapters 23.1-02 and 23.1-03.

5. "Act" includes North Dakota Century Code chapters 23.1-02 and 23.1-03.

6. North Dakota state form number 8418, "application for radioactive material license", must be used instead of nuclear regulatory commission form 313 as specified in 10 Code of Federal Regulations part 70.

7. North Dakota state form number 8414, "notice to employees", must be posted instead of United States nuclear regulatory commission form 3 that is specified in 10 Code of Federal Regulations part 70.

8. For references to 10 Code of Federal Regulations part 170, section 33.1-10-11 for applicable fee schedules.

History: Effective January 1, 2019; amended effective July 1, 2021.

General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

PART 70--DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

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Appendix A to Part 70--Reportable Safety Events

Authority: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, sec. 234, 83 Stat. 444, as amended, (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282, 2297f); secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246 (42 U.S.C. 5841, 5842, 5845, 5846). Sec. 193, 104 Stat. 2835 as amended by Pub. L. 104–134, 110 Stat. 1321, 1321–349 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109–58, 119 Stat. 594 (2005).

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

Section 70.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 70.21(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under sec. 57d, Pub. L. 93–377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.81 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.82 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

Source: 21 FR 764, Feb. 3, 1956, unless otherwise noted.

[72 FR 63974, Nov. 14, 2007; 73 FR 63572, Oct. 24, 2008]

Subpart A--General Provisions

§ 70.1 Purpose.

(a) Except as provided in paragraphs (c) and (d) of this section, the regulations of this part establish procedures and criteria for the issuance of licenses to receive title to, own, acquire, deliver, receive, possess, use, and transfer special nuclear material; and establish and provide for the terms and conditions upon which the Commission will issue such licenses.

(b) The regulations contained in this part are issued pursuant to the Atomic Energy Act of 1954, as amended (68 Stat. 919) and Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242).

(c) The regulations in part 72 of this chapter establish requirements, procedures, and criteria for the issuance of licenses to possess:

(1) Spent fuel, power reactor-related Greater than Class C (GTCC) waste, and other radioactive materials associated with spent fuel storage in an independent spent fuel storage installation (ISFSI), or

(2) Spent fuel, high-level radioactive waste, power reactor-related GTCC waste, and other radioactive materials associated with the storage in a monitored retrievable storage installation (MRS), and the terms and conditions under which the Commission will issue such licenses.

(d) As provided in part 76 of this chapter, the regulations of this part establish procedures and criteria for physical security and material control and accounting for the issuance of a certificate of compliance or the approval of a compliance plan.

(e) As provided in the Atomic Energy Act of 1954, as amended, the regulations in this part establish requirements, procedures, and criteria for the issuance of licenses to uranium enrichment facilities.

[21 FR 764, Feb. 3, 1956, as amended at 32 FR 4056, Mar. 15, 1967; 40 FR 8791, Mar. 3, 1975; 43 FR 6924, Feb. 17, 1978; 45 FR 74712, Nov. 12, 1980; 53 FR 31682, Aug. 19, 1988; 59 FR 48960, Sept. 23, 1994; 62 FR 6669, Feb. 12, 1997; 66 FR 51838, Oct. 11, 2001]

§ 70.2 Scope.

Except as provided in §§ 70.11 to 70.13, inclusive, the regulations in this part apply to all persons in the United States. This part also gives notice to all persons who knowingly provide to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 70.10.

[56 FR 40691, Aug. 15, 1991]

§ 70.3 License requirements.

No person subject to the regulations in this part shall receive title to, own, acquire, deliver, receive, possess, use, or transfer special nuclear material except as authorized in a license issued by the Commission pursuant to these regulations.

[32 FR 2562, Feb. 7, 1967, as amended at 43 FR 6924, Feb. 17, 1978]

§ 70.4 Definitions.

Act means the Atomic Energy Act of 1954 (68 Stat 919), including any amendments thereto;

Acute, as used in this part, means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less).

Agreement State as designated in part 150 of this chapter means any State with which the Commission has entered into an effective agreement under subsection 274b. of the Act. Non-agreement State means any other State.

Alert means events may occur, are in progress, or have occurred that could lead to a release of radioactive material[s] but that the release is not expected to require a response by an offsite response organization to protect persons offsite.

Atomic energy means all forms of energy released in the course of nuclear fission or nuclear transformation;

Atomic weapon means any device utilizing atomic energy, exclusive of the means for transporting or propelling the device (where such means is a separable and divisible part of the device), the principal purpose of which is for use as, or for development of, a weapon, a weapon prototype, or a weapon test device;

Available and reliable to perform their function when needed, as used in subpart H of this part, means that, based on the analyzed, credible conditions in the integrated safety analysis, items relied on for safety will perform their intended safety function when needed, and management measures will be implemented that ensure compliance with the performance requirements of § 70.61 of this part, considering factors such as necessary maintenance, operating limits, common-cause failures, and the likelihood and consequences of failure or degradation of the items and measures.

Commencement of construction means any clearing of land, excavation, or other substantial action that would adversely affect the natural environment of a site but does not include changes desirable for the temporary use of the land for public recreational uses, necessary borings to determine site characteristics or other preconstruction monitoring to establish background information related to the suitability of a site or to the protection of environmental values.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives;

Configuration management (CM) means a management measure that provides oversight and control of design information, safety information, and records of modifications (both temporary and permanent) that might impact the ability of items relied on for safety to perform their functions when needed.

Contiguous sites means licensee controlled locations, deemed by the Commission to be in close enough proximity to each other, that the special nuclear material must be considered in the aggregate for the purpose of physical protection.

Corporation means the United States Enrichment Corporation (USEC), or its successor, a Corporation that is authorized by statute to lease the gaseous diffusion enrichment plants in Paducah, Kentucky, and Piketon, Ohio, from the Department of Energy, or any person authorized to operate one or both of the gaseous diffusion plants, or other facilities, pursuant to a plan for the privatization of USEC that is approved by the President.

Critical mass of special nuclear material (SNM), as used in Subpart H, means special nuclear material in a quantity exceeding 700 grams of contained uranium-235; 520 grams of uranium-233; 450 grams of plutonium; 1500 grams of contained uranium-235, if no uranium enriched to more than 4 percent by weight of uranium-235 is present; 450 grams of any combination thereof; or one-half such quantities if massive moderators or reflectors made of graphite, heavy water, or beryllium may be present.

Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits--

(1) Release of the property for unrestricted use and termination of the license; or

(2) Release of the property under restricted conditions and termination of the license.

Department and Department of Energy means the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 et seq.), to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565 at 577-578, 42 U.S.C. 7151).

Double contingency principle means that process designs should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

Effective dose equivalent means the sum of the products of the dose equivalent to the body organ or tissue and the weighting factors applicable to each of the body organs or tissues that are irradiated. Weighting factors are: 0.25 for gonads, 0.15 for breast, 0.12 for red bone marrow, 0.12 for lungs, 0.03 for thyroid, 0.03 for bone surface, and 0.06 for each of the other five organs receiving the highest dose equivalent.

Effective kilograms of special nuclear material means: (1) For plutonium and uranium-233 their weight in kilograms; (2) For uranium with an enrichment in the isotope U-235 of 0.01 (1%) and above, its element weight in kilograms multiplied by the square of its enrichment expressed as a decimal weight fraction; and (3) For uranium with an enrichment in the isotope U-235 below 0.01

(1%), by its element weight in kilograms multiplied by 0.0001.

Formula quantity means strategic special nuclear material in any combination in a quantity of 5000 grams or more computed by the formula, grams=(grams contained U-235)+2.5 (grams U-233+grams plutonium). This class of material is sometimes referred to as a Category I quantity of material.

Government agency means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government;

Hazardous chemicals produced from licensed materials means substances having licensed material as precursor compound(s) or substances that physically or chemically interact with licensed materials; and that are toxic, explosive, flammable, corrosive, or reactive to the extent that they can endanger life or health if not adequately controlled. These include substances commingled with licensed material, and include substances such as hydrogen fluoride that is produced by the reaction of uranium hexafluoride and water, but do not include substances prior to process addition to licensed material or after process separation from licensed material.

Integrated safety analysis (ISA) means a systematic analysis to identify facility and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the items relied on for safety. As used here, integrated means joint consideration of, and protection from, all relevant hazards, including radiological, nuclear criticality, fire, and chemical. However, with respect to compliance with the regulations of this part, the NRC requirement is limited to consideration of the effects of all relevant hazards on radiological safety, prevention of nuclear criticality accidents, or chemical hazards directly associated with NRC licensed radioactive material. An ISA can be performed process by process, but all processes must be integrated, and process interactions considered.

Integrated safety analysis summary means a document or documents submitted with the license application, license amendment application, license renewal application, or pursuant to § 70.62(c)(3)(ii) that provides a synopsis of the results of the integrated safety analysis and contains the information specified in § 70.65(b). The ISA Summary can be submitted as one document for the entire facility, or as multiple documents that cover all portions and processes of the facility.

Items relied on for safety mean structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in § 70.61 or to mitigate their potential consequences. This does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety.

License, except where otherwise specified, means a license issued pursuant to the regulations in

this part;

Management measures mean the functions performed by the licensee, generally on a continuing basis, that are applied to items relied on for safety, to ensure the items are available and reliable to perform their functions when needed. Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements.

Person means (1) any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department, except that the Department shall be considered a person within the meaning of the regulations in this part to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (2) any legal successor, representative, agent, or agency of the foregoing;

Plutonium processing and fuel fabrication plant means a plant in which the following operations or activities are conducted: (1) Operations for manufacture of reactor fuel containing plutonium including any of the following: (i) Preparation of fuel material; (ii) formation of fuel material into desired shapes; (iii) application of protective cladding; (iv) recovery of scrap material; and (v) storage associated with such operations; or (2) Research and development activities involving any of the operations described in paragraph (1) of this definition except for research and development activities utilizing unsubstantial amounts of plutonium.

Principal activities, as used in this part, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

Produce, when used in relation to special nuclear material, means (1) to manufacture, make, produce, or refine special nuclear material; (2) to separate special nuclear material from other substances in which such material may be contained; or (3) to make or to produce new special nuclear material;

Research and development means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes;

Restricted Data means all data concerning (1) design, manufacture or utilization of atomic weapons; (2) the production of special nuclear material; or (3) the use of special nuclear material in the production of energy, but shall not include data declassified or removed from the Restricted

Data category pursuant to section 142 of the Act;

Sealed source means any special nuclear material that is encased in a capsule designed to prevent leakage or escape of the special nuclear material.

Site Area emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

Source material means source material as defined in section 11z. of the Act and in the regulations contained in part 40 of this chapter;

Special nuclear material means (1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of section 51 of the act, determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing but does not include source material;

Special nuclear material of low strategic significance means:

(1) Less than an amount of special nuclear material of moderate strategic significance as defined in paragraph (1) of the definition of strategic nuclear material of moderate strategic significance in this section, but more than 15 grams of uranium-235 (contained in uranium enriched to 20 percent or more in U-235 isotope) or 15 grams of uranium-233 or 15 grams of plutonium or the combination of 15 grams when computed by the equation, grams = (grams contained U-235) + (grams plutonium) + (grams U-233); or

(2) Less than 10,000 grams but more than 1,000 grams of uranium-235 (contained in uranium enriched to 10 percent or more but less than 20 percent in the U-235 isotope); or

(3) 10,000 grams or more of uranium-235 (contained in uranium enriched above natural but less than 10 percent in the U-235 isotope).

This class of material is sometimes referred to as a Category III quantity of material.

Special nuclear material of moderate strategic significance means:

(1) Less than a formula quantity of strategic special nuclear material but more than 1,000 grams of uranium-235 (contained in uranium enriched to 20 percent or more in the U-235 isotope) or more than 500 grams of uranium-233 or plutonium, or in a combined quantity of more than 1,000 grams when computed by the equation, grams = (grams contained U-235) + 2 (grams U-233 + grams plutonium); or

(2) 10,000 grams or more of uranium-235 (contained in uranium enriched to 10 percent or more

but less than 20 percent in the U-235 isotope).

This class of material is sometimes referred to as a Category II quantity of material.

Special nuclear material scrap means the various forms of special nuclear material generated during chemical and mechanical processing, other than recycle material and normal process intermediates, which are unsuitable for use in their present form, but all or part of which will be used after further processing.

Strategic special nuclear material means uranium-235 (contained in uranium enriched to 20 percent or more in the U235 isotope), uranium-233, or plutonium.

Transient shipment means a shipment of nuclear material, originating and terminating in foreign countries, on a vessel or aircraft which stops at a United States port.

Unacceptable performance deficiencies mean deficiencies in the items relied on for safety or the management measures that need to be corrected to ensure an adequate level of protection as defined in 10 CFR 70.61(b), (c), or (d).

United States, when used in a geographical sense, includes Puerto Rico and all territories and possessions of the United States.

Uranium enrichment facility means:

(1) Any facility used for separating the isotopes of uranium or enriching uranium in the isotope 235, except laboratory scale facilities designed or used for experimental or analytical purposes only; or

(2) Any equipment or device, or important component part especially designed for such equipment or device, capable of separating the isotopes of uranium or enriching uranium in the isotope 235.

Worker, when used in Subpart H of this Part, means an individual who receives an occupational dose as defined in 10 CFR 20.1003.

[21 FR 764, Feb. 3, 1956]

Editorial Note: For *Federal Register* citations affecting § 70.4, see the List of CFR Sections Affected.

§ 70.5 Communications.

(a) Unless otherwise specified or covered under the regional licensing program as provided in paragraph (b) of this section, any communication or report concerning the regulations in this part and any application filed under these regulations may be submitted to the Commission as follows:

(1) By mail addressed to: ATTN: Document Control Desk, Director, Office of Nuclear Material Safety and Safeguards or Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(2) By hand delivery to the Director, Office of Nuclear Material Safety and Safeguards or Director, Office of Nuclear Security and Incident Response at the NRC's offices at 11555 Rockville Pike, Rockville, Maryland.

(3) Where practicable, by electronic submission, for example, via Electronic Information Exchange, and CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html*, by calling (301) 415-0439, by e-mail to *EIE@nrc.gov*, or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information.

(4) Classified communications shall be transmitted to the NRC Headquarters' classified mailing address as specified in appendix A to part 73 of this chapter or delivered by hand in accordance with paragraph (a)(2) of this section.

(b) The Commission has delegated to the four Regional Administrators licensing authority for selected parts of its decentralized licensing program for nuclear materials as described in paragraph (b)(1) of this section. Any communication, report, or application covered under this licensing program must be submitted to the appropriate Regional Administrator. The Administrators' jurisdictions and mailing addresses are listed in paragraph (b)(2) of this section.

(1) The delegated licensing program includes authority to issue, renew, amend, cancel, modify, suspend, or revoke licenses for nuclear materials issued pursuant to 10 CFR parts 30 through 36, 39, 40, and 70 to all persons for academic, medical, and industrial uses, with the following exceptions:

(i) Activities in the fuel cycle and special nuclear material in quantities sufficient to constitute a critical mass in any room or area. This exception does not apply to license modifications relating to termination of special nuclear material licenses that authorize possession of larger quantities when the case is referred for action from NRC's Headquarters to the Regional Administrators.

(ii) Health and safety design review of sealed sources and devices and approval, for licensing purposes, of sealed sources and devices.

(iii) Processing of source material for extracting of metallic compounds (including Zirconium, Hafnium, Tantalum, Titanium, Niobium, etc.).

(iv) Distribution of products containing radioactive material to persons exempt pursuant to 10 CFR 32.11 through 32.26.

(v) New uses or techniques for use of byproduct, source, or special nuclear material.

(vi) Reviews pursuant to § 70.32(c).

(vii) Uranium enrichment facilities.

(2) *Submissions--(i) Region I.* The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region I non-Agreement States and the District of Columbia: Connecticut, Delaware, Maine, Massachusetts, New Jersey, Pennsylvania, and Vermont. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment or renewal of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region I, Nuclear Material Section B, 475 Allendale Road, Suite 102, King of Prussia, Pennsylvania 19406-1415; where e-mail is appropriate it should be addressed to *RidsRgn1MailCenter@nrc.gov*.

(ii) *Region II.* The regional licensing program involves all Federal facilties in the region and non-Federal licensees in the following Region II non-Agreement States and territories: Virginia, West Virginia, Puerto Rico, and the Virgin Islands. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment or renewal of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region I, Nuclear Material Section B, 475 Allendale Road, Suite 102, King of Prussia, PA 19406-1415~~U.S. Nuclear Regulatory Commission, Region II, Material Licensing/Inspection Branch, Sam Nunn Atlanta Federal Center, Suite 23T85, 61 Forsyth Street, SW, Atlanta, GA 30303-8931~~; where e-mail is appropriate it should be addressed to *RidsRgn2MailCenter@nrc.gov*.

(iii) *Region III.* The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region III non-Agreement States: Indiana, Michigan, Minnesota, Missouri, Ohio, and Wisconsin. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, or renewal of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region III, Material Licensing Section, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352; where e-mail is appropriate it should be addressed to *RidsRgn3MailCenter@nrc.gov*.

(iv) *Region IV.* The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region IV non-Agreement States and a territory: Alaska, Hawaii, Montana, Oklahoma, South Dakota, Wyoming, and Guam. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment or renewal of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region IV, Material Radiation Protection Section, 611 Ryan

Plaza Drive, Suite 400, Arlington, Texas 76011-4005; where e-mail is appropriate it should be addressed to *RidsRgn4MailCenter@nrc.gov*.

[48 FR 16032, Apr. 14, 1983, as amended at 49 FR 19631, May 9, 1984; 49 FR 47824, Dec. 7, 1984; 50 FR 14694, Apr. 15, 1985; 51 FR 36001, Oct. 8, 1986; 52 FR 38392, Oct. 16, 1987; 52 FR 48093, Dec. 18, 1987; 53 FR 3862, Feb. 10, 1988; 53 FR 4111, Feb. 12, 1988; 53 FR 43421, Oct. 27, 1988; 54 FR 6877, Feb. 15, 1989; 57 FR 18392, Apr. 30, 1992; 58 FR 7737, Feb. 9, 1993; 58 FR 64112, Dec. 6, 1993; 59 FR 17466, Apr. 13, 1994; 60 FR 24552, May 9, 1995; 62 FR 22880, Apr. 28, 1997; 68 FR 58816, Oct. 10, 2003; 70 FR 69421, Nov. 16, 2005; 71 FR 15012, Mar. 27, 2006; 72 FR 33386, Jun. 18, 2007; 83 FR 57231, Nov. 21, 2018; 87 FR 20693, Apr. 8, 2022]

§ 70.6 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 70.7 Employee protection.

(a) Discrimination by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(1) The protected activities include but are not limited to:

(i) Providing the Commission or his or her employer information about alleged violations of either of the statutes named in paragraph (a) introductory text of this section or possible violations of requirements imposed under either of those statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) introductory text or under these requirements if the employee has identified the alleged illegality to the employer;

(iii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) introductory text.

(v) Assisting or participating in, or is about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraphs (a), (e), or (f) of this section by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant may be grounds for--

(1) Denial, revocation, or suspension of the license.

(2) Imposition of a civil penalty on the licensee, applicant, or a contractor or subcontractor of the licensee or applicant.

(3) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each specific licensee, each applicant for a specific license, and each general licensee subject to part 19 shall prominently post the revision of NRC Form 3, "Notice to Employees," referenced in 10 CFR 19.11(c).

(2) The posting of NRC Form 3 must be at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license

termination.

(3) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of this chapter, by calling (301) 415-5877, via e-mail to *forms@nrc.gov*, or by accessing the NRC Web site at *http://www.nrc.gov* and selecting forms from the index found on the home page.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in paragraph (a)(1) of this section including, but not limited to, providing information to the NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

[58 FR 52413, Oct. 8, 1993, as amended at 60 FR 24552, May 9, 1995; 61 FR 6765, Feb. 22, 1996; 68 FR 58817, Oct. 10, 2003; 72 FR 63974, Nov. 14, 2007]

§ 70.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0009.

(b) The approved information collection requirements contained in this part appear in §§ 70.9, 70.17, 70.19, 70.20a, 70.20b, 70.21, 70.22, 70.24, 70.25, 70.32, 70.33, 70.34, 70.38, 70.39, 70.42, 70.50, 70.51, 70.52, 70.59, 70.61, 70.62, 70.64, 70.65, 70.72, 70.73, 70.74, and Appendix A.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 70.21(g), ~~Form N–71 and associated forms~~IAEA Design Information Questionnaire forms are approved under control number 3150–0056.

(2) In § 70.38, NRC form 314 is approved under control number 3150-0028.

(3) In § 70.21(g), DOC/NRC Forms AP–1, AP–A, and associated forms are approved under control number 0694–0135.

[49 FR 19628, May 9, 1984, as amended at 52 FR 19305, May 22, 1987; 56 FR 40769, Aug. 16,

1991; 57 FR 18392, Apr. 30, 1992; 58 FR 39634, July 26, 1993; 62 FR 52189, Oct. 6, 1997; 65 FR 56225, Sept. 18, 2000; 67 FR 78412, Dec. 23, 2002; 73 FR 78606, Dec. 23, 2008; 85 FR 65656, Oct. 16, 2020]

§ 70.9 Completeness and accuracy of information.

(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

(b) Each applicant or licensee shall notify the Commission of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or common defense and security. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Commission of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification shall be provided to the Administrator of the appropriate Regional Office within two working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.

[52 FR 49373, Dec. 31, 1987]

§ 70.10 Deliberate misconduct.

(a) Any licensee, applicant for a license, employee of a licensee or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or applicant for a license, who knowingly provides to any licensee, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities in this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or

(2) Deliberately submit to the NRC, a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

(c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

[63 FR 1899, Jan. 13, 1998]

Subpart B--Exemptions

§ 70.11 Persons using special nuclear material under certain Department of Energy and Nuclear Regulatory Commission contracts.

Except to the extent that Department facilities or activities of the types subject to licensing pursuant to section 202 of the Energy Reorganization Act of 1974 are involved, any prime contractor of the Department is exempt from the requirements for a license set forth in section 53 of the Act and from the regulations in this part to the extent that such contractor, under his prime contract with the Department receives title to, owns, acquires, delivers, receives, possesses, uses, or transfers special nuclear material for:

(a) The performance of work for the Department at a United States Government-owned or controlled site, including the transportation of special nuclear material to or from such site and the performance of contract services during temporary interruptions of such transportation; (b) research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or (c) the use or operation of nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel. In addition to the foregoing exemptions, and subject to the requirement for licensing of Department facilities and activities pursuant to section 202 of the Energy Reorganization Act of 1974, any prime contractor or subcontractor of the Department or the Commission is exempt from the requirements for a license set forth in section 53 of the Act and from the regulations in this part to the extent that such prime contractor or subcontractor receives title to, owns, acquires, delivers, receives, possesses, uses, or transfers special nuclear material under his prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

[40 FR 14085, Mar. 28, 1975; 40 FR 16047, Apr. 9, 1975; as amended at 43 FR 6924, Feb. 17, 1978; 65 FR 54950, Sept. 12, 2000]

§ 70.12 Carriers.

Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the regulations in this part to the extent that they transport special nuclear material in the regular course of carriage for another or storage incident thereto. This exemption does not

apply to the storage in transit or transport of material by persons covered by the general license issued under § 70.20a and § 70.20b.

[46 FR 12696, Feb. 18, 1981]

§ 70.13 Department of Defense.

The regulations in this part do not apply to the Department of Defense to the extent that the Department receives, possesses and uses special nuclear material in accordance with the direction of the President pursuant to section 91 of the Act.

§ 70.14 Foreign military aircraft.

The regulations in this part do not apply to persons who carry special nuclear material (other than plutonium) in aircraft of the armed forces of foreign nations subject to 49 U.S.C. 40103(d).

[46 FR 12194, Feb. 13, 1981. Redesignated at 65 FR 56225, Sept. 18, 2000; 71 FR 15012, Mar. 27, 2006]

§ 70.17 Specific exemptions.

(a) The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

(b) [Reserved]

(c) The DOE is exempt from the requirements of the regulations in this part to the extent that its activities are subject to the requirements of part 60 or part 63 of this chapter.

(d) Except as specifically provided in part 61 of this chapter, any licensee is exempt from the requirements of the regulations in this part to the extent that its activities are subject to the requirements of part 61 of this chapter.

[37 FR 5749, Mar. 21, 1972, as amended at 45 FR 65536, Oct. 3, 1980; 46 FR 13987, Feb. 25, 1981; 47 FR 57481, Dec. 27, 1982; Redesignated at 65 FR 56225, Sept. 18, 2000, as amended at 66 FR 55815, Nov. 2, 2001]

Subpart C--General Licenses

§ 70.18 Types of licenses.

Licenses for special nuclear material are of two types: general and specific. Any general license

provided in this part is effective without the filing of applications with the Commission or the issuance of licensing documents to particular persons. Specific licenses are issued to named persons upon applications filed pursuant to the regulations in this part.

[29 FR 5884, May 5, 1964]

§ 70.19 General license for calibration or reference sources.

(a) A general license is hereby issued to those persons listed below to receive title to, own, acquire, deliver, receive, possess, use and transfer in accordance with the provisions of paragraphs (b) and (c) of this section, plutonium in the form of calibration or reference sources:

(1) Any person in a non-agreement State who holds a specific license issued by the Commission or the Atomic Energy Commission which authorizes him to receive, possess, use and transfer byproduct material, source material, or special nuclear material;

(2) Any Government agency as defined in § 70.4 that holds a specific license issued by the Commission that authorizes it to receive, possess, use, or transfer byproduct material, source material, or special nuclear material; and

(3) Any person in an agreement State who holds a specific license issued by the Commission or the Atomic Energy Commission which authorizes him to receive, possess, use and transfer special nuclear material.

(b) The general license in paragraph (a) of this section applies only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued pursuant to § 70.39 or in accordance with the specifications contained in a specific license issued by an agreement State which authorizes manufacture of the sources for distribution to persons generally licensed by the agreement State.

(c) The general license in paragraph (a) of this section is subject to the provisions of §§ 70.32, 70.50, 70.55, 70.56, 70.91, 70.81, and 70.82; the provisions of §§ 74.11 and 74.19 of this chapter; and to the provisions of parts 19, 20, and 21 of this chapter. In addition, persons who receive title to own, acquire, deliver, receive, possess, use or transfer one or more calibration or reference sources under this general license:

(1) Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of plutonium in such sources;

(2) Shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:[1]

The receipt, possession, use and transfer of this source, Model-- --- , Serial No.-----, are

subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS PLUTONIUM. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(Name of Manufacturer or Initial Transferor)

(3) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Commission or the Atomic Energy Commission or an Agreement State to receive the source.

(4) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain plutonium which might otherwise escape during storage.

(5) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(d) The general license in paragraph (a) of this section does not authorize the manufacture, import, or export of calibration or reference sources containing plutonium.

[29 FR 5884, May 5, 1964, as amended at 32 FR 8124, June 7, 1967; 38 FR 22221, Aug. 17, 1973; 40 FR 8792, Mar. 3, 1975; 42 FR 28896, June 6, 1977; 43 FR 6924, Feb. 17, 1978; 48 FR 32329, July 15, 1983; 56 FR 40769, Aug. 16, 1991; 57 FR 33428, July 29, 1992; 67 FR 78142, Dec. 23, 2002; 72 FR 35144, June 27, 2007]

[1] Sources generally licensed under this section prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

§ 70.20 General license to own special nuclear material.

A general license is hereby issued to receive title to and own special nuclear material without regard to quantity. Notwithstanding any other provision of this chapter, a general licensee under this section is not authorized to acquire, deliver, receive, possess, use, transfer, import, or export special nuclear material, except as authorized in a specific license.

[33 FR 9810, July 9, 1968]

§ 70.20a General license to possess special nuclear material for transport.

(a) A general license is issued to any person to possess formula quantities of strategic special nuclear material of the types and quantities subject to the requirements of §§ 73.20, 73.25, 73.26 and 73.27 of this chapter, and irradiated reactor fuel containing material of the types and quantities

subject to the requirements of § 73.37 of this chapter, in the regular course of carriage for another or storage incident. Carriers generally licensed under § 70.20b are exempt from the requirements of this section. Carriers of irradiated reactor fuel for the United States Department of Energy are also exempt from the requirements of this section. The general license is subject to the applicable provisions of §§ 70.7 (a) through (e), 70.32 (a) and (b), and §§ 70.42, 70.52, 70.55, 70.91, 70.81, 70.82 and 10 CFR 74.11.

(b) Notwithstanding any other provision of this chapter, the general license issued under this section does not authorize any person to conduct any activity that would be authorized by a license issued pursuant to parts 30 through 36, 39, 40, 50, 72, 110, or other sections of this part.

(c) Notwithstanding any other provision of this chapter, the duties of a general licensee under this section while in possession of formula quantities of strategic special nuclear material or irradiated reactor fuel in the regular course of carriage for another or storage incident thereto shall be limited to providing for the physical protection of such material against theft or sabotage. Unless otherwise provided by this section, a general license under this section is not subject to the requirements of Parts 19, 20, 70 and 73.

(d) Any person who possesses formula quantities of strategic special nuclear material under this general license:

(1) Shall have submitted and received approval of a transportation security plan. The security plan shall outline the procedures that will be used to meet the requirements of §§ 73.20, 73.25, 73.26, 73.27 and 73.70(g) of this chapter including a plan for the selection, qualification, and training of armed escorts, or the specification and design of a specially designed truck or trailer as appropriate.

(2) Shall assure that the transportation is in accordance with the applicable physical protection requirements of §§ 73.20, 73.25, 73.26, 73.27 and 73.70(g) of this chapter and the applicable approved transportation security plan.

(3) Shall be subject to part 26 and § 73.80 of this chapter.

(e) Any person who possesses irradiated reactor fuel under this general license shall:

(1) Assure or receive certification from the shipper that the transportation is in accordance with the applicable physical protection requirements of § 73.37 of this chapter; and

(2) Comply with the reporting requirements of § 73.71 of this chapter.

[44 FR 26851, May 8, 1979, as amended at 44 FR 68186, Nov. 28, 1979; 46 FR 12696, Feb. 18, 1981; 47 FR 30458, July 14, 1982; 53 FR 31682, Aug. 19, 1988; 58 FR 7737, Feb. 9, 1993; 58 FR 31471, June 3, 1993; 67 FR 78142, Dec. 23, 2002; 72 FR 35144, June 27, 2007]

§ 70.20b General license for carriers of transient shipments of formula quantities of strategic special nuclear material, special nuclear material of moderate strategic significance, special nuclear material of low strategic significance, and irradiated reactor fuel.

(a) A general license is hereby issued to any person to possess transient shipments of the following kinds and quantities of special nuclear material:

(1) A formula quantity of special nuclear material of the types and quantities subject to the requirements of §§ 73.20, 73.25, 73.26, and 73.27 of this chapter.

(2) Special nuclear material of moderate and low strategic significance of the types and quantities subject to the requirements of § 73.67 of this chapter.

(3) Irradiated reactor fuel of the type and quantity subject to the requirements of § 73.37 of this chapter.

(b) Persons generally licensed under this section are exempt from the requirements of parts 19 and 20 of this chapter and the requirements of this part, except §§ 70.32 (a) and (b), 70.52, 70.55, 70.91, 70.81, and 70.82.

(c) Persons generally licensed under this section to possess a transient shipment of special nuclear material of the kind and quantity specified in paragraph (a)(1) of this section shall provide physical protection for that shipment in accordance with or equivalent to §§ 73.20(a), 73.20(b), 73.25, and 73.71(b) of this chapter from the time a shipment enters a United States port until it exits that or another United States port.

(d) Persons generally licensed under this section to possess a transient shipment of special nuclear material of moderate or low strategic significance of the kind and quantity specified in paragraph (a)(2) of this section shall provide physical protection for that shipment in accordance with or equivalent to § 73.67 of this chapter and shall comply with the requirements of § 73.71(b) of this chapter.

(e) Persons generally licensed under this section to possess a transient shipment of irradiated reactor fuel of the kind and quantity specified in paragraph (a)(3) of this section shall provide physical protection for that shipment in accordance with or equivalent to § 73.37 of this chapter and shall comply with the requirements of § 73.71(b) of this chapter.

(f)(1) Persons generally licensed under this section, who plan to carry transient shipments with scheduled stops at United States ports, shall notify in writing the Director, Office of Nuclear Security and Incident Response, using an appropriate method listed in § 70.5(a). Classified notifications shall be sent to the NRC headquarters classified mailing address listed in appendix A to part 73 of this chapter.

(2) A person generally licensed under this section shall assure that:

(i) The notification will be received at least 10 days before transport of the shipment commences at the shipping facility;

(ii) The NRC Headquarters Operations Center shall be notified by telephone at least 2 days before commencement of the shipment at the numbers listed in appendix A to part 73 of this chapter. Classified notifications shall be made by secure telephone.

(iii) The NRC Headquarters Operations Center shall be notified by telephone of schedule changes greater than ±6 hours at the numbers listed in appendix A to part 73 of this chapter. Classified notifications shall be made by secure telephone.

(3) Persons who are generally licensed under paragraph (a)(1) of this section must include the information listed in paragraphs (f)(3)(i) through (ix) of this section. Persons who are generally licensed under § 70.20b(a)(2) and § 70.20b(a)(3) must include the information listed in paragraphs (f)(3) (i) through (viii) of this section.

(i) Location of all scheduled stops in United States territory;

(ii) Arrival and departure times for all scheduled stops in United States territory;

(iii) The type of transport vehicle;

(iv) A physical description of the shipment (elements, isotopes, and enrichments);

(v) The number and types of containers;

(vi) The name and telephone number of the carrier's representative at each stopover location in United States territory;

(vii) The estimated time and date that shipment will commence and that each country (other than the United States) along the route is scheduled to be entered;

(viii) For shipments between countries that are not party to the Convention on the Physical Protection of Nuclear Material, provide assurances, as far as is practicable, that this nuclear material will be protected during international transport at levels described in Annex I to that Convention (see appendices E and F of part 73 of this chapter); and

(ix) A physical protection plan for implementing the requirement of § 70.20b(c), which will include the use of armed personnel to protect the shipment during the time the shipment is in a United States port.

(g) Persons generally licensed under this section making unscheduled stops at United States ports,

immediately after the decision to make an unscheduled stop, shall:

(1) Provide to the Director, Office of Nuclear Security and Incident Response, the information required under paragraph (f) of this section.

(2) In the case of persons generally licensed under paragraph (a)(1) of this section, arrange for local law enforcement authorities or trained and qualified private guards to protect the shipment during the stop.

(3) In the case of persons generally licensed under paragraph (a)(2) of this section, arrange for the shipment to be protected as required in § 73.67(e) of this chapter.

(4) In the case of persons generally licensed under paragraph (a)(3) of this section, arrange for the shipment to be protected as required in § 73.37(e) of this chapter.

(5) Implement these arrangements within a reasonable time after the arrival of the shipment at a United States port to remain in effect until the shipment exits that or another United States port.

[52 FR 9652, Mar. 26, 1987, as amended at 60 FR 24552, May 9, 1995; 67 FR 3585, Jan. 25, 2002; 68 FR 58817, Oct. 10, 2003; 72 FR 35144, June 27, 2007; 83 FR 57231, Nov. 21, 2018]

Subpart D--License Applications

§ 70.21 Filing.

(a)(1) A person may apply for a license to possess and use special nuclear material in a plutonium processing or fuel fabrication plant, or for a uranium enrichment facility license, by filing the application with the Director of the NRC's Office of Nuclear Material Safety and Safeguards in accordance with the instructions in § 70.5(a). If the application is on paper or CD-ROM, only one copy need be provided. If the application is to be submitted electronically, see guidance for electronic submissions to the Commission.

(2) A person may apply for any other license issued under this part, by filing the application in accordance with the instructions in § 70.5(a). If the application is on paper, only one copy need be provided. If the application is to be submitted electronically, see guidance for electronic submissions to the Commission.

(3) Information contained in previous applications, statements, or reports filed with the Commission may be incorporated by reference if the references are clear and specific.

(b) An application for license filed pursuant to the regulations in this part will be considered also as an application for licenses authorizing other activities for which licenses are required by the Act, provided the application specifies the additional activities for which licenses are requested and complies with regulations of the Commission as to applications for such licenses.

(c) Any application which contains Restricted Data shall be prepared in such manner that all Restricted Data are separated from the unclassified information.

(d) Applications and documents submitted to the Commission in connection with applications may be made available for public inspection in accordance with the provisions of the regulations contained in part 2 of this chapter.

(e) Each application for a special nuclear material license, other than a license exempted from part 170 of this chapter, shall be accompanied by the fee prescribed in § 170.31 of this chapter. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in § 170.31 of this chapter.

(f) An application for a license to possess and use special nuclear material for processing and fuel fabrication, scrap recovery or conversion of uranium hexafluoride, or for the conduct of any other activity which the Commission has determined pursuant to subpart A of part 51 of this chapter will significantly affect the quality of the environment shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted, and shall be accompanied by an Environmental Report required under subpart A of part 51 of this chapter.

(g)(1) In response to a written request by the Commission, each applicant for a construction authorization or license and each recipient of a construction authorization or a license to possess and use special nuclear material shall submit facility information, as described in § 75.10 of this chapter, on ~~Form N–71 and associated forms~~IAEA Design Information Questionnaire forms and site information on DOC/NRC Form AP–A and associated forms;

(2) As required by the Additional Protocol, applicants and licensees specified in paragraph (a) of this section shall submit location information described in § 75.11 of this chapter on DOC/NRC Form AP–1 and associated forms; and

(3) Shall permit verification thereof by the International Atomic Energy Agency (IAEA) and take other action as necessary to implement the US/IAEA Safeguards Agreement, as described in Part 75 of this chapter.

(h) A license application for a uranium enrichment facility must be accompanied by an Environmental Report required under subpart A of part 51 of this chapter.

[21 FR 764, Feb. 3, 1956, as amended at 23 FR 1122, Feb. 21, 1958; 31 FR 4670, Mar. 19, 1966; 34 FR 19546, Dec. 11, 1969; 36 FR 146, Jan. 6, 1971; 37 FR 5749, Mar. 21, 1972; 49 FR 9406, Mar. 12, 1984; 49 FR 19628 and 19632, May 9, 1984; 49 FR 21699, May 23, 1984; 57 FR 18392, Apr. 30, 1992; 68 FR 58817, Oct. 10, 2003; 73 FR 78606, Dec. 23, 2008; 85 FR 65656, Oct. 16, 2020]

§ 70.22 Contents of applications.

(a) Each application for a license shall contain the following information:

(1) The full name, address, age (if an individual), and citizenship of the applicant and the names and addresses of three personal references. If the applicant is a corporation or other entity, it shall indicate the State where it was incorporated or organized, the location of the principal office, the names, addresses, and citizenship of its principal officers, and shall include information known to the applicant concerning the control or ownership, if any, exercised over the applicant by any alien, foreign corporation, or foreign government;

(2) The activity for which the special nuclear material is requested, or in which special nuclear material will be produced, the place at which the activity is to be performed and the general plan for carrying out the activity;

(3) The period of time for which the license is requested;

(4) The name, amount, and specifications (including the chemical and physical form and, where applicable, isotopic content) of the special nuclear material the applicant proposes to use or produce;

(5) [Reserved]

(6) The technical qualifications, including training and experience of the applicant and members of his staff to engage in the proposed activities in accordance with the regulations in this chapter;

(7) A description of equipment and facilities which will be used by the applicant to protect health and minimize danger to life or property (such as handling devices, working areas, shields, measuring and monitoring instruments, devices for the disposal of radioactive effluents and wastes, storage facilities, criticality accident alarm systems, etc.);

(8) Proposed procedures to protect health and minimize danger to life or property (such as procedures to avoid accidental criticality, procedures for personnel monitoring and waste disposal, post-criticality accident emergency procedures, etc.).

Note: Where the nature of the proposed activities is such as to require consideration of the applicant's financial qualifications to engage in the proposed activities in accordance with the regulations in this chapter, the Commission may request the applicant to submit information with respect to his financial qualifications.

(9) As provided by § 70.25, certain applications for specific licenses filed under this part must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. In the case of renewal applications submitted on or before July 27, 1990, this submittal may follow the renewal application but must be submitted on or before July 27, 1990.

(b) Each application for a license to possess special nuclear material, to possess equipment capable

of enriching uranium, to operate an uranium enrichment facility, to possess and use at any one time and location special nuclear material in a quantity exceeding one effective kilogram, except for applications for use as sealed sources and for those uses involved in the operation of a nuclear reactor licensed pursuant to part 50 of this chapter and those involved in a waste disposal operation, must contain a full description of the applicant's program for control and accounting of such special nuclear material or enrichment equipment that will be in the applicant's possession under license to show how compliance with the requirements of §§ 74.31, 74.33, 74.41, or 74.51 of this chapter, as applicable, will be accomplished.

(c) [Reserved]

(d) The Commission may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Commission to determine whether the application should be granted or denied or whether a license should be modified or revoked. All applications and statements shall be signed by the applicant or licensee or a corporate officer thereof.

(e) Each application and statement shall contain complete and accurate disclosure as to all matters and things required to be disclosed.

(f) Each application for a license to possess and use special nuclear material in a plutonium processing and fuel fabrication plant shall contain, in addition to the other information required by this section, a description of the plant site, a description and safety assessment of the design bases of the principal structure, systems, and components of the plant, including provisions for protection against natural phenomena, and a description of the quality assurance program to be applied to the design, fabrication, construction, testing and operation of the structures, systems, and components of the plant.[2]

(g)(1) Each application for a license that would authorize the transport or delivery to a carrier for transport of special nuclear material in an amount specified in § 73.1(b)(2) of this chapter must include (i) a description of the plan for physical protection of special nuclear material in transit in accordance with §§ 73.20, 73.25, 73.26, 73.27, and 73.67(a), (e), and (g) for 10 kg or more of special nuclear material of low strategic significance, and § 73.70(g) of this chapter including, as appropriate, a plan for the selection, qualification, and training of armed escorts, or the specification and design of a specially designed truck or trailer, and (ii) a licensee safeguards contingency plan or response procedures, as appropriate, for dealing with threats, thefts, and radiological sabotage relating to the special nuclear material in transit.

(2) Each application for such a license involving formula quantities of strategic special nuclear material must include the first four categories of information contained in the applicant's safeguards contingency plan. (The first four categories of information, as set forth in appendix C to part 73 of this chapter, are Background, Generic Planning Base, Licensee Planning Base, and Responsibility Matrix. The fifth category of information, Procedures, does not have to be submitted for approval.)

(3) The licensee shall retain this description of the plan for physical protection of special nuclear material in transit and the safeguards contingency plan or safeguards response procedures and each change to the plan or procedures as a record for a period of three years following the date on which the licensee last possessed the appropriate type and quantity of special nuclear material requiring this record under each license.

(h)(1) Each application for a license to possess or use, at any site or contiguous sites subject to licensee control, a formula quantity of strategic special nuclear material, as defined in § 70.4, other than a license for possession or use of this material in the operation of a nuclear reactor licensed pursuant to part 50 of this chapter, must include a physical security plan. The plan must describe how the applicant will meet the applicable requirements of part 73 of this chapter in the conduct of the activity to be licensed, including the identification and description of jobs as required by 10 CFR 11.11(a). The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of 10 CFR parts 11 and 73, if applicable.

(2) The licensee shall retain a copy of this physical security plan and each change to the plan as a record for a period of three years following the date on which the licensee last possessed the appropriate type and quantity of special nuclear material requiring this record under each license.

(i)(1) Each application to possess enriched uranium or plutonium for which a criticality accident alarm system is required, uranium hexafluoride in excess of 50 kilograms in a single container or 1000 kilograms total, or in excess of 2 curies of plutonium in unsealed form or on foils or plated sources, must contain either:

(i) An evaluation showing that the maximum dose to a member of the public offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or an intake of 2 milligrams of soluble uranium, or

(ii) An emergency plan for responding to the radiological hazards of an accidental release of special nuclear material and to any associated chemical hazards directly incident thereto.

(2) One or more of the following factors may be used to support an evaluation submitted under paragraph (i)(1)(i) of this section:

(i) The radioactive material is physically separated so that only a portion could be involved in an accident;

(ii) All or part of the radioactive material is not subject to release during an accident or to criticality because of the way it is stored or packaged;

(iii) In the case of fires or explosions, the release fraction would be lower than 0.001 due to the chemical or physical form of the material;

(iv) The solubility of the material released would reduce the dose received;

(v) The facility design or engineered safety features in the facility would cause the release fraction to be lower than 0.001;

(vi) Operating restrictions or procedures would prevent a release large enough to cause a member of the public offsite to receive a dose exceeding 1 rem effective dose equivalent; or

(vii) Other factors appropriate for the specific facility.

(3) Emergency plans submitted under paragraph (i)(1)(ii) of this section must include the following information:

(i) *Facility description*. A brief description of the licensee's facility and area near the site.

(ii) *Types of accidents*. An identification of each type of radioactive materials accident for which protective actions may be needed.

(iii) *Classification of accidents*. A classification system for classifying accidents as alerts or site area emergencies.

(iv) *Detection of accidents*. Identification of the means of detecting each type of accident in a timely manner.

(v) *Mitigation of consequences*. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(vi) *Assessment of releases*. A brief description of the methods and equipment to assess releases of radioactive materials.

(vii) *Responsibilities*. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the NRC; also responsibilities for developing, maintaining, and updating the plan.

(viii) *Notification and coordination*. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the NRC operations center immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.[1]

(ix) Information to be communicated. A brief description of the types of information on facility

status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the NRC.

(x) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(xi) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(xii) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(xiii) Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the special nuclear material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to NRC. The licensee shall provide any comments received within the 60 days to the NRC with the emergency plan.

(j)(1) Each application for a license to possess or use at any site or contiguous sites subject to control by the licensee uranium-235 (contained in uranium enriched to 20 percent or more in the uranium-235 isotope), uranium-233, or plutonium alone or in any combination in a quantity of 5,000 grams or more computed by the formula, grams = (grams contained U - 235) + 2.5 (grams U-233 + grams plutonium) other than a license for possession or use of this material in the operation of a nuclear reactor licensed pursuant to part 50 of this chapter, must include a licensee safeguards contingency plan for dealing with threats, thefts, and radiological sabotage, as defined in part 73 of this chapter, relating to nuclear facilities licensed under part 50 of this chapter or to the possession of special nuclear material licensed under this part.

(2) Each application for such a license must include the first four categories of information contained in the applicant's safeguards contingency plan. (The first four categories of information, as set forth in appendix C to part 73 of this chapter, are Background, Generic Planning Base, Licensee Planning Base, and Responsibility Matrix.) The fifth category of information, Procedures, does not have to be submitted for approval.

(3) The licensee shall retain a copy of this safeguards contingency plan as a record until the Commission terminates each license obtained by this application or any application for renewal of a license and retain each change to the plan as a record for three years after the date of the change.

(k) Each application for a license to possess or use at any site or contiguous sites subject to licensee control, special nuclear material of moderate strategic significance or 10 kg or more of special nuclear material of low strategic significance as defined under § 70.4, other than a license for possession or use of this material in the operation of a nuclear power reactor licensed pursuant to part 50 of this chapter, must include a physical security plan that demonstrates how the applicant plans to meet the requirements of paragraphs (d), (e), (f), and (g) of § 73.67 of this chapter, as appropriate. The licensee shall retain a copy of this physical security plan as a record for the period during which the licensee possesses the appropriate type and quantity of special nuclear material under each license, and if any portion of the plan is superseded, retain that superseded portion of the plan for 3 years after the effective date of the change.

(l) Each applicant for a license shall protect Safeguards Information against unauthorized disclosure in accordance with the requirements in § 73.21 and the requirements of § 73.22, or 73.23 of this chapter, as applicable, and shall protect classified information in accordance with the requirements of parts 25 and 95 of this chapter, as applicable.

(m) Each application for a license to possess equipment capable of enriching uranium or operate an enrichment facility, and produce, possess, or use more than one effective kilogram of special nuclear material at any site or contiguous sites subject to control by the applicant, must contain a full description of the applicant's security program to protect against theft, and to protect against unauthorized viewing of classified enrichment equipment, and unauthorized disclosure of classified matter in accordance with the requirements of 10 CFR parts 25 and 95.

(n) A license application that involves the use of special nuclear material in a uranium enrichment facility must include the applicant's provisions for liability insurance.

[21 FR 764, Feb. 3, 1956; 73 FR 63572, Oct. 24, 2008; 86 FR 43397, Aug. 9, 2021; 86 FR 47209, Aug. 24, 2021 (corrected version)]

Editorial Note: For Federal Register citations affecting § 70.22, see the List of CFR Sections Affected.

[1] These reporting requirements do not superceed or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title

III, Pub. L. 99-499 or other state or federal reporting requirements.

[2] The description of the quality assurance program should include a discussion of how the criteria in appendix B of part 50 of this chapter will be met.

§ 70.23 Requirements for the approval of applications.

(a) An application for a license will be approved if the Commission determines that:

(1) The special nuclear material is to be used for the conduct of research or development activities of a type specified in section 31 of the Act,[1] in activities licensed by the Commission under section 103 or 104 of the Act, or for such other uses as the Commission determines to be appropriate to carry out the purposes of the Act;

(2) The applicant is qualified by reason of training and experience to use the material for the purpose requested in accordance with the regulations in this chapter;

(3) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property;

(4) The applicant's proposed procedures to protect health and to minimize danger to life or property are adequate;

(5) Where the nature of the proposed activities is such as to require consideration by the Commission, that the applicant appears to be financially qualified to engage in the proposed activities in accordance with the regulations in this part;

(6) Where the applicant is required to submit a summary description of the fundamental material controls provided in his procedures for the control of and accounting for special nuclear material pursuant to § 70.22 (b), the applicant's proposed controls are adequate;

(7) Where the proposed activity is processing and fuel fabrication, scrap recovery, conversion of uranium hexafluoride, uranium enrichment facility construction and operation, or any other activity which the Commission determines will significantly affect the quality of the environment, the Director of Nuclear Material Safety and Safeguards or his designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to subpart A of part 51 of this chapter, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to this conclusion is grounds for denial to possess and use special nuclear material in the plant or facility. As used in this paragraph, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site

exploration, roads necessary for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

(8) Where the proposed activity is the operation of a plutonium processing and fuel fabrication plant, construction of the principal structures, systems, and components approved pursuant to paragraph (b) of this section has been completed in accordance with the application;

(9) Where the applicant is required to submit a plan for physical protection of special nuclear material in transit pursuant to § 70.22(g), of this chapter, the applicant's plan is adequate;

(10) Where the applicant is required to submit a physical security plan pursuant to § 70.22(h), the applicant's proposed plan is adequate;

(11) Where the proposed activity is processing and fuel fabrication, scrap recovery, conversion of uranium hexafluoride, or involves the use of special nuclear material in a uranium enrichment facility, the applicant's proposed emergency plan is adequate.

(12) Where the proposed activity is use of special nuclear material in a uranium enrichment facility, the applicable provisions of part 140 of this chapter have been satisfied.

(b) The Commission will approve construction of the principal structures, systems, and components of a plutonium processing and fuel fabrication plant on the basis of information filed pursuant to § 70.22(f) when the Commission has determined that the design bases of the principal structures, systems, and components, and the quality assurance program provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents.[3] Failure to obtain Commission approval prior to beginning of such construction may be grounds for denial of a license to possess and use special nuclear material in a plutonium processing and fuel fabrication plant.

[36 FR 17574, Sept. 2, 1971, as amended at 37 FR 5749, Mar. 21, 1972; 38 FR 30534, 30538, Nov. 6, 1973; 39 FR 26286, July 18, 1974; 42 FR 17126, Mar. 31, 1977; 43 FR 6924, Feb. 17, 1978; 49 FR 9406, Mar. 12, 1984; 54 FR 14064, Apr. 7, 1989; 57 FR 18392, Apr. 30, 1992; 67 FR 78142, Dec. 23, 2002]

[1] The types of research and development activities specified in section 31 are those relating to:

(1) Nuclear processes;

(2) The theory and production of atomic energy, including processes, materials, and devices related to such production;

(3) Utilization of special nuclear material and radioactive material for medical, biological, agricultural, health or military purposes;

(4) Utilization of special nuclear material, atomic energy, and radioactive material and processes entailed in the utilization or production of atomic energy or such material for all other purposes, including industrial use, the generation of usable energy, and the demonstration of the practical value of utilization or production facilities for industrial or commercial purposes; and

(5) The protection of health and the promotion of safety during research and production activities.

[3] The criteria in appendix B of part 50 of this chapter will be used by the Commission in determining the adequacy of the quality assurance program.

§ 70.23a Hearing required for uranium enrichment facility.

The Commission will hold a hearing under 10 CFR part 2, subparts A, C, G, and I, on each application for issuance of a license for construction and operation of a uranium enrichment facility. The Commission will publish public notice of the hearing in the Federal Register at least thirty (30) days before the hearing.

[57 FR 18392, Apr. 30, 1992; 69 FR 2280, Jan. 14, 2004]

§ 70.24 Criticality accident requirements.

(a) Each licensee authorized to possess special nuclear material in a quantity exceeding 700 grams of contained uranium-235, 520 grams of uranium-233, 450 grams of plutonium, 1,500 grams of contained uranium-235 if no uranium enriched to more than 4 percent by weight of uranium-235 is present, 450 grams of any combination thereof, or one-half such quantities if massive moderators or reflectors made of graphite, heavy water or beryllium may be present, shall maintain in each area in which such licensed special nuclear material is handled, used, or stored, a monitoring system meeting the requirements of either paragraph (a)(1) or (a)(2), as appropriate, and using gamma- or neutron-sensitive radiation detectors which will energize clearly audible alarm signals if accidental criticality occurs. This section is not intended to require underwater monitoring when special nuclear material is handled or stored beneath water shielding or to require monitoring systems when special nuclear material is being transported when packaged in accordance with the requirements of part 71 of this chapter.

(1) The monitoring system shall be capable of detecting a criticality that produces an absorbed dose in soft tissue of 20 rads of combined neutron and gamma radiation at an unshielded distance of 2 meters from the reacting material within one minute. Coverage of all areas shall be provided by two detectors.

(2) Persons licensed prior to December 6, 1974, to possess special nuclear material subject to this section may maintain a monitoring system capable of detecting a criticality which generates radiation levels of 300 rems per hour one foot from the source of the radiation. The monitoring devices in the system shall have a preset alarm point of not less than 5 millirems per hour (in order to avoid false alarms) nor more than 20 millirems per hour. In no event may any such device be

farther than 120 feet from the special nuclear material being handled, used, or stored; lesser distances may be necessary to meet the requirements of this paragraph (a)(2) on account of intervening shielding or other pertinent factors.

(3) The licensee shall maintain emergency procedures for each area in which this licensed special nuclear material is handled, used, or stored to ensure that all personnel withdraw to an area of safety upon the sounding of the alarm. These procedures must include the conduct of drills to familiarize personnel with the evacuation plan, and designation of responsible individuals for determining the cause of the alarm, and placement of radiation survey instruments in accessible locations for use in such an emergency. The licensee shall retain a copy of current procedures for each area as a record for as long as licensed special nuclear material is handled, used, or stored in the area. The licensee shall retain any superseded portion of the procedures for three years after the portion is superseded.

(b) Each licensee authorized to possess special nuclear material in quantities in excess of those specified in paragraph (a) shall:

(1) Provide the means for identifying quickly which individuals have received doses of 10 rads or more.

(2) Maintain facilities and supplies at the site for decontamination of personnel, arrangements for the services of a physician and other medical personnel qualified to handle radiation emergencies, arrangements for transportation of injured or contaminated individuals to treatment facilities, and arrangements for treatment of individuals at treatment facilities outside the site boundary.

(c) Holders of licenses for construction or operation of a nuclear reactor issued pursuant to part 50 of this chapter, except critical assembly reactors, are exempt for the requirements of paragraph (b) of this section with respect to special nuclear material used or to be used in the reactor.

(d)(1) The requirements in paragraphs (a) through (c) of this section do not apply to a holder of a construction permit or operating license for a nuclear power reactor issued under part 50 of this chapter or a combined license issued under part 52 of this chapter, if the holder complies with the requirements of paragraph (b) of 10 CFR 50.68.

(2) An exemption from § 70.24 held by a licensee who thereafter elects to comply with requirements of paragraph (b) of 10 CFR 50.68 does not exempt that licensee from complying with any of the requirements in § 50.68, but shall be ineffective so long as the licensee elects to comply with § 50.68.

[39 FR 39021, Nov. 5, 1974, as amended at 41 FR 31522, July 29, 1976; 53 FR 19252, May 27, 1988; 62 FR 63828, Dec. 3, 1997; 63 FR 63130, Nov. 12, 1998]

§ 70.25 Financial assurance and recordkeeping for decommissioning.

(a) Each applicant for a specific license of the types described in paragraphs (a)(1) and (2) of this section shall submit a decommissioning funding plan as described in paragraph (e) of this section.

(1) A specific license for a uranium enrichment facility;

(2) A specific license authorizing the possession and use of unsealed special nuclear material in quantities exceeding 10^5 times the applicable quantities set forth in appendix B to part 30. A decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 105 is greater than 1 (unity rule), where R is the sum of the ratios of the quantity of each isotope to the applicable value in appendix B to part 30.

(b) Each applicant for a specific license authorizing possession and use of unsealed special nuclear material in quantities specified in paragraph (d) of this section shall either--

(1) Submit a decommissioning funding plan as described in paragraph (e) of this section; or

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by paragraph (d) of this section using one of the methods described in paragraph (f) of this section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section must be submitted to NRC before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to NRC, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section.

(c)(1) Each holder of a specific license issued on or after July 27, 1990, which is of a type described in paragraph (a) or (b) of this section, shall provide financial assurance for decommissioning in accordance with the criteria set forth in this section.

(2) Each holder of a specific license issued before July 27, 1990, and of a type described in paragraph (a) of this section shall submit a decommissioning funding plan as described in paragraph (e) of this section or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000 in accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.

(3) Each holder of a specific license issued before July 27, 1990, and of a type described in paragraph (b) of this section shall submit, on or before July 27, 1990, a decommissioning funding plan, described in paragraph (e) of this section, or a certification of financial assurance for decommissioning in accordance with the criteria set forth in this section.

(4) Any licensee who has submitted an application before July 27, 1990, for renewal of license in accordance with § 70.33 shall provide financial assurance for decommissioning in accordance with paragraphs (a) and (b) of this section. This assurance must be submitted when this rule becomes effective November 24, 1995.

(d) Table of required amounts of financial assurance for decommissioning by quantity of material. Licensees required to submit the $1,125,000 amount must do so by December 2, 2004. Licensees required to submit the $225,000 amount must do so by June 2, 2005. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan.

greater than 10^4 but less than or equal to 10^5 times the applicable quantities of appendix B to part 30. (For a combination of isotopes, if R, as defined in § 70.25(a), divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.)	$1,125,000
greater than 10^3 but less than or equal to 10^4 times the applicable quantities of appendix B to part 30. (For a combination of isotopes, if R, as defined in § 70.25(a), divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.)	$225,000

(e)(1) Each decommissioning funding plan must be submitted for review and approval and must contain –

(i) A detailed cost estimate for decommissioning, in the amount reflecting:

(A) The cost of an independent contractor to perform all decommissioning activities;

(B) The cost of meeting the 10 CFR 20.1402 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 10 CFR 20.1403, the cost estimate may be based on meeting the 10 CFR 20.1403 criteria;

(C) The volume of onsite subsurface material containing residual radioactivity that will require remediation; and

(D) An adequate contingency factor.

(ii) Identification of and justification for using the key assumptions contained in the DCE;

(iii) A description of the method of assuring funds for decommissioning from paragraph (f) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(v) A signed original, or, if permitted, a copy, of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

(i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(ii) Waste inventory increasing above the amount previously estimated;

(iii) Waste disposal costs increasing above the amount previously estimated;

(iv) Facility modifications;

(v) Changes in authorized possession limits;

(vi) Actual remediation costs that exceed the previous cost estimate;

(vii) Onsite disposal; and

(viii) Use of a settling pond.

(f) Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A to part 30. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. For commercial corporations that issue bonds, a guarantee of

funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix C to part 30. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in appendix D to part 30. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in appendix E to part 30. A guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issurer notifies the Commission, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Commission within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(iii) The surety method or insurance must remain in effect until the Commission has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licenssee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in paragraph (f)(2) of this section.

(4) In the case of Federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in paragraph (d) of this section, and indicating that funds for decommissioning will be obtained when necessary.

(5) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(g) Each person licensed under this part shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Commission considers important to decommissioning consists of--

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after cleanup of any leak), a list contained in a single document and updated every 2 years, of the following:

(i) All areas designated and formerly designated as restricted areas as defined under 10 CFR 20.1003 (For requirements prior to January 1, 1994, see 10 CFR 20.3 as contained in the CFR edition revised as of January 1, 1993.);

(ii) All areas outside of restricted areas that require documentation under § 70.25(g)(1);

(iii) All areas outside of restricted areas where current and previous wastes have been buried as documented under 10 CFR 20.2108; and

(iv) All areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 10 CFR part 20, subpart E, or apply for approval for disposal under 10 CFR 20.2002.

(4) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

[53 FR 24053, June 27, 1988, as amended at 56 FR 23474, May 21, 1991; 57 FR 18393, Apr. 30, 1992; 58 FR 39634, July 26, 1993; 58 FR 67662, Dec. 22, 1993; 58 FR 68731, Dec. 29, 1993; 59

FR 1618, Jan. 12, 1994; 60 FR 38239, July 26, 1995; 61 FR 24675, May 16, 1996; 62 FR 39091, July 21, 1997; 63 FR 29544, June 1, 1998; 68 FR 57337, Oct. 3, 2003]

Subpart E--Licenses

§ 70.31 Issuance of licenses.

(a) Upon a determination that an application meets the requirements of the act and of the regulations of the Commission, the Commission will issue a license in such form and containing such conditions and limitations as it deems appropriate or necessary to effectuate the purposes of the act.

(b) [Reserved]

(c) Each license issued to a person for use of special nuclear material in activities in which special nuclear material will be produced shall (subject to the provisions of § 70.41(b)) be deemed to authorize such person to receive title to, own, acquire, receive, possess, use, and transfer the special nuclear material produced in the course of such authorized activities.

(d) No license will be issued by the Commission to any person within the United States if the Commission finds that the issuance of such license would be inimical to the common defense and security or would constitute an unreasonable risk to the health and safety of the public.

(e) No license to construct and operate a uranium enrichment facility may be issued until a hearing pursuant to 10 CFR part 2, subparts G and I, is completed and decision issued on the application.

[21 FR 764, Feb. 3, 1956, as amended at 32 FR 2563, Feb. 7, 1967; 32 FR 4056, Mar. 15, 1967; 43 FR 6925, Feb. 17, 1978; 57 FR 18393, Apr. 30, 1992]

§ 70.32 Conditions of licenses.

(a) Each license shall contain and be subject to the following conditions:

(1) [Reserved]

(2) No right to the special nuclear material shall be conferred by the license except as defined by the license;

(3) Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of the Act;

(4) All special nuclear material shall be subject to the right of recapture or control reserved by section 108 and to all other provisions of the Act;

(5) No special nuclear material may be used in any utilization or production facility except in accordance with the provisions of the Act;

(6) The licensee shall not use the special nuclear material to construct an atomic weapon or any component of an atomic weapon;

(7) Except to the extent that the indemnification and limitation of liability provisions of part 140 of this chapter apply, the licensee will hold the United States and the Department harmless from any damages resulting from the use or possession of special nuclear material leased from the Department by the licensee;

(8) The license shall be subject to and the licensee shall observe, all applicable rules, regulations and orders of the Commission.

(9)(i) Each licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(A) The licensee;

(B) An entity (as that term is defined in 11 U.S.C. 101(15~~4~~)) controlling the licensee or listing the license or licensee as property of the estate; or

(C) An affiliate (as that term is defined in 11 U.S.C. 101(2~~a~~)) of the licensee.

(ii) This notification must indicate:

(A) The bankruptcy court in which the petition for bankruptcy was filed; and

(B) The date of the filing of the petition.

(b) The Commission may incorporate in any license such additional conditions and requirements with respect to the licensee's ownership, receipt, possession, use, and transfer of special nuclear material as it deems appropriate or necessary in order to:

(1) Promote the common defense and security;

(2) Protect health or to minimize danger to life or property;

(3) Protect restricted data;

(4) Guard against the loss or diversion of special nuclear material;

(5) Require such reports and the keeping of such records, and to provide for such inspections, of

activities under the license as may be necessary or appropriate to effectuate the purposes of the act and regulations thereunder.

(c)(1) Each license authorizing the possession and use at any one time and location of uranium source material at an uranium enrichment facility or special nuclear material in a quantity exceeding one effective kilogram, except for use as sealed sources and those uses involved in the operation of a nuclear reactor licensed pursuant to part 50 of this chapter and those involved in a waste disposal operation, shall contain and be subject to a condition requiring the licensee to maintain and follow:

(i) The program for control and accounting of uranium source material at a uranium enrichment facility and special nuclear material at all applicable facilities as implemented pursuant to § 70.22(b), or §§ 74.31(b), 74.33(b), 74.41(b), or 74.51(c) of this chapter, as appropriate;

(ii) The measurement control program for uranium source material at a uranium enrichment facility and for special nuclear material at all applicable facilities as implemented pursuant to §§ 74.31(b), 74.33(b), 74.45(c), or 74.59(e) of this chapter, as appropriate; and

(iii) Other material control procedures as the Commission determines to be essential for the safeguarding of uranium source material at an uranium enrichment facility or of special nuclear material and providing that the licensee shall make no change that would decrease the effectiveness of the material control and accounting program implemented pursuant to § 70.22(b), or §§ 74.31(b), 74.33(b), 74.41(b), or 74.51(c) of this chapter, and the measurement control program implemented pursuant to §§ 74.31(b), 74.33(b), 74.41(b), or 74.59(e) of this chapter without the prior approval of the Commission. A licensee desiring to make changes that would decrease the effectiveness of its material control and accounting program or its measurement control program shall submit an application for amendment to its license pursuant to § 70.34.

(2) The licensee shall maintain records of changes to the material control and accounting program made without prior Commission approval for a period of 5 years from the date of the change. Licensees located in all four Regions as indicated in appendix A of part 73 of this chapter shall furnish to the Director, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in § 70.5(a), a report containing a description of each change within:

(i) Two months of the change if it pertains to uranium-233, uranium-235 contained in uranium enriched 20 percent or more in the uranium-235 isotope, or plutonium, except plutonium containing 80 percent or more by weight of the isotope Pu-238, and

(ii) Six months of the change if it pertains to uranium enriched less than 20 percent in the uranium-235 isotope, or plutonium containing 80 percent or more by weight of the isotope Pu-238.

(d) The licensee shall make no change which would decrease the effectiveness of the plan for physical protection of special nuclear material in transit prepared pursuant to § 70.22(g) or § 73.20(c) of this chapter without the prior approval of the Commission. A licensee desiring to make

such changes shall submit an application for a change in the technical specifications incorporated in his or her license, if any, or for an amendment to the license pursuant to § 50.90 or § 70.34 of this chapter, as appropriate. The licensee may make changes to the plan for physical protection of special nuclear material without prior Commission approval if these changes do not decrease the effectiveness of the plan. The licensee shall retain a copy of the plan as a record for the period during which the licensee possesses a formula quantity of special nuclear material requiring this record under each license and each change to the plan for three years from the effective date of the change. Within two months after each change, a report containing a description of the change must be furnished to the Director of the NRC's Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in § 70.5(a); and a copy must be sent to the appropriate NRC Regional Office shown in appendix A to part 73 of this chapter.

(e) The licensee shall make no change which would decrease the effectiveness of a security plan prepared pursuant to §§ 70.22(h), 70.22(k), or 73.20(c) without the prior approval of the Commission. A licensee desiring to make such a change shall submit an application for an amendment to its license pursuant to § 70.34. The licensee shall maintain records of changes to the plan made without prior Commission approval, for three years from the effective date of the change, and shall, within two months after the change is made, furnish a report containing a description of each change to the Director, Office of Nuclear Material Safety and Safeguards; the report may be sent using an appropriate method listed in § 70.5(a), and a copy of the report must be sent to the appropriate NRC Regional Office shown in appendix A to part 73 of this chapter.

(f) [Reserved]

(g) The licensee shall prepare and maintain safeguards contingency plan procedures in accordance with appendix C to part 73 of this chapter for bringing about the actions and decisions contained in the Responsibility Matrix of its safeguards contingency plan. The licensee shall retain the current safeguards contingency plan procedures as a record for the entire period during which the licensee possesses the appropriate type and quantity of special nuclear material under each license for which the procedures were developed and, if any portion of the plan is superseded, retain that superseded portion for 3 years after the effective date of the change. The licensee shall not make a change that would decrease the safeguards effectiveness of the first four categories of information (i.e., Background, Generic Planning Base, Licensee Planning Base, and Responsibility Matrix) contained in any licensee safeguards contingency plan prepared pursuant to §§ 70.22(g), 70.22(j), 72.184, 73.20(c), 73.26(e)(1), 73.46(h)(1), or 73.50(g)(1) of this chapter without the prior approval of the NRC. A licensee desiring to make such a change shall submit an application for an amendment to its license pursuant to § 70.34. The licensee may make changes to the licensee safeguards contingency plan without prior NRC approval if the changes do not decrease the safeguards effectiveness of the plan. The licensee shall maintain each change to the plan made without prior approval as a record during the period for which possession of a formula quantity of special nuclear material is authorized under a license and retain the superseded portion for 3 years after the effective date of the change, and shall, within 60 days after the change is made, furnish a report containing a description of each change to the Director of Nuclear Material Safety and Safeguards; the report may be sent using an appropriate method listed in § 70.5(a), and a copy of the report must be sent to the Regional Administrator of the appropriate NRC Regional Office as

specified in appendix A to part 73 of this chapter.

(h) [Reserved]

(i) Licensees required to submit emergency plans in accordance with § 70.22(i) shall follow the emergency plan approved by the Commission. The licensee may change the approved plan without Commission approval if the changes do not decrease the effectiveness of the plan. Within six months after each change is made, the licensee shall, using an appropriate method listed in § 70.5(a), furnish the Director, Office of Nuclear Material Safety and Safeguards, a copy of each change, with copies to the appropriate NRC Regional Office specified in appendix D to part 20 of this chapter and to affected offsite response organizations. Proposed changes that decrease the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Commission.

(j) Each licensee who possesses special nuclear material, or who transports, or delivers to a carrier for transport, a formula quantity of strategic special nuclear material, special nuclear material of moderate strategic significance, or special nuclear material of low strategic significance, or more than 100 grams of irradiated reactor fuel shall ensure that Safeguards Information is protected against unauthorized disclosure in accordance with the requirements in § 73.21 and the requirements of § 73.22 or § 73.23 of this chapter, as applicable, and shall protect classified information in accordance with the requirements of parts 25 and 95 of this chapter, as applicable.

(k) No person may commence operation of a uranium enrichment facility until the Commission verifies through inspection that the facility has been constructed in accordance with the requirements of the license. The Commission shall publish notice of the inspection results in the Federal Register.

[21 FR 764, Feb. 3, 1956; 73 FR 63572, Oct. 24, 2008; 83 FR 57231, Nov. 21, 2018; 86 FR 43397, Aug. 9, 2021; 86 FR 47209, Aug. 24, 2021 (corrected version)]

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Editorial Note: For Federal Register citations affecting § 70.32, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 70.33 Renewal of licenses.

(a) Applications for renewal of a license should be filed in accordance with §§ 70.21 and 70.22. Information contained in previous applications, statements or reports filed with the Commission under the license may be incorporated by reference: Provided, That such references are clear and specific.

(b) If any licensee granted the extension described in 10 CFR 70.38(a)(2) has a currently pending renewal application for that extended license, that application will be considered withdrawn by the

licensee and any renewal fees paid by the licensee for that application will be refunded.

[21 FR 764, Feb. 3, 1956, as amended at 59 FR 36037, July 15, 1994; 61 FR 1115, Jan. 16, 1996]

§ 70.34 Amendment of licenses.

Applications for amendment of a license shall be filed in accordance with § 70.21(a) and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

§ 70.35 Commission action on applications to renew or amend.

In considering an application by a licensee to renew or amend his license, the Commission will apply the criteria set forth in § 70.23.

§ 70.36 Inalienability of licenses.

(a) No license granted under the regulations in this part and no right to possess or utilize special nuclear material granted by any license issued pursuant to the regulations in this part shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Commission shall after securing full information, find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

(b) An application for transfer of license must include:

(1) The identity, technical and financial qualifications of the proposed transferee; and

(2) Financial assurance for decommissioning information required by § 70.25.

[21 FR 764, Feb. 3, 1956, as amended at 35 FR 11461, July 17, 1970]

§ 70.37 Disclaimer of warranties.

Neither the Government nor the Commission makes any warranty or other representation that special nuclear material (a) will not result in injury or damage when used for purposes approved by the Commission, (b) will accomplish the results for which it is requested and approved by the Commission, or (c) is safe for any other use.

§ 70.38 Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

(a) Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under § 70.33 not less than 30 days before

the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days before the expiration date stated in the existing license, the existing license expires at the end of the day on which the Commission makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(b) Each specific license revoked by the Commission expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Commission Order.

(c) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of special nuclear material until the Commission notifies the licensee in writing that the license is terminated. During this time, the licensee shall--

(1) Limit actions involving special nuclear material to those related to decommissioning; and

(2) Continue to control entry to restricted areas until they are suitable for release in accordance with NRC requirements.

(d) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in § 70.5, each licensee shall provide notification to the NRC in writing and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity, so that the building or outdoor area is suitable for release in accordance with NRC requirements, or submit within 12 months of notification a decommissioning plan, if required by paragraph (g)(1) of this section, and begin decommissioning upon approval of that plan if--

(1) The license has expired pursuant to paragraph (a) or (b) of this section; or

(2) The licensee has decided to permanently cease principal activities, as defined in this part, at the entire site or in any separate building or outdoor area; or

(3) No principal activities under the license have been conducted for a period of 24 months; or

(4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.

(e) Coincident with the notification required by paragraph (d) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to § 70.25 in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph (g)(4)(v) of this section.

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective November 24, 1995.

(2) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Commission.

(f) The Commission may grant a request to delay or postpone initiation of the decommissioning process if the Commission determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to paragraph (d) of this section. The schedule for decommissioning set forth in paragraph (d) of this section may not commence until the Commission has made a determination on the request.

(g)(1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Commission and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The Commission may approve an alternate schedule for submittal of a decommissioning plan required pursuant to paragraph (d) of this section if the Commission determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(3) The procedures listed in paragraph (g)(1) of this section may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(ii) A description of planned decommissioning activities;

(iii) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(iv) A description of the planned final radiation survey; and

(v) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(vi) A description of the physical security plan and material control and accounting plan provisions in place during decommissioning.

(vii) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, a justification for the delay based on the criteria in paragraph (i) of this section.

(5) The proposed decommissioning plan will be approved by the Commission if the information therein demonstrates that the decommissioning will be completed as soon as practical and that the health and safety of workers and the public will be adequately protected.

(h)(1) Except as provided in paragraph (i) of this section, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(2) Except as provided in paragraph (i) of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(i) The Commission may approve a request for an alternate schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Commission determines that the alternative is warranted by consideration of the following:

(1) Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(3) Whether a significant volume reduction in wastes requiring disposal will be achieved by

allowing short-lived radionuclides to decay;

(4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis, such as regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(j) As the final step in decommissioning, the licensee shall--

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E. The licensee shall, as appropriate--

(i) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters removable and fixed for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(k) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Commission determines that:

(1) Special nuclear material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3)(i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E.

(4) Records required by § 70.51(b)(6) have been received.

[59 FR 36037, July 15, 1994, as amended at 60 FR 38240, July 26, 1995; 61 FR 1115, Jan. 16, 1996; 61 FR 24675, May 16, 1996; 61 FR 29637, 29638, June 12, 1996; 62 FR 39091, July 21, 1997; 66 FR 24049, May 11, 2001; 73 FR 42675; Jul. 23, 2008]

§ 70.39 Specific licenses for the manufacture or initial transfer of calibration or reference sources.

(a) An application for a specific license to manufacture or initially transfer calibration or reference sources containing plutonium, for distribution to persons generally licensed under § 70.19, will be approved if:

(1) The applicant satisfies the general requirements of § 70.23.

(2) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(i) Chemical and physical form and maximum quantity of plutonium in the source;

(ii) Details of construction and design;

(iii) Details of the method of incorporation and binding of the plutonium in the source;

(iv) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of plutonium, to demonstrate that the plutonium contained in each source will not be released or be removed from the source under normal conditions of use;

(v) Details of quality control procedures to be followed in manufacture of the source;

(vi) Description of labeling to be affixed to the source or the storage container for the source;

(vii) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.

(3) Each source will contain no more than 5 microcuries of plutonium.

(4) The Commission determines, with respect to any type of source containing more than 0.005 microcurie of plutonium, that:

(i) The method of incorporation and binding of the plutonium in the source is such that the plutonium will not be released or be removed from the source under normal conditions of use and handling of the source; and

(ii) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by paragraph (a)(5) of this section.

(5) For any type of source which is designed to contain more than 0.005 microcurie of plutonium, the applicant has conducted prototype tests, in the order listed, on each of five prototypes of such source, which contains more than 0.005 microcurie of plutonium, as follows:

(i) *Initial measurement*. The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

(ii) *Dry wipe test*. The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.

(iii) *Wet wipe test*. The entire radioactive surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after it has dried or by direct measurement of the radioactivity on the source following the wet wipe.

(iv) *Water soak test*. The source shall be immersed in water at room temperature for a period of 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source after it has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

(v) *Dry wipe test*. On completion of the preceding tests in paragraphs (a)(5)(i) through (iv) of this section, the dry wipe test described in paragraph (a)(5)(ii) of this section shall be repeated.

(vi) *Observations*. Removal of more than 0.005 microcurie of radioactivity in any test prescribed by this paragraph shall be cause for rejection of the source design. Results of prototype tests submitted to the Commission shall be given in terms of radioactivity in microcuries and percent of removal from the total amount of radioactive material deposited on the source.

(b) Each person licensed under this section shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement.[1]

The receipt, possession, use and transfer of this source, Model-- --- , Serial No.-----, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS PLUTONIUM. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(Name of Manufacturer or Initial Transferor)

(c) Each person licensed under this section shall perform a dry wipe test upon each source containing more than 0.1 microcurie of plutonium prior to transferring the source to a general licensee under § 70.19. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.005 microcurie of plutonium. If any such test discloses more than 0.005 microcurie of radioactive material, the source shall be deemed to be leaking or losing plutonium and shall not be transferred to a general licensee under § 70.19.

[29 FR 5884, May 5, 1964, as amended at 32 FR 2563, Feb. 7, 1967; 38 FR 1272, Jan. 11, 1973; 40 FR 8792, Mar. 3, 1975; 42 FR 43966, Sept. 1, 1977; 43 FR 6925, Feb. 17, 1978]

1. Sources generally licensed under this section prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

§ 70.40 Ineligibility of certain applicants.

A license may not be issued to the Corporation if the Commission determines that:

(a) The Corporation is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government; or

(b) The issuance of such a license would be inimical to--

(1) The common defense and security of the United States; or

(2) The maintenance of a reliable and economical domestic source of enrichment services.

[62 FR 6669, Feb. 12, 1997]

Subpart F--Acquisition, Use, and Transfer of Special Nuclear Material, Creditors' Rights

§ 70.41 Authorized use of special nuclear material.

(a) Each licensee shall confine his possession and use of special nuclear material to the locations and purposes authorized in his license. Except as otherwise provided in the license, each license issued pursuant to the regulations in this part shall carry with it the right to receive title to, own, acquire, receive, possess and use special nuclear material. Preparation for shipment and transport of special nuclear material shall be in accordance with the provisions of part 71 of this chapter.

(b) The possession, use and transfer of any special nuclear material produced by a licensee, in connection with or as a result of use of special nuclear material received under his license, shall be subject to the provisions of the license and the regulations in this part.

[21 FR 764, Feb. 3, 1956, as amended at 38 FR 33970, Dec. 10, 1973; 43 FR 6925, Feb. 17, 1978]

§ 70.42 Transfer of special nuclear material.

(a) No licensee shall transfer special nuclear material except as authorized pursuant to this section.

(b) Except as otherwise provided in his license and subject to the provisions of paragraphs (c) and (d) of this section, any licensee may transfer special nuclear material:

(1) To the Department;

(2) To the agency in any Agreement State which regulates radioactive materials pursuant to an agreement with the Commission or the Atomic Energy Commission under section 274 of the Act, if the quantity transferred is not sufficient to form a critical mass;

(3) To any person exempt from the licensing requirements of the Act and regulations in this part, to the extent permitted under such exemption;

(4) To any person in an Agreement State, subject to the jurisdiction of that State, who has been exempted from the licensing requirements and regulations of that State, to the extent permitted under such exemption;

(5) To any person authorized to receive such special nuclear material under terms of a specific license or a general license or their equivalents issued by the Commission or an Agreement State;

(6) To any person abroad pursuant to an export license issued under part 110 of this chapter; or

(7) As otherwise authorized by the Commission in writing.

(c) Before transferring special nuclear material to a specific licensee of the Commission or an Agreement State or to a general licensee who is required to register with the Commission or with an Agreement State prior to receipt of the special nuclear material, the licensee transferring the material shall verify that the transferee's license authorizes receipt of the type, form, and quantity of special nuclear material to be transferred.

(d) The following methods for the verification required by paragraph (c) of this section are acceptable:

(1) The transferor may have in his or her possession, and read, a current copy of the transferee's specific license or registration certificate. The transferor shall retain a copy of each license or

certificate for three years from the date that it was obtained.

(2) The transferor may have in its possession a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of special nuclear material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date. The transferor shall retain the written certification as a record for three years from the date of receipt of the certification;

(3) For emergency shipments the transferor may accept oral certification by the transferee that he or she is authorized by license or registration certification to receive the type, form, and quantity of special nuclear material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date, provided that the oral certification is confirmed in writing within ten days. The transferor shall retain the written confirmation of the oral certification for three years from the date of receipt of the confirmation;

(4) The transferor may obtain other sources of information compiled by a reporting service from official records of the Commission or the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registrations. The transferor shall retain the compilation of information as a record for three years from the date that it was obtained; or

(5) When none of the methods of verification described in paragraphs (d) (1) to (4) of this section are readily available or when a transferor desires to verify that information received by one of these methods is correct or up-to-date, the transferor may obtain and record confirmation from the Commission or the licensing agency of an Agreement State that the transferee is licensed to receive the special nuclear material. The transferor shall retain the record of confirmation for three years from the date the record is made.

[38 FR 33970, Dec. 10, 1973, as amended at 40 FR 8792, Mar. 3, 1975; 43 FR 6925, Feb. 21, 1978; 53 FR 19253, May 27, 1988]

§ 70.44 Creditor regulations.

(a) Pursuant to section 184 of the Act, the Commission consents, without individual application, to the creation of any mortgage, pledge, or other lien upon any special nuclear material, not owned by the United States, which is subject to licensing: Provided:

(1) That the rights of any creditor so secured may be exercised only in compliance with and subject to the same requirements and restrictions as would apply to the licensee pursuant to the provisions of the license, the Atomic Energy Act of 1954, as amended, and regulations issued by the Commission pursuant to said Act; and

(2) That no creditor so secured may take possession of the special nuclear material pursuant to the provisions of this section prior to either the issuance of a license by the Commission authorizing

such possession or the transfer of a license pursuant to § 70.36.

(b) Nothing contained in this section shall be deemed to affect the means of acquiring, or the priority of, any tax lien or other lien provided by law.

(c) As used in this section, creditor includes, without implied limitation, the trustee under any mortgage, pledge, or lien on special nuclear material made to secure any creditor, any trustee or receiver of the special nuclear material appointed by a court of competent jurisdiction in any action brought for the benefit of any creditor secured by such mortgage, pledge, or lien, any purchaser of such special nuclear material at the sale thereof upon foreclosure of such mortgage, pledge, or lien or upon exercise of any power of sale contained therein, or any assignee of any such purchaser.

[32 FR 2563, Feb. 7, 1967, as amended at 35 FR 11461, July 17, 1970]

Subpart G--Special Nuclear Material Control Records, Reports, and Inspections

§ 70.50 Reporting requirements.

(a) *Immediate report*. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(b) *Twenty-four hour report*. Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material:

(1) An unplanned contamination event that:

(i) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of §§ 20.1001-20.2401 of 10 CFR part 20 for the material; and

(iii) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

(i) The equipment is required by regulation or licensee condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(ii) The equipment is required to be available and operable when it is disabled or fails to function; and

(iii) No redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(i) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of §§ 20.1001-20.2401 of 10 CFR part 20 for the material; and

(ii) The damage affects the integrity of the licensed material or its container.

(c) *Preparation and submission of reports*. Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees shall make reports required by paragraphs (a) and (b) of this section, and by § 70.74 and Appendix A of this part, if applicable, by telephone to the department of environmental quality~~NRC Operations Center~~.[1] To the extent that the information is available at the time of notification, the information provided in these reports must include:

(i) Caller's name, position title, and call-back telephone number;

(ii) Date, time, and exact location of the event;

(iii) Description of the event, including:

(A) Radiological or chemical hazards involved, including isotopes, quantities, and chemical and physical form of any material released;

(B) Actual or potential health and safety consequences to the workers, the public, and the environment, including relevant chemical and radiation data for actual personnel exposures to radiation or radioactive materials or hazardous chemicals produced from licensed materials (e.g., level of radiation exposure, concentration of chemicals, and duration of exposure);

(C) The sequence of occurrences leading to the event, including degradation or failure of structures, systems, equipment, components, and activities of personnel relied on to prevent potential accidents or mitigate their consequences; and

(D) Whether the remaining structures, systems, equipment, components, and activities of personnel relied on to prevent potential accidents or mitigate their consequences are available and

reliable to perform their function;

(iv) External conditions affecting the event;

(v) Additional actions taken by the licensee in response to the event;

(vi) Status of the event (e.g., whether the event is on-going or was terminated);

(vii) Current and planned site status, including any declared emergency class;

(viii) Notifications, related to the event, that were made or are planned to any local, State, or other Federal agencies;

(ix) Status of any press releases, related to the event, that were made or are planned.

(2) Written report. Each licensee that makes a report required by paragraph (a) or (b) of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the report contains all the necessary information, and the appropriate distribution is made. These written reports must be sent to the NRC's Document Control Desk, using an appropriate method listed in § 70.5(a), with a copy to the appropriate NRC regional office listed in appendix D to part 20 of this chapter. The reports must include the following:

(i) Complete applicable information required by § 70.50(c)(1);

(ii) The probable cause of the event, including all factors that contributed to the event and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(iii) Corrective actions taken or planned to prevent occurrence of similar or identical events in the future and the results of any evaluations or assessments; and

(iv) For licensees subject to Subpart H of this part, whether the event was identified and evaluated in the Integrated Safety Analysis.

(d) The provisions of § 70.50 do not apply to licensees subject to § 50.72. They do apply to those Part 50 licensees possessing material licensed under Part 70 that are not subject to the notification requirements in § 50.72.

[56 FR 40769, Aug. 16, 1991; 56 FR 64980, Dec. 13, 1991, as amended at 59 FR 14087, Mar. 25, 1994; 65 FR 56226, Sept. 18, 2000; 68 FR 58817, Oct. 10, 2003; 85 FR 65656, Oct. 16, 2020]

~~† The commercial telephone number for the NRC Operations Center is (301) 816-5100.~~

§ 70.51 Records requirements.

(a) Before license termination, licensees shall forward the following records to the appropriate NRC Regional Office:

(1) Records of disposal of licensed material made under 10 CFR 20.2002 (including burials authorized before January 28, 1981[1]), 20.2003, 20.2004, 20.2005;

(2) Records required by 10 CFR 20.2103(b)(4); and

(3) Records required by § 70.25(g).

(b) If licensed activities are transferred or assigned in accordance with § 70.32(a)(3), the licensee shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under 10 CFR 20.2002 (including burials authorized before January 28, 1981[1]), 20.2003, 20.2004, 20.2005;

(2) Records required by 10 CFR 20.2103(b)(4); and

(3) Records required by § 70.25(g).

(c)(1) Records which must be maintained pursuant to this part may be the original or a reproduced copy, or microform if the reproduced copy or microform is duly authenticated by authorized personnel, and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(2) If there is a conflict between the Commission's regulations in this part, license condition, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this part for these records shall apply unless the Commission, under § 70.17 has granted a specific exemption from the record retention requirements specified in the regulations in this part.

[38 FR 30544, Nov. 6, 1973, as amended at 38 FR 32784, Nov. 28, 1973; 41 FR 18303, May 3, 1976; 43 FR 6925, Feb. 17, 1978; 50 FR 7579, Feb. 25, 1985; 52 FR 10038, Mar. 30, 1987; 53 FR 19253, May 27, 1988; 56 FR 55998, Oct. 31, 1991; 61 FR 24675, May 16, 1996; 67 FR 78142, Dec. 23, 2002; 72 FR 35144, June 27, 2007]

[1]A previous § 20.304 permitted burial of small quantities of licensed materials in soil before January 28, 1981, without specific Commission authorization. See § 20.304 contained in the 10 CFR, parts 0 to 199, edition revised as of January 1, 1981.

§ 70.52 Reports of accidental criticality.

(a) Each licensee shall notify the NRC Headquarters Operations Center by telephone at the numbers specified in appendix A to part 73 of this chapter within 1 hour after discovery of any case of accidental criticality.~~Each licensee shall notify the NRC Operations Center[1] within one hour after discovery of any case of accidental criticality.~~

(b) This notification must be made to the NRC Operations Center via the Emergency Notification System if the licensee is party to that system. If the Emergency Notification System is inoperative or unavailable, the licensee shall make the required notification via commercial telephonic service or other dedicated telephonic system or any other method that will ensure that a report is received by the NRC Operations Center within one hour.

[52 FR 21657, June 9, 1987, as amended at 59 FR 14087, Mar. 25, 1994; 67 FR 78143, Dec. 23, 2002; 85 FR 65656, Oct. 16, 2020]

~~[1]Commercial telephone number of the NRC Operations Center is (301) 816-5100.~~

§ 70.55 Inspections.

(a) Each licensee shall afford to the Commission at all reasonable times opportunity to inspect special nuclear material and the premises and facilities wherein special nuclear material is used, produced, or stored.

(b) Each licensee shall make available to the Commission for inspection, upon reasonable notice, records kept by the licensee pertaining to his receipt, possession, use, acquisition, import, export, or transfer of special nuclear material.

(c)(1) In the case of fuel cycle facilities where nuclear reactor fuel is fabricated or processed each licensee shall upon request by the Director, Office of Nuclear Material Safety and Safeguards or the appropriate NRC Regional Administrator, provide rent-free office space for the exclusive use of Commission inspection personnel. Heat, air conditioning, light, electrical outlets and janitorial services shall be furnished by each licensee. The office shall be convenient to and have full access to the facility and, shall provide the inspector both visual and acoustic privacy.

(2) For a site with a single fuel facility licensed pursuant to part 70, the space provided shall be adequate to accommodate a full-time inspector, a part-time secretary and transient NRC personnel and will be generally commensurate with other office facilities at the site. A space of 250 square feet either within the site's office complex or in an office trailer or other on site space is suggested as a guide. For sites containing multiple fuel facilities, additional space may be requested to accommodate additional full-time inspector(s). The office space that is provided shall be subject to the approval of the Director, Office of Nuclear Material Safety and Safeguards or the appropriate NRC Regional Administrator. All furniture, supplies and communication equipment will be furnished by the Commission.

(3) The licensee shall afford any NRC resident inspector assigned to that site or other NRC inspectors identified by the Director, Office of Nuclear Material Safety and Safeguards, as likely to inspect the facility, immediate unfettered access, equivalent to access provided regular plant employees, following proper identification and compliance with applicable access control measures for security, radiological protection, and personal safety.

[21 FR 764, Feb. 3, 1956. Redesignated at 25 FR 1607, Feb. 25, 1960, and 25 FR 12730, Dec. 13, 1960, and amended at 32 FR 2563, Feb. 7, 1967; 44 FR 47919, Aug. 16, 1979; 52 FR 31612, Aug. 21, 1987; 54 FR 6877, Feb. 15, 1989; 55 FR 5979, Feb. 21, 1990]

§ 70.56 Tests.

Each licensee shall perform, or permit the Commission to perform, such tests as the Commission deems appropriate or necessary for the administration of the regulations in this part, including tests of (a) special nuclear material, (b) facilities wherein special nuclear material is utilized, produced or stored, (c) radiation detection and monitoring instruments, and (d) other equipment and devices used in connection with the production, utilization or storage of special nuclear material.

[21 FR 764, Feb. 3, 1956. Redesignated at 25 FR 1607, Feb. 25, 1960, and 25 FR 12730, Dec. 13, 1960]

§ 70.59 Effluent monitoring reporting requirements.

Within 60 days after January 1 and July 1 of each year, and using an appropriate method listed in § 70.5(a), each licensee authorized to possess and use special nuclear material for processing and fuel fabrication, scrap recovery, conversion of uranium hexafluoride, or in a uranium enrichment facility shall submit a report addressed: ATTN: Document Control Desk, Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, with a copy to the appropriate NRC Regional Office shown in appendix D to part 20 of this chapter. The report must specify the quantity of each of the principal radionuclides released to unrestricted areas in liquid and gaseous effluents during the previous six months of operation, and such other information as the Commission may require to estimate maximum potential annual radiation doses to the public resulting from effluent releases. If quantities of radioactive materials released during the reporting periods are significantly above the licensee's design objectives previously reviewed as part of the licensing action, the report must cover this specifically. On the basis of these reports and any additional information the Commission may obtain from the licensee or others, the Commission may from time to time require the licensee to take such action as the Commission deems appropriate.

[40 FR 53230, Nov. 17, 1975, as amended at 41 FR 21627, May 27, 1976; 42 FR 25721, May 19, 1977; 52 FR 31612, Aug. 21, 1987; 57 FR 18393, Apr. 30, 1992; 68 FR 58817, Oct. 10, 2003]

Subpart H--Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material

Source: 65 FR 56226, Sept. 18, 2000, unless otherwise noted.

§ 70.60 Applicability.

The regulations in § 70.61 through § 70.76 apply, in addition to other applicable Commission regulations, to each applicant or licensee that is or plans to be authorized to possess greater than a critical mass of special nuclear material, and engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, scrap recovery of special nuclear material, or any other activity that the Commission determines could significantly affect public health and safety. The regulations in § 70.61 through § 70.76 do not apply to decommissioning activities performed pursuant to other applicable Commission regulations including § 70.25 and § 70.38 of this part. Also, the regulations in § 70.61 through § 70.76 do not apply to activities that are certified by the Commission pursuant to part 76 of this chapter or licensed by the Commission pursuant to other parts of this chapter. Unless specifically addressed in § 70.61 through § 70.76, implementation by current licensees of the Subpart H requirements shall be completed no later than the time of the ISA Summary submittal required in § 70.62(c)(3)(ii).

§ 70.61 Performance requirements.

(a) Each applicant or licensee shall evaluate, in the integrated safety analysis performed in accordance with § 70.62, its compliance with the performance requirements in paragraphs (b), (c), and (d) of this section.

(b) The risk of each credible high-consequence event must be limited. Engineered controls, administrative controls, or both, shall be applied to the extent needed to reduce the likelihood of occurrence of the event so that, upon implementation of such controls, the event is highly unlikely or its consequences are less severe than those in paragraphs (b)(1)-(4) of this section. High consequence events are those internally or externally initiated events that result in:

(1) An acute worker dose of 1 Sv (100 rem) or greater total effective dose equivalent;

(2) An acute dose of 0.25 Sv (25 rem) or greater total effective dose equivalent to any individual located outside the controlled area identified pursuant to paragraph (f) of this section;

(3) An intake of 30 mg or greater of uranium in soluble form by any individual located outside the controlled area identified pursuant to paragraph (f) of this section; or

(4) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that:

(i) Could endanger the life of a worker, or

(ii) Could lead to irreversible or other serious, long-lasting health effects to any individual located outside the controlled area identified pursuant to paragraph (f) of this section. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as part of the information submitted pursuant to § 70.65 of this subpart.

(c) The risk of each credible intermediate-consequence event must be limited. Engineered controls, administrative controls, or both shall be applied to the extent needed so that, upon implementation of such controls, the event is unlikely or its consequences are less than those in paragraphs (c)(1)-(4) of this section. Intermediate consequence events are those internally or externally initiated events that are not high consequence events, that result in:

(1) An acute worker dose of 0.25 Sv (25 rem) or greater total effective dose equivalent;

(2) An acute dose of 0.05 Sv (5 rem) or greater total effective dose equivalent to any individual located outside the controlled area identified pursuant to paragraph (f) of this section;

(3) A 24-hour averaged release of radioactive material outside the restricted area in concentrations exceeding 5000 times the values in Table 2 of Appendix B to Part 20; or

(4) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that:

(i) Could lead to irreversible or other serious, long-lasting health effects to a worker, or

(ii) Could cause mild transient health effects to any individual located outside the controlled area as specified in paragraph (f) of this section. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as part of the information submitted pursuant to § 70.65 of this subpart.

(d) In addition to complying with paragraphs (b) and (c) of this section, the risk of nuclear criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety. Preventive controls and measures must be the primary means of protection against nuclear criticality accidents.

(e) Each engineered or administrative control or control system necessary to comply with paragraphs (b), (c), or (d) of this section shall be designated as an item relied on for safety. The safety program, established and maintained pursuant to § 70.62 of this subpart, shall ensure that each item relied on for safety will be available and reliable to perform its intended function when needed and in the context of the performance requirements of this section.

(f) Each licensee must establish a controlled area, as defined in § 20.1003. In addition, the licensee

must retain the authority to exclude or remove personnel and property from the area. For the purpose of complying with the performance requirements of this section, individuals who are not workers, as defined in § 70.4, may be permitted to perform ongoing activities (e.g., at a facility not related to the licensed activities) in the controlled area, if the licensee:

(1) Demonstrates and documents, in the integrated safety analysis, that the risk for those individuals at the location of their activities does not exceed the performance requirements of paragraphs (b)(2), (b)(3), (b)(4)(ii), (c)(2), and (c)(4)(ii) of this section; or

(2) Provides training that satisfies 10 CFR 19.12(a)(1)-(5) to these individuals and ensures that they are aware of the risks associated with accidents involving the licensed activities as determined by the integrated safety analysis, and conspicuously posts and maintains notices stating where the information in 10 CFR 19.11(a) may be examined by these individuals. Under these conditions, the performance requirements for workers specified in paragraphs (b) and (c) of this section may be applied to these individuals.

[87 FR 20693, Apr. 8, 2022]

§ 70.62 Safety program and integrated safety analysis.

(a) **Safety program.** (1) Each licensee or applicant shall establish and maintain a safety program that demonstrates compliance with the performance requirements of § 70.61. The safety program may be graded such that management measures applied are graded commensurate with the reduction of the risk attributable to that item. Three elements of this safety program; namely, process safety information, integrated safety analysis, and management measures, are described in paragraphs (b) through (d) of this section.

(2) Each licensee or applicant shall establish and maintain records that demonstrate compliance with the requirements of paragraphs (b) through (d) of this section.

(3) Each licensee or applicant shall maintain records of failures readily retrievable and available for NRC inspection, documenting each discovery that an item relied on for safety or management measure has failed to perform its function upon demand or has degraded such that the performance requirements of § 70.61 are not satisfied. These records must identify the item relied on for safety or management measure that has failed and the safety function affected, the date of discovery, date (or estimated date) of the failure, duration (or estimated duration) of the time that the item was unable to perform its function, any other affected items relied on for safety or management measures and their safety function, affected processes, cause of the failure, whether the failure was in the context of the performance requirements or upon demand or both, and any corrective or compensatory action that was taken. A failure must be recorded at the time of discovery and the record of that failure updated promptly upon the conclusion of each failure investigation of an item relied on for safety or management measure.

(b) *Process safety information.* Each licensee or applicant shall maintain process safety

information to enable the performance and maintenance of an integrated safety analysis. This process safety information must include information pertaining to the hazards of the materials used or produced in the process, information pertaining to the technology of the process, and information pertaining to the equipment in the process.

(c) *Integrated safety analysis.* (1) Each licensee or applicant shall conduct and maintain an integrated safety analysis, that is of appropriate detail for the complexity of the process, that identifies:

(i) Radiological hazards related to possessing or processing licensed material at its facility;

(ii) Chemical hazards of licensed material and hazardous chemicals produced from licensed material;

(iii) Facility hazards that could affect the safety of licensed materials and thus present an increased radiological risk;

(iv) Potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including natural phenomena;

(v) The consequence and the likelihood of occurrence of each potential accident sequence identified pursuant to paragraph (c)(1)(iv) of this section, and the methods used to determine the consequences and likelihoods; and

(vi) Each item relied on for safety identified pursuant to § 70.61(e) of this subpart, the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements of § 70.61.

(2) Integrated safety analysis team qualifications. To assure the adequacy of the integrated safety analysis, the analysis must be performed by a team with expertise in engineering and process operations. The team shall include at least one person who has experience and knowledge specific to each process being evaluated, and persons who have experience in nuclear criticality safety, radiation safety, fire safety, and chemical process safety. One member of the team must be knowledgeable in the specific integrated safety analysis methodology being used.

(3) Requirements for existing licensees. Individuals holding an NRC license on September 18, 2000 shall, with regard to existing licensed activities:

(i) By April 18, 2001, submit for NRC approval, a plan that describes the integrated safety analysis approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process.

(ii) By October 18, 2004, or in accordance with the approved plan submitted under §

70.62(c)(3)(i), complete an integrated safety analysis, correct all unacceptable performance deficiencies, and submit, for NRC approval, an integrated safety analysis summary, including a description of the management measures, in accordance with § 70.65. The Commission may approve a request for an alternative schedule for completing the correction of unacceptable performance deficiencies if the Commission determines that the alternative is warranted by consideration of the following:

(A) Adequate compensatory measures have been established;

(B) Whether it is technically feasible to complete the correction of the unacceptable performance deficiency within the allotted 4-year period;

(C) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis and that are beyond the control of the licensee.

(iii) Pending the correction of unacceptable performance deficiencies identified during the conduct of the integrated safety analysis, the licensee shall implement appropriate compensatory measures to ensure adequate protection.

(d) *Management measures.* Each applicant or licensee shall establish management measures to ensure compliance with the performance requirements of § 70.61. The measures applied to a particular engineered or administrative control or control system may be graded commensurate with the reduction of the risk attributable to that control or control system. The management measures shall ensure that engineered and administrative controls and control systems that are identified as items relied on for safety pursuant to § 70.61(e) of this subpart are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed, to comply with the performance requirements of § 70.61 of this subpart.

§ 70.64 Requirements for new facilities or new processes at existing facilities.

(a) *Baseline design criteria.* Each prospective applicant or licensee shall address the following baseline design criteria in the design of new facilities. Each existing licensee shall address the following baseline design criteria in the design of new processes at existing facilities that require a license amendment under § 70.72. The baseline design criteria must be applied to the design of new facilities and new processes, but do not require retrofits to existing facilities or existing processes (e.g., those housing or adjacent to the new process); however, all facilities and processes must comply with the performance requirements in § 70.61. Licensees shall maintain the application of these criteria unless the analysis performed pursuant to § 70.62(c) demonstrates that a given item is not relied on for safety or does not require adherence to the specified criteria.

(1) Quality standards and records. The design must be developed and implemented in accordance with management measures, to provide adequate assurance that items relied on for safety will be available and reliable to perform their function when needed. Appropriate records of these items

must be maintained by or under the control of the licensee throughout the life of the facility.

(2) Natural phenomena hazards. The design must provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site.

(3) Fire protection. The design must provide for adequate protection against fires and explosions.

(4) Environmental and dynamic effects. The design must provide for adequate protection from environmental conditions and dynamic effects associated with normal operations, maintenance, testing, and postulated accidents that could lead to loss of safety functions.

(5) Chemical protection. The design must provide for adequate protection against chemical risks produced from licensed material, facility conditions which affect the safety of licensed material, and hazardous chemicals produced from licensed material.

(6) Emergency capability. The design must provide for emergency capability to maintain control of:

(i) Licensed material and hazardous chemicals produced from licensed material;

(ii) Evacuation of on-site personnel; and

(iii) Onsite emergency facilities and services that facilitate the use of available offsite services.

(7) Utility services. The design must provide for continued operation of essential utility services.

(8) Inspection, testing, and maintenance. The design of items relied on for safety must provide for adequate inspection, testing, and maintenance, to ensure their availability and reliability to perform their function when needed.

(9) Criticality control. The design must provide for criticality control including adherence to the double contingency principle.

(10) Instrumentation and controls. The design must provide for inclusion of instrumentation and control systems to monitor and control the behavior of items relied on for safety.

(b) Facility and system design and facility layout must be based on defense-in-depth practices.[1] The design must incorporate, to the extent practicable:

(1) Preference for the selection of engineered controls over administrative controls to increase overall system reliability; and

(2) Features that enhance safety by reducing challenges to items relied on for safety.

[1] As used in § 70.64, Requirements for new facilities or new processes at existing facilities, defense-in-depth practices means a design philosophy, applied from the outset and through completion of the design, that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges. The risk insights obtained through performance of the integrated safety analysis can be then used to supplement the final design by focusing attention on the prevention and mitigation of the higher-risk potential accidents.

§ 70.65 Additional content of applications.

(a) In addition to the contents required by § 70.22, each application must include a description of the applicant's safety program established under § 70.62.

(b) The integrated safety analysis summary must be submitted with the license or renewal application (and amendment application as necessary), but shall not be incorporated in the license. However, changes to the integrated safety analysis summary shall meet the conditions of § 70.72. The integrated safety analysis summary must contain:

(1) A general description of the site with emphasis on those factors that could affect safety (i.e., meteorology, seismology);

(2) A general description of the facility with emphasis on those areas that could affect safety, including an identification of the controlled area boundaries;

(3) A description of each process (defined as a single reasonably simple integrated unit operation within an overall production line) analyzed in the integrated safety analysis in sufficient detail to understand the theory of operation; and, for each process, the hazards that were identified in the integrated safety analysis pursuant to § 70.62(c)(1)(i)-(iii) and a general description of the types of accident sequences;

(4) Information that demonstrates the licensee's compliance with the performance requirements of § 70.61, including a description of the management measures; the requirements for criticality monitoring and alarms in § 70.24; and, if applicable, the requirements of § 70.64;

(5) A description of the team, qualifications, and the methods used to perform the integrated safety analysis;

(6) A list briefly describing each item relied on for safety which is identified pursuant to § 70.61(e) in sufficient detail to understand their functions in relation to the performance requirements of § 70.61;

(7) A description of the proposed quantitative standards used to assess the consequences to an

individual from acute chemical exposure to licensed material or chemicals produced from licensed materials which are on-site, or expected to be on-site as described in § 70.61(b)(4) and (c)(4);

(8) A descriptive list that identifies all items relied on for safety that are the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of § 70.61; and

(9) A description of the definitions of unlikely, highly unlikely, and credible as used in the evaluations in the integrated safety analysis.

§ 70.66 Additional requirements for approval of license application.

(a) An application for a license from an applicant subject to subpart H will be approved if the Commission determines that the applicant has complied with the requirements of § 70.21, 70.22, 70.23, and 70.60 through 70.65.

(b) Submittals by existing licensees in accordance with § 70.62(c)(3)(i) will be approved if the Commission determines that:

(1) The integrated safety analysis approach is in accordance with the requirements of § 70.61, 70.62(c)(1), and 70.62(c)(2); and

(2) The schedule is in compliance with § 70.62(c)(3)(ii).

(c) Submittals by existing licensees in accordance with § 70.62(c)(3)(ii) will be approved if the Commission determines that:

(1) The requirements of § 70.65(b) are satisfied; and

(2) The performance requirements in § 70.61 (b), (c) and (d) are satisfied, based on the information in the ISA Summary, together with other information submitted to NRC or available to NRC at the licensee's site.

§ 70.72 Facility changes and change process.

(a) The licensee shall establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. This system must be documented in written procedures and must assure that the following are addressed prior to implementing any change:

(1) The technical basis for the change;

(2) Impact of the change on safety and health or control of licensed material;

(3) Modifications to existing operating procedures including any necessary training or retraining

before operation;

(4) Authorization requirements for the change;

(5) For temporary changes, the approved duration (e.g., expiration date) of the change; and

(6) The impacts or modifications to the integrated safety analysis, integrated safety analysis summary, or other safety program information, developed in accordance with § 70.62.

(b) Any change to site, structures, processes, systems, equipment, components, computer programs, and activities of personnel must be evaluated by the licensee as specified in paragraph (a) of this section, before the change is implemented. The evaluation of the change must determine, before the change is implemented, if an amendment to the license is required to be submitted in accordance with § 70.34.

(c) The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval, if the change:

(1) Does not:

(i) Create new types of accident sequences that, unless mitigated or prevented, would exceed the performance requirements of § 70.61 and that have not previously been described in the integrated safety analysis summary; or

(ii) Use new processes, technologies, or control systems for which the licensee has no prior experience;

(2) Does not remove, without at least an equivalent replacement of the safety function, an item relied on for safety that is listed in the integrated safety analysis summary and is necessary for compliance with the performance
requirements of § 70.61;

(3) Does not alter any item relied on for safety, listed in the integrated safety analysis summary, that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of § 70.61; and

(4) Is not otherwise prohibited by this section, license condition, or order.

(d)(1) For changes that require pre-approval under § 70.72, the licensee shall submit an amendment request to the NRC in accordance with § 70.34 and § 70.65 of this chapter.

(2) For changes that do not require pre-approval under § 70.72, the licensee shall submit to NRC annually, within 30 days after the end of the calendar year during which the changes occurred, a

brief summary of all changes to the records required by § 70.62(a)(2) of this subpart.

(3) For all changes that affect the integrated safety analysis summary, the licensee shall submit to NRC annually, within 30 days after the end of the calendar year during which the changes occurred, revised integrated safety analysis summary pages.

(e) If a change covered by § 70.72 is made, the affected on-site documentation must be updated promptly.

(f) The licensee shall maintain records of changes to its facility carried out under this section. These records must include a written evaluation that provides the bases for the determination that the changes do not require prior Commission approval under paragraph (c) or (d) of this section. These records must be maintained until termination of the license.

[71 FR 56344, Sep. 27, 2006]

§ 70.73 Renewal of licenses.

Applications for renewal of a license must be filed in accordance with §§ 2.109, 70.21, 70.22, 70.33, 70.38, and 70.65 of this chapter. Information contained in previous applications, statements, or reports filed with the Commission under the license may be incorporated by reference, provided that these references are clear and specific.

§ 70.74 Additional reporting requirements.

(a) Reports to NRC Operations Center. (1) Each licensee shall report to the NRC Operations Center the events described in Appendix A to Part 70.

(2) Reports must be made by a knowledgeable licensee representative and by any method that will ensure compliance with the required time period for reporting.

(3) The information provided must include a description of the event and other related information as described in § 70.50(c)(1).

(4) Follow-up information to the reports must be provided until all information required to be reported in § 70.50(c)(1) of this subpart is complete.

(5) Each licensee shall provide reasonable assurance that reliable communication with the NRC Operations Center is available during each event.

(b) Written reports. Each licensee that makes a report required by paragraph (a)(1) of this section shall submit a written follow-up report within 30 days of the initial report. The written report must contain the information as described in § 70.50(c)(2).

§ 70.76 Backfitting.

(a) For each licensee, this provision shall apply to Subpart H requirements as soon as the NRC approves that licensee's ISA Summary pursuant to § 70.66. For requirements other than Subpart H, this provision applies regardless of the status of the approval of a licensee's ISA Summary.

(1) Backfitting is defined as the modification of, or addition to, systems, structures, or components of a facility; or to the procedures or organization required to operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position.

(2) Except as provided in paragraph (a)(4) of this section, the Commission shall require a systematic and documented analysis pursuant to paragraph (b) of this section for backfits which it seeks to impose.

(3) Except as provided in paragraph (a)(4) of this section, the Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (b) of this section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

(4) The provisions of paragraphs (a)(2) and (a)(3) of this section are inapplicable and, therefore, backfit analysis is not required and the standards in paragraph (a)(3) of this section do not apply where the Commission finds and declares, with appropriately documented evaluation for its finding, any of the following:

(i) That a modification is necessary to bring a facility into compliance with Subpart H of this part;

(ii) That a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee;

(iii) That regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security; or

(iv) That the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

(5) The Commission shall always require the backfitting of a facility if it determines that the regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security.

(6) The documented evaluation required by paragraph (a)(4) of this section must include a statement of the objectives of and reasons for the modification and the basis for invoking the

exception. If immediate effective regulatory action is required, then the documented evaluation may follow, rather than precede, the regulatory action.

(7) If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written license commitments, or there are two or more ways to reach an adequate level of protection, then ordinarily the licensee is free to choose the way that best suits its purposes. However, should it be necessary or appropriate for the Commission to prescribe a specific way to comply with its requirements or to achieve adequate protection, then cost may be a factor in selecting the way, provided that the objective of compliance or adequate protection is met.

(b) In reaching the determination required by paragraph (a)(3) of this section, the Commission will consider how the backfit should be scheduled in light of other ongoing regulatory activities at the facility and, in addition, will consider information available concerning any of the following factors as may be appropriate and any other information relevant and material to the proposed backfit:

(1) Statement of the specific objectives that the proposed backfit is designed to achieve;

(2) General description of the activity that would be required by the licensee in order to complete the backfit;

(3) Potential change in the risk to the public from the accidental release of radioactive material and hazardous chemicals produced from licensed material;

(4) Potential impact on radiological exposure or exposure to hazardous chemicals produced from licensed material of facility employees;

(5) Installation and continuing costs associated with the backfit, including the cost of facility downtime;

(6) The potential safety impact of changes in facility or operational complexity, including the relationship to proposed and existing regulatory requirements;

(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

(8) The potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfit; and

(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(c) No license will be withheld during the pendency of backfit analyses required by the

Commission's rules.

(d) The Executive Director for Operations shall be responsible for implementation of this section, and all analyses required by this section shall be approved by the Executive Director for Operations or his or her designee.

Subpart I--Modification and Revocation of Licenses

§ 70.81 Modification and revocation of licenses.

(a) The terms and conditions of all licenses shall be subject to amendment, revision, or modification by reason of amendments to the Atomic Energy Act of 1954, or by reason of rules, regulations or orders issued in accordance with the Act or any amendments thereto;

(b) Any license may be revoked, suspended or modified for any material false statements in the application or any statement of fact required under section 182 of the Act or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Commission to refuse to grant a license on an original application, or for failure to construct or operate a facility in accordance with the terms of the construction permit or license, the technical specifications in the application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of any regulation of the Commission.

(c) Upon revocation, suspension or modification of a license, the Commission may immediately retake possession of all special nuclear material held by the licensee. In cases found by the Commission to be of extreme importance to the national defense or security, or to the health and safety of the public, the Commission may recapture any special nuclear material held by the licensee prior to any of the procedures provided under section 551-558 of title 5 of the United States Code.

(d) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded opportunity to demonstrate or achieve compliance with all lawful requirements.

[21 FR 764, Feb. 3, 1956, as amended at 35 FR 11461, July 17, 1970. Redesignated at 65 FR 56226, Sept. 18, 2000]

§ 70.82 Suspension and operation in war or national emergency.

Whenever Congress declares that a state of war or national emergency exists, the Commission, if it finds it necessary to the common defense and security may,

(a) Suspend any license it has issued.

(b) Order the recapture of special nuclear material.

(c) Order the operation of any licensed facility.

(d) Order entry into any plant or facility in order to recapture special nuclear material or to operate the facility. Just compensation shall be paid for any damages caused by recapture of special nuclear material or by operation of any facility, pursuant to this section.

[21 FR 764, Feb. 3, 1956, as amended at 32 FR 4056, Mar. 15, 1967; 35 FR 11461, July 17, 1970. Redesignated at 65 FR 56226, Sept. 18, 2000]

Subpart J--Enforcement

§ 70.91 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55077, Nov. 24, 1992. Redesignated at 65 FR 56226, Sept. 18, 2000]

§ 70.92 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 70 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 70 that are not issued under sections 161b, 161i, or 161o, for the purposes of section 223 are as follows: § 70.1, 70.2, 70.4, 70.5, 70.6, 70.8, 70.11, 70.12, 70.13, 70.14, 70.17, 70.18, 70.23, 70.31, 70.33, 70.34, 70.35, 70.37, 70.66, 70.73, 70.76, 70.81, 70.82, 70.63, 70.91, and 70.92.

[57 FR 55077, Nov. 24, 1992. Redesignated and amended at 65 FR 56226, Sept. 18, 2000]

Appendix A to Part 70--Reportable Safety Events

Licensees must comply with reporting requirements in this appendix, except for (a)(1), (a)(2), and (b)(4), after they have submitted an ISA Summary in accordance with § 70.62(c)(3)(ii). Licensees must comply with (a)(1), (a)(2), and (b)(4) after October 18, 2000. As required by 10 CFR 70.74, licensees subject to the requirements in subpart H of part 70, shall report:

(a) One hour reports. Events to be reported to the NRC Operations Center within 1 hour of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 30 days:

(1) An inadvertent nuclear criticality.

(2) An acute intake by an individual of 30 mg or greater of uranium in a soluble form.

(3) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that exceeds the quantitative standards established to satisfy the requirements in § 70.61(b)(4).

(4) An event or condition such that no items relied on for safety, as documented in the Integrated Safety Analysis summary, remain available and reliable, in an accident sequence evaluated in the Integrated Safety Analysis, to perform their function:

(i) In the context of the performance requirements in § 70.61(b) and § 70.61(c), or

(ii) Prevent a nuclear criticality accident (i.e., loss of all controls in a particular sequence).

(5) Loss of controls such that only one item relied on for safety, as documented in the Integrated Safety Analysis summary, remains available and reliable to prevent a nuclear criticality accident,

and has been in this state for greater than eight hours.

(b) Twenty-four hour reports. Events to be reported to the NRC Operations Center within 24 hours of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 30 days:

(1) Any event or condition that results in the facility being in a state that was not analyzed, was improperly analyzed, or is different from that analyzed in the Integrated Safety Analysis, and which results in failure to meet the performance requirements of § 70.61.

(2) Loss or degradation of items relied on for safety that results in failure to meet the performance requirement of § 70.61.

(3) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed materials that exceeds the quantitative standards that satisfy the requirements of § 70.61(c)(4).

(4) Any natural phenomenon or other external event, including fires internal and external to the facility, that has affected or may have affected the intended safety function or availability or reliability of one or more items relied on for safety.

(5) An occurrence of an event or process deviation that was considered in the Integrated Safety Analysis and:

(i) Was dismissed due to its likelihood; or

(ii) Was categorized as unlikely and whose associated unmitigated consequences would have exceeded those in § 70.61(b) had the item(s) relied on for safety not performed their safety function(s).

(c) Concurrent Reports. Any event or situation, related to the health and safety of the public or onsite personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made, shall be reported to the NRC Operations Center concurrent to the news release or other notification.

[65 FR 56231, Sept. 18, 2000]

CHAPTER 33.1-10-18
GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

Section
33.1-10-18-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 31

33.1-10-18-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 31.

10 Code of Federal Regulations 31.1, 31.2, 31.3, 31.5, 31.6, 31.7, 31.8, 31.9, 31.10, 31.11, and 31.12 are adopted by reference as they exist on October 1, 2015, with the following exceptions:

1. Not adopted by reference are 10 Code of Federal Regulations 31.3(b) and (c) and 31.6(a).

2. Requirements in 10 Code of Federal Regulations 31 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States nuclear regulatory commission", or "director of nuclear material safety and safeguards" appear in 10 Code of Federal Regulations part 31, substitute the words "department of environmental quality" except when used in 10 Code of Federal Regulations 31.8(c)(2) and 31.11(d)(2).

4. Reporting required in 10 Code of Federal Regulations 31.5(c)(5), 31.5(c)(8)(ii), 31.5(c)(9)(i), 31.5 (c)(11), and 31.5(c)(14) shall be submitted to the department of environmental quality as follows:

   a. By mail addressed to: Radiation Control Program, Department of Environmental Quality, 4201 Normandy Street, Second Floor, Bismarck, ND 58503-1324.

   b. By hand delivery to: Radiation Control Program, Department of Environmental Quality, 4201 Normandy Street, Second Floor, Bismarck, ND.

   c. By electronic submission to ram@nd.gov. Electronic submissions must be made in a manner that enables the department of environmental quality to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time.

5. North Dakota state form number 8423, "certificate - in vitro testing with radioactive material under general license", must be used instead of nuclear regulatory commission form 483 as specified in 10 Code of Federal Regulations part 31.

6. References in 10 Code of Federal Regulations part 31 to specific licenses issued by an agreement state also include specific licenses issued by the United States nuclear regulatory commission.

History: Effective January 1, 2019.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

PART 31—GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

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31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

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31.13 [Reserved]

31.14 [Reserved]

31.15 [Reserved]

31.16 [Reserved]

31.17 [Reserved]

31.18 [Reserved]

31.19 [Reserved]

31.20 [Reserved]

31.21 Maintenance of records.

31.22 Violations.

31.23 Criminal penalties.

Authority: Atomic Energy Act of 1954, secs. 81, 161, 183, 223, 234, 274 (42 U.S.C. 2111, 2201, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); 44 U.S.C. 3504 note.

[72 FR 55926, Oct. 1, 2007; 73 FR 42673, Jul. 23, 2008; 77 FR 39905, Jul. 6, 2012; 77 FR 43690, Jul. 25, 2012; 80 FR 54233, Sep. 9, 2015]

§ 31.1 Purpose and scope.

This part establishes general licenses for the possession and use of byproduct material and a general license for ownership of byproduct material. Specific provisions of 10 CFR Part 30 are applicable to general licenses established by this part. These provisions are specified in § 31.2 or in the particular general license.

[65 FR 79187, Dec. 18, 2000]

§ 31.2 Terms and conditions.

The general licenses provided in this part are subject to the general provisions of Part 30 of this chapter (Secs. 30.1 through 30.10), the provisions of §§ 30.14(d), 30.34(a) to (e), 30.41, 30.50 to 30.53, 30.61 to 30.63, and Parts 19, 20, and 21, of this chapter[1] unless indicated otherwise in the specific provision of the general license.

[65 FR 79187, Dec. 18, 2000]

[1] Attention is directed particularly to the provisions of Part 20 of this chapter concerning labeling of containers.

§ 31.3 [Reserved]

[30 FR 8189, June 26, 1965, as amended at 34 FR 6652, Apr. 18, 1969; 35 FR 3982, Mar. 3, 1970; 77 FR 43690, Jul. 25, 2012]

§ 31.4 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0016.

(b) The approved information collection requirements contained in this part appear in §§31.5, 31.8, 31.11, and 31.12.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 31.11, NRC Form 483 is approved under control number 3150-0038.

(2) [Reserved]

[62 FR 52186, Oct. 6, 1997, as amended at 67 FR 67099, Nov. 4, 2002; 72 FR 55926, Oct. 1, 2007]

§ 31.5 Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.[5]

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of paragraphs (b), (c) and (d) of this section, byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b)(1) The general license in paragraph (a) of this section applies only to byproduct material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in--

(i) A specific license issued under § 32.51 of this chapter; or

(ii) An equivalent specific license issued by an Agreement State; or

(iii) An equivalent specific license issued by a State with provisions comparable to § 32.51 of this chapter.

(2) The devices must have been received from one of the specific licensees described in paragraph (b)(1) of this section or through a transfer made under paragraph (c)(9) of this section.

(c) Any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section:

(1) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(2) Shall assure that the device is tested for leakage of radioactive material and proper operation of

the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:

(i) Devices containing only krypton need not be tested for leakage of radioactive material, and

(ii) Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(3) Shall assure that the tests required by paragraph (c)(2) of this section and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(i) In accordance with the instructions provided by the labels; or

(ii) By a person holding a specific license pursuant to parts 30 and 32 of this chapter or from an Agreement State to perform such activities;

(4) Shall maintain records showing compliance with the requirements of paragraphs (c)(2) and (c)(3) of this section. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(i) Each record of a test for leakage or radioactive material required by paragraph (c)(2) of this section must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

(ii) Each record of a test of the on-off mechanism and indicator required by paragraph (c)(2) of this section must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

(iii) Each record that is required by paragraph (c)(3) of this section must be retained for three years from the date of the recorded event or until the device is transferred or disposed of.

(5) Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 bequerel (0.005 microcurie) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued under parts 30 and 32 of this chapter or by an Agreement State. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the byproduct material in the device or as otherwise approved by the Commission. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for

ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Director, Office of Nuclear Material Safety and Safeguards, ATTN: GLTS, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 within 30 days. Under these circumstances, the criteria set out in § 20.1402 of this chapter, "Radiological criteria for unrestricted use," may be applicable, as determined by the Commission on a case-by-case basis;

(6) Shall not abandon the device containing byproduct material;

(7) Shall not export the device containing byproduct material except in accordance with part 110 of this chapter;

(8)(i) Shall transfer or dispose of the device containing byproduct material only by export as provided by paragraph (c)(7) of this section, by transfer to another general licensee as authorized in paragraph (c)(9) of this section, or to a person authorized to receive the device by a specific license issued under parts 30 and 32 of this chapter, or part 30 of this chapter that authorizes waste collection, or equivalent regulations of an Agreement State, or as otherwise approved under paragraph (c)(8)(iii) of this section.

(ii) Shall, within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the Director, Office of Nuclear Material Safety and Safeguards, ATTN: Document Control Desk/GLTS, using an appropriate method listed in § 30.6(a) of this chapter. The report must contain--

(A) The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

(B) The name, address, and license number of the person receiving the device (license number not applicable if exported); and

(C) The date of the transfer.

(iii) Shall obtain written NRC approval before transferring the device to any other specific licensee not specifically identified in paragraph (c)(8)(i) of this section; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

(A) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(B) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by paragraph (c)(1) of this section) so that the device is labeled in compliance with § 20.1904 of this chapter; however the manufacturer, model number, and serial number must be retained;

(C) Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

(D) Reports the transfer under paragraph (c)(8)(ii) of this section.

(9) Shall transfer the device to another general licensee only if--

(i) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this section, a copy of § 31.2, 30.51, 20.2201, and 20.2202 of this chapter, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Director, Office of Nuclear Material Safety and Safeguards, ATTN: Document Control Desk/GLTS, using an appropriate method listed in § 30.6(a) of this chapter--

(A) The manufacturer's (or initial transferor's) name;

(B) The model number and the serial number of the device transferred;

(C) The transferee's name and mailing address for the location of use; and

(D) The name, title, and phone number of the responsible individual identified by the transferee in accordance with paragraph (c)(12) of this section to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(ii) The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

(10) Shall comply with the provisions of §§ 20.2201, and 20.2202 of this chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of parts 19, 20, and 21, of this chapter.

(11) Shall respond to written requests from the Nuclear Regulatory Commission to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director, Office of Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a) of this chapter, a written justification for the request.

(12) Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

(13)(i) Shall register, in accordance with paragraphs (c)(13)(ii) and (iii) of this section, devices containing at least 370 megabecquerels (10 millicuries) of cesium-137, 3.7 megabecquerels (0.1 millicurie) of strontium-90, 37 megabecquerels (1 millicurie) of cobalt-60, 3.7 megabecquerels (0.1 millicurie) of radium-226, or 37 megabecquerels (1 millicurie) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under paragraph

(c)(13)(iii)(D) of this section, represents a separate general licensee and requires a separate registration and fee.

(ii) If in possession of a device meeting the criteria of paragraph (c)(13)(i) of this section, shall register these devices annually with the Commission and shall pay the fee required by Sec. 170.31 of this chapter. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Commission. The registration information must be submitted to the NRC within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of paragraph (c)(13)(i) of this section is subject to the bankruptcy notification requirement in § 30.34(h) of this chapter.

(iii) In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Commission--

(A) Name and mailing address of the general licensee.

(B) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).

(C) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under paragraph (c)(12) of this section.

(D) Address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage.

(E) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

(F) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(iv) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in paragraph (c)(13)(i) of this section are not subject to registration requirements if the devices are used in areas subject to NRC jurisdiction for a period less than 180 days in any calendar year. The Commission will not request registration information from such licensees.

(14) Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Director, Office of Nuclear Material Safety and Safeguards, ATTN: GLTS, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

(15) May not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph

(c)(2) of this section need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(d) The general license in paragraph (a) of this section does not authorize the manufacture or import of devices containing byproduct material.

[5] Persons possessing byproduct material in devices under a general license in § 31.5 before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of § 31.5 in effect on January 14, 1975.

[39 FR 43532, Dec. 16, 1974, as amended at 40 FR 8785, Mar. 3, 1975; 40 FR 14085, Mar. 28, 1975; 42 FR 25721, May 19, 1977; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 53 FR 19246, May 27, 1988; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993; 64 FR 42275, Aug. 4, 1999; 65 FR 79188, Dec. 18, 2000; 68 FR 58804, Oct. 10, 2003; 72 FR 55926, Oct. 1, 2007; 72 FR 58486, Oct. 16, 2007; 73 FR 5718, Jan. 31, 2008; 73 FR 42673, July 23, 2008; 79 FR 75739, Dec. 19, 2014]

§ 31.6 General license to install devices generally licensed in § 31.5.

Any person who holds a specific license issued by an Agreement State authorizing the holder to manufacture, install, or service a device described in § 31.5 within such Agreement State is hereby granted a general license to install and service such device in any non-Agreement State and a general license to install and service such device in offshore waters, as defined in § 150.3(f) of this chapter: *Provided*, That:

(a) [Reserved]

(b) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the Agreement State.

(c) Such person assures that any labels required to be affixed to the device under regulations of the Agreement State which licensed manufacture of the device bear a statement that removal of the label is prohibited.

[30 FR 8189, June 26, 1965, as amended at 30 FR 10947, Aug. 24, 1965; 39 FR 43533, Dec. 16, 1974; 46 FR 44151, Sept. 3, 1981]

§ 31.7 Luminous safety devices for use in aircraft.

(a) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided each device contains not more than 10 curies of tritium or 300 millicuries of promethium-147 and that each

device has been manufactured, assembled or initially transferred in accordance with a license issued under the provisions of § 32.53 of this chapter or manufactured or assembled in accordance with a specific license issued by an Agreement State which authorizes manufacture or assembly of the device for distribution to persons generally licensed by the Agreement State.

(b) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in this section are exempt from the requirements of parts 19, 20, and 21, of this chapter, except that they shall comply with the provisions of §§ 20.2201, and 20.2202 of this chapter.

(c) This general license does not authorize the manufacture, assembly, repair or import of luminous safety devices containing tritium or promethium-147.

(d) This general license does not authorize the export of luminous safety devices containing tritium or promethium-147.

(e) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

[30 FR 8189, June 26, 1965, as amended at 33 FR 6463, Apr. 27, 1968; 38 FR 22220, Aug. 17, 1973; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993]

§ 31.8 Americium-241 and radium-226 in the form of calibration or reference sources.

(a) A general license is issued to those persons listed in this section to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of paragraphs (b) and (c) of this section, americium-241 or radium-226 in the form of calibration or reference sources:

(1) Any person in a non-Agreement State who holds a specific license issued under this chapter which authorizes receipt, possession, use, and transfer of byproduct material, source material, or special nuclear material; and

(2) Any Government agency, as defined in § 30.4 of this chapter, which holds a specific license issued under this chapter which authorizes it to receive, possess, use, and transfer byproduct material, source material, or special nuclear material.

(b) The general license in paragraph (a) of this section applies only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued under § 32.57 of this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by an Agreement State which authorizes manufacture of the sources for distribution to persons generally licensed by the Agreement State, or in accordance with a specific license issued by a State with comparable provisions to § 32.57.

(c) The general license in paragraph (a) of this section is subject to the provisions of §§30.14(d),

30.34 (a) to (e), and 30.50 to 30.63 of this chapter, and to the provisions of parts 19, 20, and 21, of this chapter. In addition, persons who own, receive, acquire, possess, use, and transfer one or more calibration or reference sources under this general license:

(1) Shall not possess at any one time, at any one location of storage or use, more than 0.185 megabecquerel (5 microcuries) of americium-241 or 0.185 megabecquerel (5 microcuries) of radium-226 in such sources;

(2) Shall not receive, possess, use, or transfer a source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:[1]

> The receipt, possession, use, and transfer of this source, Model XX, Serial No. XX, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.
>
> CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS AMERICIUM–241 [or RADIUM–226, as appropriate]. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.
>
> _____
> (Name of manufacturer or initial transferor)

(3) Shall not transfer, abandon, or dispose of a source except by transfer to a person authorized by a license issued under this chapter or by an Agreement State to receive the source.

(4) Shall store a source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241 or radium-226 which might otherwise escape during storage.

(5) Shall not use a source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(d) This general license does not authorize the manufacture or import of calibration or reference sources containing americium-241 or radium-226.

(e) This general license does not authorize the export of calibration or reference sources containing americium-241 or radium-226.

[30 FR 8189, June 26, 1965, as amended at 38 FR 22220, Aug. 17, 1973; 40 FR 8785, Mar. 3, 1975; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 56 FR 40767, Aug. 16, 1991; 72 FR 55927, Oct. 1, 2007]

[1] Sources generally licensed under this section before January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975. Sources containing radium-226

generally licensed under this section and manufactured before November 30, 2007 shall be labeled in accordance with the applicable State regulations at the time of manufacture or import.

§ 31.9 General license to own byproduct material.

A general license is hereby issued to own byproduct material without regard to quantity. Notwithstanding any other provision of this chapter, a general licensee under this paragraph is not authorized to manufacture, produce, transfer, receive, possess, use, import or export byproduct material, except as authorized in a specific license.

[30 FR 8189, June 26, 1965]

§ 31.10 General license for strontium 90 in ice detection devices.

(a) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium 90 contained in ice detection devices, provided each device contains not more than fifty microcuries of strontium 90 and each device has been manufactured or initially transferred in accordance with the specifications contained in a license issued pursuant to § 32.61 of this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by an Agreement State which authorizes manufacture of the ice detection devices for distribution to persons generally licensed by the Agreement State.

(b) Persons who own, receive, acquire, possess, use, or transfer strontium 90 contained in ice detection devices pursuant to the general license in paragraph (a) of this section:

(1) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license pursuant to part 30 or 32 of this chapter or from an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of § 20.2001.

(2) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon;

(3) Are exempt from the requirements of parts 19, 20, and 21, of this chapter except that such persons shall comply with the provisions of §§ 20.2001, 20.2201, and 20.2202 of this chapter.

(c) The general license does not authorize the manufacture, assembly, disassembly, repair, or import of strontium 90 in ice detection devices.

[30 FR 9905, Aug. 10, 1965, as amended at 38 FR 22220, Aug. 17, 1973; 40 FR 8785, Mar. 3, 1975; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993]

§ 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

(a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:

(1) Iodine-125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(2) Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(3) Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(4) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(5) Iron-59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings, or animals.

(6) Selenium-75, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(7) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(8) Cobalt-57, in units not exceeding 0.37 megabecquerel (10 microcuries) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(b) A person shall not receive, acquire, possess, use, or transfer byproduct material under the general license established by paragraph (a) of this section unless that person:

(1) Has filed NRC Form 483, "Registration Certificate—In Vitro Testing with Byproduct Material Under General License," with the Director, Office of Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a) of this chapter, and has received from the Commission a validated copy of NRC Form 483 with a registration number assigned; or

(2) Has a license that authorizes the medical use of byproduct material that was issued under part 35 of this chapter.

(c) A person who receives, acquires, possesses, or uses byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:

(1) The general licensee shall not possess at any one time, under the general license in paragraph (a) of this section, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, cobalt-57 and/or iron-59 in excess of 7.4 megabecquerels (200 microcuries).

(2) The general licensee shall store the byproduct material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(3) The general licensee shall use the byproduct material only for the uses authorized by paragraph (a) of this section.

(4) The general licensee shall not transfer the byproduct material except by transfer to a person authorized to receive it by a license pursuant to this chapter or from an Agreement State, nor transfer the byproduct material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(5) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in paragraph (a)(7) of this section as required by § 20.2001.

(d) The general licensee shall not receive, acquire, possess, or use byproduct material pursuant to paragraph (a) of this section:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of § 32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State, or before November 30, 2007, and the provisions of a specific license issued by a State with comparable provisions to § 32.71 that authorize manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, cobalt-57, or Mock Iodine-125 for distribution to persons generally licensed by the Agreement State or the State with comparable provisions to § 32.71.

(2) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:[1]

> This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of Manufacturer)

(e) The registrant possessing or using byproduct materials under the general license of paragraph (a) of this section shall report in writing to the Director, Office of Nuclear Material Safety and Safeguards, any changes in the information furnished by him in the "Registration Certificate—In Vitro Testing With Byproduct Material Under General License." Form NRC–483. The report shall be furnished within 30 days after the effective date of such change.

(f) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements of parts 19, 20, and 21, of this chapter with respect to byproduct materials covered by that general license, except that such persons using the Mock Iodine-125 described in paragraph (a)(7) of this section shall comply with the provisions of §§ 20.2001, 20.2201, and 20.2202.

[1] Labels authorized by the regulations in effect on September 26, 1979, may be used until one year from September 27, 1979.

[33 FR 16553, Nov. 14, 1968, as amended at 38 FR 1271, Jan. 11, 1973; 38 FR 34110, Dec. 11, 1973; 39 FR 26147, July 17, 1974; 40 FR 8785, Mar. 3, 1975; 41 FR 16446, Apr. 19, 1976; 42 FR 21604, Apr. 28, 1977; 42 FR 26987, May 26, 1977; 42 FR 28896, June 6, 1977; 44 FR 50325, Aug. 28, 1979; 51 FR 36967, Oct. 16, 1986; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993; 68 FR 58804, Oct. 10, 2003; 72 FR 55927 Oct. 1, 2007; 73 FR 5718, Jan. 31, 2008; 79 FR 75739, Dec. 19, 2014]

§ 31.12 General license for certain items and self-luminous products containing radium-226.

(a) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of paragraphs (b), (c), and (d) of this section, radium-226 contained in the following products manufactured prior to November 30, 2007.

(1) Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(2) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(3) Luminous items installed in air, marine, or land vehicles.

(4) All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

(5) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of

radium-226. For the purposes of this paragraph, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.

(b) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in paragraph (a) of this section are exempt from the provisions of 10 CFR parts 19, 20, and 21, and § 30.50 and 30.51 of this chapter, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this chapter.

(c) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in paragraph (a) of this section:

(1) Shall notify the NRC should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 within 30 days.

(2) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to § 20.2008 of this chapter or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the NRC.

(3) Shall not export products containing radium-226 except in accordance with part 110 of this chapter.

(4) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under part 30 of this chapter, or equivalent regulations of an Agreement State, or as otherwise approved by the NRC.

(5) Shall respond to written requests from the NRC to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director of the Office of Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a) of this chapter, a written justification for the request.

(d) The general license in paragraph (a) of this section does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

[53 FR 19246, May 27, 1988; 72 FR 55927 Oct. 1, 2007; 79 FR 75739, Dec. 19, 2014]

§ 31.13 [Reserved].

[57 FR 55072, Nov. 24, 1992; 72 FR 55927 Oct. 1, 2007]

§ 31.14 [Reserved].

[57 FR 55073, Nov. 24, 1992; 72 FR 55927 Oct. 1, 2007]

§ 31.15 [Reserved].

[72 FR 55927 Oct. 1, 2007]

§ 31.16 [Reserved].

[72 FR 55927 Oct. 1, 2007]

§ 31.17 [Reserved].

[72 FR 55927 Oct. 1, 2007]

§ 31.18 [Reserved].

[72 FR 55927 Oct. 1, 2007]

§ 31.19 [Reserved].

[72 FR 55927 Oct. 1, 2007]

§ 31.20 [Reserved].

[72 FR 55927 Oct. 1, 2007]

§ 31.21 Maintenance of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as letters, stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[72 FR 55927 Oct. 1, 2007]

§ 31.22 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[72 FR 55927 Oct. 1, 2007]

§ 31.23 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 31 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 31 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 31.1, 31.2, 31.4, 31.9, 31.22, and 31.23.

[72 FR 55927 Oct. 1, 2007; 77 FR 43690, Jul. 25, 2012]

CHAPTER 33.1-10-20
SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

Section
33.1-10-20-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 32

33.1-10-20-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 32.

10 Code of Federal Regulations 32.1, 32.2, 32.3, 32.13, 32.17, 32.24, 32.51, 32.51(a), 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.59, 32.61, 32.62, 32.71, 32.72, 32.74, 32.101, 32.102, 32.103, 32.110, 32.201, 32.210, and 32.301 are adopted by reference as they exist on September 8, 2021, with the following exceptions:

1. Not adopted by reference is 10 Code of Federal Regulations 32.1(c)(1).

2. Requirements in 10 Code of Federal Regulations part 32 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", "NRC regional office", or "director of nuclear material safety and safeguards" appear in 10 Code of Federal Regulations part 32, substitute the words "department of environmental quality" except when used in 32.51(a)(3)(iii), 32.54(a), 32.58, 32.71(d), 32.72(b)(5), and 32.74(a)(3).

4. Reporting required in 10 Code of Federal Regulations 32.56(a) shall be submitted to the department of environmental quality as follows:

   a. By mail addressed to: Radiation Control Program, Department of Environmental Quality, 4201 Normandy Street, Second Floor, Bismarck, ND 58503-1324.

   b. By hand delivery to: Radiation Control Program, Department of Environmental Quality, 4201 Normandy Street, Second Floor, Bismarck, ND.

   c. By electronic submission to ram@nd.gov. Electronic submissions must be made in a manner that enables the department of environmental quality to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time.

5. North Dakota state form number 8418, "application for radioactive material license", must be used instead of nuclear regulatory commission form 313 as specified in 10 Code of Federal Regulations part 32.

6. For references to 10 Code of Federal Regulations part 170, see chapter 33.1-10-11 for applicable fee schedules.

History: Effective January 1, 2019; amended effective July 1, 2021.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

PART 32--SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

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32.25 Conditions of licenses issued under § 32.22: Quality control, labeling, and reports of transfer.

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32.27 Same: Safety criteria.

32.28 Same: Table of organ doses.

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32.40 [Removed].

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32.54 Same: Labeling of devices.

32.55 Same: Quality assurance; prohibition of transfer.

32.56 Same: Material transfer reports.

32.57 Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer.

32.58 Same: Labeling of devices.

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32.60 [Reserved]

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32.201 Serialization of nationally tracked sources.

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32.210 Registration of product information.

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32.301 Violations.

32.303 Criminal penalties.

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

Source: 30 FR 8192, June 26, 1965, unless otherwise noted.

[72 FR 55928, Oct. 1, 2007; 72 FR 58488, Oct. 16, 2007]

§ 32.1 Purpose and scope.

(a) This part prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing byproduct material for sale or distribution to:

(1) Persons exempted from the licensing requirements of part 30 of this chapter, or

(2) Persons generally licensed under part 31 or 35 of this chapter.

This part also prescribes certain regulations governing holders of these licenses. In addition, this part prescribes requirements for the issuance of specific licenses to persons who introduce byproduct material into a product or material owned by or in the possession of the licensee or

another and regulations governing holders of such licenses. Further, this part describes procedures and prescribes requirements for the issuance of certificates of registration (covering radiation safety information about a product) to manufacturers or initial transferors of sealed source or devices containing sealed sources which are to be used by persons specifically licensed under part 30 of this chapter or equivalent regulations of an Agreement State.

(b) The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of part 30 of this chapter apply to applications, licenses and certificates of registration subject to this part.

(c)(1) The requirements in this part, including provisions that are specific to licensees, shall apply to Government agencies and Federally recognized Indian Tribes with respect to accelerator-produced radioactive material or discrete sources of radium-226 on November 30, 2007 except that the agency or tribe may continue to manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and to persons generally licensed under part 31 of this chapter, and radioactive drugs and sources and devices to medical use licensees, until the date of the NRC's final licensing determination, provided that the agency or tribe submits a new license application for these activities on or before December 1, 2008 or an amendment application for these activities on or before June 2, 2008.

(2) The requirements in this part, including provisions that are specific to licensees, shall apply to all persons other than those included in paragraph (c)(1) of this section with respect to accelerator-produced radioactive material or discrete sources of radium-226 on August 8, 2009, or earlier as noticed by the NRC, except that these persons may continue to manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and to persons generally licensed under part 31 of this chapter, and to sell or manufacture radioactive drugs and sources and devices to medical use licensees until the date of the NRC's final licensing determination, provided that the person submits a license application within 12 months from the waiver expiration date of August 7, 2009 or within 12 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever is earlier; or that the person submits an amendment request within 6 months from the waiver expiration date of August 7, 2009 or within 6 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

[30 FR 8192, June 26, 1965, as amended at 52 FR 27786, July 24, 1987; 63 FR 1896, Jan. 13, 1998; 72 FR 55928 Oct. 1, 2007]

§ 32.2 Definitions.

As used in this part:

Dose commitment means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it

is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

Lot Tolerance Percent Defective means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

Nationally tracked source is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E to part 20 of this Chapter. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

[34 FR 6653, Apr. 18, 1969, as amended at 39 FR 22129, June 20, 1974; 71 FR 65686, Nov. 8, 2006]

§ 32.3 Maintenance of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy of a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[53 FR 19246, May 27, 1988]

§ 32.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0001.

(b) The approved information collection requirements contained in this part appear in §§ 32.11, 32.12, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.21a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.29, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.61, 32.62, 32.71, 32.72, 32.74, and 32.210.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 32.11, NRC Form 313 is approved under control number 3150-0120.

(2) [Reserved]

[49 FR 19625, May 9, 1984, as amended at 59 FR 61780, Dec. 2, 1994; 62 FR 52186, Oct. 6 1997; 62 FR 63640, Dec. 2, 1997; 72 FR 58486, Oct. 16, 2007]

Subpart A--Exempt Concentrations and Items

§ 32.11 Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license.

An application for a specific license on Form NRC-313 authorizing the introduction of byproduct material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material containing the byproduct material will be approved if the applicant:

(a) Satisfies the general requirements specified in § 30.33 of this chapter; *provided, however*, that the requirements of § 30.33(a)(2) and (3) do not apply to an application for a license to introduce byproduct material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material containing the byproduct material, if the possession and use of the byproduct material to be introduced is authorized by a license issued by an Agreement State;

(b) Provides a description of the product or material into which the byproduct material will be introduced, intended use of the byproduct material and the product or material into which it is introduced, method of introduction, initial concentration of the byproduct material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioisotopes in the product or material at the time of transfer; and

(c) Provides reasonable assurance that the concentrations of byproduct material at the time of transfer will not exceed the concentrations in § 30.70 of this chapter, that reconcentration of the byproduct material in concentrations exceeding those in § 30.70 is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

[30 FR 8192, June 26, 1965, as amended at 49 FR 19625, May 9, 1984; 72 FR 58487, Oct. 16, 2007]

§ 32.12 Same: Records and material transfer reports.

(a) Each person licensed under § 32.11 shall maintain records of transfer of byproduct material and file a report with the Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the byproduct material is transferred for use under § 30.14 of this chapter or equivalent regulations of an Agreement State.

(b) The report must identify the:

(1) Type and quantity of each product or material into which byproduct material has been introduced during the reporting period;

(2) Name and address of the person who owned or possessed the product or material, into which byproduct material has been introduced, at the time of introduction;

(3) The type and quantity of radionuclide introduced into each product or material; and

(4) The initial concentrations of the radionuclide in the product or material at time of transfer of the byproduct material by the licensee.

(c)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission or to an Agreement State.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.11 shall file a report for the current calendar year within 30 days after ceasing distribution.

(d) If no transfers of byproduct material have been made under § 32.11 during the reporting period, the report must so indicate.

(e) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

[48 FR 12333, Mar. 24, 1983; 48 FR 14863, Apr. 6, 1983; 68 FR 58804, Oct. 10, 2003; 72 FR 58487, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, July 23, 2008]

§ 32.13 Same: Prohibition of introduction.

No person may introduce byproduct material into a product or material knowing or having

reason to believe that it will be transferred to persons exempt under § 30.14 of this chapter or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.11.

[30 FR 8192, June 26, 1965; 72 FR 58487, Oct. 16, 2007]

§ 32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer.

An application for a specific license to apply byproduct material to, or to incorporate byproduct material into, the products specified in § 30.15 of this chapter or to initially transfer for sale or distribution such products containing byproduct material for use pursuant to § 30.15 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding the product pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of byproduct material in each product;

(2) Details of construction and design of each product;

(3) The method of containment or binding of the byproduct material in the product;

(4) Procedures for and results of prototype testing to demonstrate that the material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product;

(5) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet;

(6) The proposed method of labeling or marking each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product;

(7) For products for which limits on levels of radiation are specified in § 30.15 of this chapter, the radiation level and the method of measurement;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the product.

(c) Each product will contain no more than the quantity of byproduct material specified for that product in § 30.15 of this chapter. The levels of radiation from each product containing byproduct material will not exceed the limits specified for that product in § 30.15 of this chapter.

(d) The Commission determines that the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

[31 FR 5316, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 43 FR 6922, Feb. 17, 1978; 63 FR 32971, June 17, 1998; 72 FR 58487, Oct. 16, 2007]

§ 32.15 Same: Quality assurance, prohibition of transfer, and labeling.

(a) Each person licensed under § 32.14 shall:

(1) Maintain quality assurance practices in the manufacture of the part or product, or the installation of the part into the product;

(2) Subject inspection lots to such testing as may be required as a condition of the license issued under § 32.14 taking a random sample of the size required by the tables in § 32.110, and for Lot Tolerance Percent Defective of 5.0 percent, accept or reject inspection lots in accordance with the directions of § 32.110; and

(3) Visually inspect each unit, except electron tubes containing byproduct material, in inspection lots. Any unit which has an observable physical defect that could affect containment of the byproduct material shall be considered as a defective unit.

(b) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (a)(2) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that the operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(c) No person licensed under § 32.14 shall transfer to other persons for use under § 30.15 of this chapter or equivalent regulations of an Agreement State:

(1) Any part or product which has been tested and found defective under the criteria and procedures specified in the license issued under § 32.14, unless the defective units have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under § 32.14; or

(2) Any inspection lot which has been rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (b) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under § 32.14.

(d) Each person licensed under § 32.14 for products for which quality control procedures are required shall:

(1) Label or mark each unit, except timepieces or hands or dials containing tritium or

promethium-147, and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified.

(2) For ionization chamber smoke detectors, label or mark each detector and its point-of-sale package so that:

(i) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:

(A) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(B) The name of the radionuclide ("americium-241" or "Am-241") and the quantity of activity; and

(C) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) of this chapter or equivalent regulations of an Agreement State.

(ii) The labeling or marking specified in paragraph (d)(2)(i) of this section is located where it will be readily visible when the detector is removed from its mounting.

(iii) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(A) The name of the radionuclide and quantity of activity;

(B) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) or equivalent regulations of an Agreement State; and

(C) The following or a substantially similar statement: "THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS."

(iv) Each detector and point-of-sale package is provided with such other information as may be required by the Commission.

[31 FR 5317, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 39 FR 22129, June 20, 1974; 43 FR 6922, Feb. 17, 1978; 72 FR 58487, Oct. 16, 2007; 73 FR 42673, July 23, 2008; 86 FR 43397, Aug. 9, 2021; 86 FR 47209, Aug 24, 2021 (corrected version)]

§ 32.16 Certain items containing byproduct material: Records and reports of transfer.

(a) Each person licensed under § 32.14 shall maintain records of all transfers of byproduct material and file a report with the Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under § 30.15 of this chapter, giving the specific paragraph designation, or equivalent regulations of an Agreement State.

(b) The report must include the following information on products transferred to other persons for use under § 30.15 or equivalent regulations of an Agreement State:

(1) A description or identification of the type of each product and the model number(s), if applicable;

(2) For each radionuclide in each type of product and each model number, if applicable, the total quantity of the radionuclide; and

(3) The number of units of each type of product transferred during the reporting period by model number, if applicable.

(c)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.14 shall file a report for the current calendar year within 30 days after ceasing distribution.

(d) If no transfers of byproduct material have been made under § 32.14 during the reporting period, the report must so indicate.

(e) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

[48 FR 12333, Mar. 24, 1983; 48 FR 23383, May 25, 1983; 68 FR 58804, Oct. 10, 2003; 72 FR 58487, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, Jul. 23, 2008]

§ 32.17 [Removed].

[32 FR 4241, Mar. 18, 1967, as amended by 38 FR 29314, Oct. 24, 1973; 43 FR 6922, Feb. 17, 1978; 72 FR 58488, Oct. 16, 2007]

§ 32.18 Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license.

An application for a specific license to manufacture, process, produce, package, repackage, or transfer quantities of byproduct material for commercial distribution to persons exempt pursuant to § 30.18 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however,* That the requirements of § 30.33(a) (2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(b) The byproduct material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(c) The byproduct material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(d) The applicant submits copies of prototype labels and brochures and the Commission approves such labels and brochures.

[35 FR 6428, Apr. 22, 1970, as amended at 43 FR 6922, Feb. 17, 1978]

§ 32.19 Same: Conditions of licenses.

Each license issued under § 32.18 is subject to the following conditions:

(a) No more than 10 exempt quantities set forth in § 30.71, Schedule B of this chapter shall be sold or transferred in any single transaction. For purposes of this requirement, an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in § 30.71, Schedule B of this chapter, provided that the sum of such fractions shall not exceed unity.

(b) Each quantity of byproduct material set forth in § 30.71, Schedule B of this chapter shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to § 30.18 of this chapter. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

(c) The immediate container of each quantity or separately packaged fractional quantity of byproduct material shall bear a durable, legible label which (1) identifies the radioisotope and the quantity of radioactivity, and (2) bears the words "Radioactive Material."

(d) In addition to the labeling information required by paragraph (c) of this section, the label affixed to the immediate container, or an accompanying brochure, shall also (1) state that the contents are exempt from NRC or Agreement State licensing requirements; (2) bear the words "Radioactive Material--Not for Human Use--Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited -- Exempt Quantities Should Not be Combined"; and (3) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the

radioactive material.

[35 FR 6428, Apr. 22, 1970]

§ 32.20 Same: Records and material transfer reports.

(a) Each person licensed under § 32.18 shall maintain records of transfer of material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.18 of this chapter or the equivalent regulations of an Agreement State and stating the kinds, quantities, and physical form of byproduct material transferred.

(b) The licensee shall file a summary report with the Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the materials are transferred for use under § 30.18 or equivalent regulations of an Agreement State.

(c) For each radionuclide in each physical form, the report shall indicate the total quantity of each radionuclide and the physical form, transferred under the specific license.

(d)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include the total quantity of each radionuclide transferred for transfers in prior years not previously reported to the Commission.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.18 shall file a report for the current calendar year within 30 days after ceasing distribution.

(e) If no transfers of byproduct material have been made under § 32.18 during the reporting period, the report must so indicate.

(f) The licensee shall maintain the record of a transfer for one year after the transfer is included in a summary report to the Commission.

[48 FR 12333, Mar. 24, 1983; 68 FR 58804, Oct. 10, 2003; 72 FR 58488, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, Jul. 23, 2008]

§ 32.21 Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea each for "in vivo" diagnostic use for humans to persons exempt from licensing; Requirements for a license.

(a) An application for a specific license to manufacture, prepare, process, produce, package,

repackage, or transfer for commercial distribution capsules containing 37 kBq (1 μCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for "in vivo" diagnostic use, to persons exempt from licensing under § 30.21 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter, provided that the requirements of § 30.33(a)(2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, prepared, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(2) The applicant meets the requirements under § 32.72(a)(2) of this part;

(3) The applicant provides evidence that each capsule contains 37 kBq (1 μCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process);

(4) The carbon-14 urea is not contained in any food, beverage, cosmetic, drug (except as described in this section) or other commodity designed for ingestion or inhalation by, or topical application to, a human being;

(5) The carbon-14 urea is in the form of a capsule, identified as radioactive, and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(6) The applicant submits copies of prototype labels and brochures and the NRC approves these labels and brochures.

(b) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing drugs.

[62 FR 63640, Dec. 2, 1997, as amended at 66 FR 64738, Dec. 14, 2001]

§ 32.21a Same: Conditions of license.

Each license issued under § 32.21 of this part is subject to the following conditions:

(a) The immediate container of the capsule(s) must bear a durable, legible label which:

(1) Identifies the radioisotope, the physical and chemical form, the quantity of radioactivity of each capsule at a specific date; and

(2) Bears the words "Radioactive Material."

(b) In addition to the labeling information required by paragraph (a) of this section, the label affixed to the immediate container, or an accompanying brochure also must:

(1) State that the contents are exempt from NRC or Agreement State licensing requirements; and

(2) Bears the words "Radioactive Material. For "In Vivo" Diagnostic Use Only. This Material Is Not To Be Used for Research Involving Human Subjects and Must Not Be Introduced into Foods, Beverages, Cosmetics, or Other Drugs or Medicinals, or into Products Manufactured for Commercial Distribution. This Material May Be Disposed of in Ordinary Trash."

[62 FR 63640, Dec. 2, 1997]

§ 32.22 Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer.

(a) An application for a specific license to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to initially transfer such products for use pursuant to § 30.19 of this chapter or equivalent regulations of an Agreement State, will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however*, That the requirements of § 30.33(a) (2) and (3) do not apply to an application for a license to transfer tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, or produced pursuant to a license issued by an Agreement State.

(2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the self-luminous product to demonstrate that the product will meet the safety criteria set forth in § 32.23. The information should include:

(i) A description of the product and its intended use or uses.

(ii) The type and quantity of byproduct material in each unit.

(iii) Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product.

(iv) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (a)(2) (iii) and (xii) of this section.

(v) Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product.

(vi) Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement.

(vii) Degree of access of human beings to the product during normal handling and use.

(viii) Total quantity of byproduct material expected to be distributed in the product annually.

(ix) The expected useful life of the product.

(x) The proposed method of labeling or marking each unit with identification of the manufacturer or initial transferor of the product and the byproduct material in the product.

(xi) Procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product.

(xii) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

(xiii) The estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.23 and the basis for such estimates.

(xiv) A determination that the probabilities with respect to the doses referred to in § 32.23(d) meet the criteria of that paragraph.

(xv) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.

(xvi) Any additional information, including experimental studies and tests, required by the Commission.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Commission may deny an application for a specific license under this section if the end uses of the product cannot be reasonably foreseen.

[34 FR 9026, June 6, 1969, as amended at 43 FR 6923, Feb. 17, 1978]

§ 32.23 Same: Safety criteria.

An applicant for a license under § 32.22 shall demonstrate that the product is designed and will be manufactured so that:

(a) In normal use and disposal of a single exempt unit, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column I of the table in § 32.24 of this part.

(b) In normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the

intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column II of the table in § 32.24.

(c) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

(d)[1] In use and disposal of a single exempt unit, or in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in § 32.24, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in § 32.24.

Negligible--not more than one such failure per year for each 1 million exempt units distributed.

[34 FR 9027, June 6, 1969]

[1] It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used as guides in estimating compliance with the criteria:

Low--not more than one such failure per year for each 10,000 exempt units distributed.

§ 32.24 Same: Table of organ doses.

Part of body	Column 1 (rem)	Column II (rem)	Column III (rem)	Column IV (rem)
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.001	0.01	0.5	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.015	0.15	7.5	200
Other organs	0.003	0.03	1.5	50

[34 FR 9329, June 13, 1969]

§ 32.25 Conditions of licenses issued under § 32.22: Quality control, labeling, and reports of transfer.

Each person licensed under § 32.22 shall:

(a) Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the Commission;

(b) Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the product and the byproduct material in the product can be identified; and

(c) Maintain records of all transfers and file a report with the Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under § 30.19 of this chapter or equivalent regulations of an Agreement State.

(3) The report must include the following information on products transferred to other persons for use under § 30.19 or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product and the model number(s);

(ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide;

(iii) The number of units of each type of product transferred during the reporting period by model number.

(4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.22 shall file a report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of byproduct material have been made under § 32.22 during the reporting period, the report must so indicate.

(6) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

[34 FR 9027, June 6, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 48 FR 12334, Mar. 24, 1983; 68 FR 58804, Oct. 10, 2003; 72 FR 58488, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, Jul. 23, 2008]

§ 32.26 Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.

An application for a specific license to manufacture, process, or produce gas and aerosol detectors containing byproduct material and designed to protect life or property from fires and airborne hazards, or to initially transfer such products for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State, will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however*, That the requirements of § 30.33(a) (2) and (3) do not apply to an application for a license to transfer byproduct material in gas and aerosol detectors manufactured, processed or produced pursuant to a license issued by an Agreement State.

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the gas and aerosol detector to demonstrate that the product will meet the safety criteria set forth in § 32.27. The information should include:

(1) A description of the product and its intended use or uses;

(2) The type and quantity of byproduct material in each unit;

(3) Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product;

(4) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (b) (3) and (12) of this section;

(5) Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product;

(6) Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement;

(7) Degree of access of human beings to the product during normal handling and use;

(8) Total quantity of byproduct material expected to be distributed in the product annually;

(9) The expected useful life of the product;

(10) The proposed methods of labeling or marking the detector and its point-of-sale package to satisfy the requirements of § 32.29(b);

(11) Procedures for prototype testing of the product to demonstrate the effectiveness of the

containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product;

(12) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features;

(13) The estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.27 and the basis for such estimates;

(14) A determination that the probabilities with respect to the doses referred to in § 32.27(c) meet the criteria of that paragraph;

(15) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet; and

(16) Any additional information, including experimental studies and tests, required by the Commission.

[34 FR 6653, Apr. 18, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 45 FR 38342, June 9, 1980]

§ 32.27 Same: Safety criteria.

An applicant for a license under § 32.26 shall demonstrate that the product is designed and will be manufactured so that:

(a) In normal use and disposal of a single exempt unit, and in normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column I of the table in § 32.28.

(b) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

(c) In use and disposal of a single exempt unit and in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the table in § 32.28, and the probability is negligible that a person

would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in § 32.28.[1]

[34 FR 6654, Apr. 18, 1969]

[1] It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used as guides in estimating compliance with the criteria:

Low--not more than one such failure per year for each 10,000 exempt units distributed.

Negligible--not more than one such failure per year for each one million exempt units distributed.

§ 32.28 Same: Table of organ doses

Part of body	Column 1 (rem)	Column II (rem)	Column III (rem)
Whole body; head and trunk: active blood-forming organs; gonads; or lens of eye	0.005	0.5	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.075	7.5	200
Other organs	0.015	1.5	50

[34 FR 6654, Apr. 18, 1969]

§ 32.29 Conditions of licenses issued under § 32.26: Quality control, labeling, and reports of transfer.

Each person licensed under § 32.26 shall:

(a) Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the Commission;

(b) Label or mark each detector and its point-of-sale package so that:

(1) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:

(i) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(ii) The name of the radionuclide and quantity of activity; and

(iii) An identification of the person licensed under § 32.26 to transfer the detector for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State.

(2) The labeling or marking specified in paragraph (b)(1) of this section is located where its will be readily visible when the detector is removed from its mounting.

(3) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(i) The name of the radionuclide and quantity of activity;

(ii) An identification of the person licensed under § 32.26 to transfer the detector for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State; and

(iii) The following or a substantially similar statement:

THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.

(4) Each detector and point-of-sale package is provided with such other information as may be required by the Commission; and

(c) Maintain records of all transfers and file a report with the Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under § 30.20 of this chapter or equivalent regulations of an Agreement State.

(3) The report must include the following information on products transferred to other persons for use under § 30.20 or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product and the model number(s);

(ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide;

(iii) The number of units of each type of product transferred during the reporting period by model number.

(4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.26 shall file a report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of byproduct material have been made under § 32.26 during the reporting period, the report must so indicate.

(6) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

[34 FR 6654, Apr. 18, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 45 FR 38342, June 9, 1980; 48 FR 12334, Mar. 24, 1983; 72 FR 58488, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, July 23, 2008]

§ 32.40 [Removed].

[30 FR 8192, June 26, 1965, as amended at 31 FR 5317, Apr. 2, 1966; 43 FR 6923, Feb. 17, 1978; 72 FR 58489, Oct. 16, 2007]

Subpart B--Generally Licensed Items

§ 32.51 Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer.

(a) An application for a specific license to manufacture, or initially transfer devices containing byproduct material to persons generally licensed under § 31.5 of this chapter or equivalent regulations of an Agreement State will be approved if:

(1) The applicant satisfies the general requirements of § 30.33 of this chapter;

(2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(i) The device can be safely operated by persons not having training in radiological protection;

(ii) Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in 1 year a dose in excess of 10 percent of the annual limits specified in § 20.1201(a) of this chapter; and

(iii) Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose

commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in § 32.24.

(3) Each device bears a durable, legible, clearly visible label or labels approved by the Commission which contain in a clearly identified and separate statement:

(i) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(ii) The requirements, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(iii) The information called for in the following statement in the same or substantially similar form:[1]

The receipt, possession, use, and transfer of this device Model_____,[2] Serial No. _____,[2] are subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION--RADIOACTIVE MATERIAL

_____

(Name of manufacturer, or initial transferor)[2]

(4) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in § 20.1901 of this chapter, and the name of the manufacturer or initial distributor.

(5) Each device meeting the criteria of § 31.5(c)(13)(i) of this chapter, bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in § 20.1901 of this chapter.

(6) The device has been registered in the Sealed Source and Device Registry.

(b) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in this application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, and by design features which have a significant bearing on the

probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Commission will consider information which includes, but is not limited to:

(1) Primary containment (source capsule);

(2) Protection of primary containment;

(3) Method of sealing containment;

(4) Containment construction materials;

(5) Form of contained radioactive material;

(6) Maximum temperature withstood during prototype tests;

(7) Maximum pressure withstood during prototype tests;

(8) Maximum quantity of contained radioactive material;

(9) Radiotoxicity of contained radioactive material; and

(10) Operating experience with identical devices or similarly designed and constructed devices.

(c) In the event the applicant desires that the general licensee under § 31.5 of this chapter, or under equivalent regulations of an Agreement State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and the bases for these estimates. The submitted information must demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the annual limits specified in § 20.1201(a) of this chapter.

[39 FR 43533, Dec. 16, 1974, as amended at 40 FR 8785, Mar. 3, 1975; 42 FR 25721, May 19, 1977; 43 FR 6923, Feb. 17, 1978; 58 FR 67660, Dec. 22, 1993; 59 FR 5520, Feb. 7, 1994; 65 FR 79189, Dec. 18, 2000]

[1] Devices licensed under § 32.51 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

[2] The model, serial number, and the name of the manufacturer, or initial transferor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the

device.

§ 32.51a Same: Conditions of licenses.

(a) If a device containing byproduct material is to be transferred for use under the general license contained in § 31.5 of this chapter, each person that is licensed under § 32.51 shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes--

(1) A copy of the general license contained in § 31.5 of this chapter; if paragraphs (c)(2) through (4) or (c)(13) of § 31.5 do not apply to the particular device, those paragraphs may be omitted.

(2) A copy of §§ 31.2, 30.51, 20.2201, and 20.2202 of this chapter;

(3) A list of the services that can only be performed by a specific licensee;

(4) Information on acceptable disposal options including estimated costs of disposal; and

(5) An indication that NRC's policy is to issue high civil penalties for improper disposal.

(b) If byproduct material is to be transferred in a device for use under an equivalent general license of an Agreement State, each person that is licensed under § 32.51 shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes--

(1) A copy of the Agreement State's regulations equivalent to §§ 31.5, 31.2, 30.51, 20.2201, and 20.2202 of this chapter or a copy of §§ 31.5, 31.2, 30.51, 20.2201, and 20.2202 of this chapter. If a copy of the NRC regulations is provided to a prospective general licensee in lieu of the Agreement State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

(2) A list of the services that can only be performed by a specific licensee;

(3) Information on acceptable disposal options including estimated costs of disposal; and

(4) The name or title, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained.

(c) An alternative approach to informing customers may be proposed by the licensee for approval by the Commission.

(d) Each device that is transferred after February 19, 2002 must meet the labeling requirements in § 32.51(a)(3) through (5).

(e) If a notification of bankruptcy has been made under § 30.34(h) or the license is to be terminated, each person licensed under § 32.51 shall provide, upon request, to the NRC and to any appropriate Agreement State, records of final disposition required under § 32.52(c).

[65 FR 79189, Dec. 18, 2000; 65 FR 80991, Dec. 22, 2000]

§ 32.52 Same: Material transfer reports and records.

Each person licensed under § 32.51 to initially transfer devices to generally licensed persons shall comply with the requirements of this section.

(a) The person shall report to the Director, Office of Nuclear Material Safety and Safeguards, ATTN: GLTS, by an appropriate method listed in § 30.6(a) of this chapter, all transfers of such devices to persons for use under the general license in § 31.5 of this chapter and all receipts of devices from persons licensed under § 31.5 of this chapter. The report must be submitted on a quarterly basis on NRC Form 653—"Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

(1) The required information for transfers to general licensees includes—

(i) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(ii) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(iii) The date of transfer;

(iv) The type, model number, and serial number of the device transferred; and

(v) The quantity and type of byproduct material contained in the device.

(2) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(3) For devices received from a § 31.5 general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(4) If the licensee makes changes to a device possessed by a § 31.5 general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(5) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(6) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(7) If no transfers have been made to or from persons generally licensed under § 31.5 of this chapter during the reporting period, the report must so indicate.

(b) The person shall report all transfers of devices to persons for use under a general license in an Agreement State's regulations that are equivalent to § 31.5 of this chapter and all receipts of devices from general licensees in the Agreement State's jurisdiction to the responsible Agreement State agency. The report must be submitted on Form 653--``Transfers of Industrial Devices Report'' or in a clear and legible report containing all of the data required by the form.

(1) The required information for transfers to general licensees includes--

(i) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(ii) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(iii) The date of transfer;

(iv) The type, model number, and serial number of the device transferred; and

(v) The quantity and type of byproduct material contained in the device.

(2) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(3) For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(4) If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the

device, and the changes to information on the device label.

(5) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(6) The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

(7) If no transfers have been made to or from a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency.

(c) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this paragraph must be maintained for a period of 3 years following the date of the recorded event.

[65 FR 79189, Dec. 18, 2000; 68 FR 58805, Oct. 10, 2003; 73 FR 5719, Jan. 31, 2008]

§ 32.53 Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer.

An application for a specific license to manufacture, assemble, repair or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under § 31.7 of this chapter, will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of tritium or promethium-147 in each device;

(2) Details of construction and design;

(3) Details of the method of binding or containing the tritium or promethium-147;

(4) Procedures for and results of prototype testing to demonstrate that the tritium or promethium-147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;

(5) Quality assurance procedures to be followed that are sufficient to ensure compliance with § 32.55;

(6) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the device.

(c) Each device will contain no more than 10 curies of tritium or 300 millicuries of promethium-147. The levels of radiation from each device containing promethium-147 will not exceed 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber.

(d) The Commission determines that:

(1) The method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(2) The tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact by any person with it;

(3) The device is so designed that it cannot easily be disassembled; and

(4) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by paragraph (e) of this section.

(e) The applicant shall subject at least five prototypes of the device to tests as follows:

(1) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

(2) The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (e)(3) of this section.

(3) Device designs are rejected for which the following has been detected for any unit:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device; or

(ii) Surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(iii) Any other evidence of physical damage.

(f) The device has been registered in the Sealed Source and Device Registry.

[30 FR 8192, June 26, 1965, as amended at 33 FR 6463, Apr. 27, 1968; 43 FR 6923, Feb. 17, 1978; 77 FR 43693 Jul. 25, 2102]

§ 32.54 Same: Labeling of devices.

(a) A person licensed under § 32.53 to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under § 31.7 of this chapter shall, except as provided in paragraph (b) of this section, affix to each device a label containing the radiation symbol prescribed by § 20.1901 of this chapter, such other information as may be required by the Commission including disposal instructions when appropriate, and the following or a substantially similar statement which contains the information called for in the following statement:[1]

The receipt, possession, use, and transfer of this device, Model* _____, Serial No.* ___, containing _____ (Identity and quantity of radioactive material) are subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION--RADIOACTIVE MATERIAL

_____
(Name of manufacturer, assembler, or initial transferor.)*

*The model, serial number, and name of manufacturer, assembler, or initial transferor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

(b) If the Commission determines that it is not feasible to affix a label to the device containing all the information called for in paragraph (a) of this section, it may waive the requirements of that paragraph and require in lieu thereof that:

(1) A label be affixed to the device identifying:

(i) The manufacturer, assembler, or initial transferor; and

(ii) The type of radioactive material; and

(2) A leaflet bearing the following information be enclosed in or accompany the container in which the device is shipped:

(i) The name of the manufacturer, assembler, or initial transferor,

(ii) The type and quantity of radioactive material,

(iii) The model number,

(iv) A statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the regulations of the U.S. NRC or of an Agreement State, and

(v) Such other information as may be required by the Commission, including disposal instructions when appropriate.

[33 FR 16331, Nov. 7, 1968, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6923, Feb. 17, 1978; 63 FR 39483, July 23, 1998]

[1] Devices licensed under § 32.53 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

§ 32.55 Same: Quality assurance; prohibition of transfer.

(a) Each person licensed under § 32.53 shall visually inspect each device and shall reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147.

(b) Each person licensed under § 32.53 shall:

(1) Maintain quality assurance systems in the manufacture of the luminous safety device in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph (c) of this section and in the license issued under § 32.53, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

(c) The licensee shall subject each inspection lot to:

(1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion.

(2) Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following criteria for defective:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device;

(ii) Levels of radiation in excess of 5 microgray (0.5 millirad) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, if the device contains promethium-147; and

(iii) Any other criteria specified in the license issued under § 32.53.

(d) No person licensed under § 32.53 shall transfer to persons generally licensed under § 31.7 of

this chapter, or under an equivalent general license of an Agreement State:

(1) Any luminous safety device tested and found defective under any condition of a license issued under § 32.53, or paragraph (b) of this section, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) Any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (b)(2) of this section, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.53; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (b)(2) and (d)(2)(i) of this section and any other criteria that may be required as a condition of the license issued under § 32.53.

[30 FR 8192, June 26, 1965, as amended at 39 FR 22129, June 20, 1974; 39 FR 26397, July 19, 1974; 77 FR 43693, Jul. 25, 2012]

§ 32.56 Same: Material transfer reports.

(a) Each person licensed under § 32.53 shall file an annual report with the Director, Office of Nuclear Material Safety and Safeguards, ATTN: Document Control Desk/GLTS, by an appropriate method listed in § 30.6(a) of this chapter, which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under § 31.7 of this chapter. The report must identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report must cover the year ending June 30 and must be filed within thirty (30) days thereafter. If no transfers have been made to persons generally licensed under § 31.7 of this chapter during the reporting period, the report must so indicate.

(b) Each person licensed under § 32.53 shall report annually all transfers of devices to persons for use under a general license in an Agreement State's regulations that are equivalent to § 31.7 of this chapter to the responsible Agreement State agency. The report must state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. If no transfers have been made to a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State agency upon request of the agency.

[60 FR 3737, Jan. 19, 1995; 68 FR 58805, Oct. 10, 2003; 73 FR 5719, Jan. 31, 2008; 77 FR 43694, Jul. 25, 2012; 79 FR 75739, Dec. 19, 2014]

§ 32.57 Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if:

(a) The applicant satisfies the general requirements of § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of americium 241 or radium-226 in the source;

(2) Details of construction and design;

(3) Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

(4) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

(5) Details of quality control procedures to be followed in manufacture of the source;

(6) Description of labeling to be affixed to the source or the storage container for the source;

(7) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.

(c) Each source will contain no more than 5 microcuries of americium-241 or radium-226.

(d) The Commission determines, with respect to any type of source containing more than 0.005 microcurie of americium-241 or radium-226, that:

(1) The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(2) The source has been subjected to and has satisfactorily passed appropriate tests required by paragraph (e) of this section.

(e) The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to tests as follows:

(1) The initial quantity of radioactive material deposited on each source is measured by direct

counting of the source.

(2) The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion.

(3) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (e)(4) of this section.

(4) Source designs are rejected for which the following has been detected for any unit: removal of more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

[30 FR 8192, June 26, 1965, as amended at 43 FR 6923, Feb. 17, 19781; 72 FR 55928, Oct. 1, 2007; 73 FR 42674, July 23, 2008; 77 FR 43694, Jul. 25, 2012]

§ 32.58 Same: Labeling of devices.

Each person licensed under § 32.57 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:[1]

The receipt, possession, use, and transfer of this source, Model , Serial No., are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION-RADIOACTIVE MATERIAL–THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or initial transferor

[30 FR 8192, June 26, 1965, as amended at 40 FR 8786, Mar. 3, 1975; 43 FR 6923, Feb. 17, 1978; 72 FR 55929 Oct. 1, 2007]

[1] Sources licensed under § 32.57 before January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

§ 32.59 Same: Leak testing of each source.

Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before

transferring the source to a general licensee under § 31.8 of this chapter or under equivalent regulations of an Agreement State. This test must be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper must be measured using methods capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 by the methods described in this section, the source must be rejected and must not be transferred to a general licensee under § 31.8 of this chapter, or equivalent regulations of an Agreement State.

[30 FR 8192, June 26, 1965; 72 FR 55929 Oct. 1, 2007; 77 FR 43694, Jul. 25, 2012]

§ 32.60 [Reserved]

§ 32.61 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under § 31.10 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of strontium-90 in the device;

(2) Details of construction and design of the source of radiation and its shielding;

(3) Radiation profile of a prototype device;

(4) Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;

(5) Details of quality control procedures to be followed in manufacture of the device;

(6) Description of labeling to be affixed to the device;

(7) Instructions for handling and installation of the device;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the device;

(c) Each device will contain no more than 50 microcuries of strontium-90 in an insoluble form;

(d) Each device will bear durable, legible labeling which includes the radiation caution symbol prescribed by § 20.1901(a) of this chapter, a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices;

(e) The Commission determines that:

(1) The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(2) The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem in a year under ordinary circumstances of use;

(3) The device is so designed that it cannot be easily disassembled;

(4) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by paragraph (f) of this section.

(5) Quality control procedures have been established to satisfy the requirements of § 32.62.

(f) The applicant shall subject at least five prototypes of the device to tests as follows:

(1) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

(2) The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (f)(3) of this section.

(3) Device designs are rejected for which the following has been detected for any unit:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device; or

(ii) Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(iii) Any other evidence of physical damage.

(g) The device has been registered in the Sealed Source and Device Registry.

[30 FR 9905, Aug. 10, 1965, as amended at 43 FR 6923, Feb. 17, 1978; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993; 77 FR 43694, Jul. 25, 2012]

§ 32.62 Same: Quality assurance; prohibition of transfer.

(a) Each person licensed under § 32.61 shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.

(b) Each person licensed under § 32.61 shall test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

(c) Each person licensed under § 32.61 shall:

(1) Maintain quality assurance systems in the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph (d) of this section and in the license issued under § 32.61, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

(d) Each person licensed under § 32.61 shall subject each inspection lot to:

(1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as absolute pressure and water immersion.

(2) Inspection for evidence of physical damage, containment failure, or for loss of strontium-90 after each stage of testing, using methods of inspection adequate to determine compliance with the following criteria for defective: a leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device and any other criteria specified in the license issued under § 32.61.

(e) No person licensed under § 32.61 shall transfer to persons generally licensed under § 31.10 of this chapter, or under an equivalent general license of an Agreement State:

(1) Any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under § 32.61, unless the defective ice detection device has been repaired or reworked, retested, and determined by an independent inspector to meet the

applicable acceptance criteria; or

(2) Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (c)(2) of this section, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.61; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (c)(2) and (e)(2)(i) of this section and any other criteria as may be required as a condition of the license issued under § 32.61.

[30 FR 9905, Aug. 10, 1965, as amended at 39 FR 22130, June 20, 1974; 39 FR 26397, July 19, 1974; 43 FR 6923, Feb. 17, 1978; 77 FR 43694, Jul. 25, 2012]

§ 32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license.

An application for a specific license to manufacturer or distribute byproduct material for use under the general license of § 31.11 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter.

(b) The byproduct material is to be prepared for distribution in prepackaged units of:

(1) Iodine-125 in units not exceeding 10 microcuries each.

(2) Iodine-131 in units not exceeding 10 microcuries each.

(3) Carbon-14 in units not exceeding 10 microcuries each.

(4) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each.

(5) Iron-59 in units not exceeding 20 microcuries each.

(6) Selenium-75 in units not exceeding 10 microcuries each.

(7) Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(8) Cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) each.

(c) Each prepackaged unit bears a durable, clearly visible label:

(1) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 0.37 megabecquerel (10 microcuries) of iodine-131,

iodine-125, selenium-75, or carbon-14; 1.85 megabecquerels (50 microcuries) of hydrogen-3 (tritium); or 0.74 megabecquerel (20 microcuries) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 0.185 kilobecquerel (0.005 microcurie) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and

(2) Displaying the radiation caution symbol described in § 20.1901(a) of this chapter and the words, "Caution, Radioactive Material", and "Not for Internal or External Use in Humans or Animals."

(d) The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:[1]

The radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
(Name of Manufacturer)

(e) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such byproduct material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in § 20.2001

[33 FR 16553, Nov. 14, 1968, as amended at 38 FR 34110, Dec. 11, 1973; 39 FR 26148, July 17, 1974; 40 FR 8786, Mar. 3, 1975; 42 FR 21604, Apr. 28, 1977; 42 FR 26987, May 26, 1977; 44 FR 50325, Aug. 28, 1979; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993; 72 FR 55929 Oct. 1, 2007]

[1] Labels authorized by the regulations in effect on September 26, 1979, may be used until one year from September 27, 1979.

Subpart C—Specially Licensed Items

§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing byproduct material for use by persons authorized

pursuant to part 35 of this chapter will be approved if:

(1) The applicant satisfies the general requirements specified in 10 CFR 30.33;

(2) The applicant submits evidence that the applicant is at least one of the following:

(i) Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

(ii) Registered or licensed with a state agency as a drug manufacturer;

(iii) Licensed as a pharmacy by a State Board of Pharmacy;

(iv) Operating as a nuclear pharmacy within a Federal medical institution; or

(v) A Positron Emission Tomography (PET) drug production facility registered with a State agency.

(3) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(4) The applicant commits to the following labeling requirements:

(i) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

(ii) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(b) A licensee described by paragraph (a)(2)(iii) or (iv) of this section:

(1) May prepare radioactive drugs for medical use, as defined in 10 CFR 35.2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraph (b)(2) and (b)(4) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR 35.27.

(2) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(i) This individual qualifies as an authorized nuclear pharmacist as defined in 10 CFR 35.2,

(ii) This individual meets the requirements specified in § 35.55(b) and 35.59 of this chapter, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (b)(4) of this section.

(3) The actions authorized in paragraphs (b)(1) and (b)(2) of this section are permitted in spite of more restrictive language in license conditions.

(4) May designate a pharmacist (as defined in § 35.2 of this chapter) as an authorized nuclear pharmacist if:

(i) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

(ii) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

(5) Shall provide to the Commission:

(i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in § 35.55(a) of this chapter; or

(ii) The Commission or Agreement State license, or

(iii) Commission master materials licensee permit, or

(iv) The permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or

(v) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

(vi) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear

pharmacist.

(c) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

(d) A licensee shall satisfy the labeling requirements in paragraph (a)(4) of this section.

(e) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

[59 FR 61780, Dec. 2, 1994; 59 FR 65244, Dec. 19, 1994, as amended at 60 FR 324, Jan. 4, 1995; 67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002; 67 FR 77652, Dec. 19, 2002; 71 FR 15007, Mar. 27, 2006; 72 FR 45150, Aug. 13, 2007; 72 FR 55929 Oct. 1, 2007; 77 FR 43695, Jul. 25, 2012; 83 FR 33046, Jul. 16, 2018]

§ 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed under part 35 of this chapter for use as a calibration, transmission, or reference source or for the uses listed in §§ 35.400, 35.500, 35.600, and 35.1000 of this chapter will be approved if:

(1) The applicant satisfies the general requirements in § 30.33 of this chapter;

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) The byproduct material contained, its chemical and physical form, and amount;

(ii) Details of design and construction of the source or device;

(iii) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(iv) For devices containing byproduct material, the radiation profile of a prototype device;

(v) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

(vi) Procedures and standards for calibrating sources and devices;

(vii) Legend and methods for labeling sources and devices as to their radioactive content;

(viii) Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device: Provided, That instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device) to persons licensed to use byproduct material identified in §§ 35.65, 35.400, 35.500, and 35.600 as appropriate, and to persons who hold an equivalent license issued by an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

(4) The source or device has been registered in the Sealed Source and Device Registry.

(b)(1) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(2) In determining the acceptable interval for test of leakage of radioactive material, the Commission will consider information that includes, but is not limited to:

(i) Primary containment (source capsule);

(ii) Protection of primary containment;

(iii) Method of sealing containment;

(iv) Containment construction materials;

(v) Form of contained radioactive material;

(vi) Maximum temperature withstood during prototype tests;

(vii) Maximum pressure withstood during prototype tests;

(viii) Maximum quantity of contained radioactive material;

(ix) Radiotoxicity of contained radioactive material;

(x) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(c) If an application is filed pursuant to paragraph (a) of this section on or before October 15, 1974, for a license to manufacture and distribute a source or device that was distributed commercially on or before August 16, 1974, the applicant may continue the distribution of such source or device to group licensees until the Commission issues the license or notifies the applicant otherwise.

[39 FR 26149, July 17, 1974, as amended at 51 FR 36967, Oct. 16, 1986; 62 FR 59276, Nov. 3, 1997; 67 FR 20370, Apr. 24, 2002; 71 FR 15008, Mar. 27, 2006; 72 FR 45150, Aug. 13, 2007; 77 FR 43695, Jul. 25, 2012]

Subpart D—Sealed Source and Device Registration

§ 32.201 Serialization of nationally tracked sources.

Each licensee who manufactures a nationally tracked source after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

[71 FR 65686, Nov. 8, 2006; 77 FR 43695, Jul. 25, 2012]

Subpart D--Specifically Licensed Items

§ 32.210 Registration of product information.

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to NRC for evaluation of radiation safety information about its product and for its registration.

(b) The request for review must be sent to the NRC's Office of Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a) of this chapter.

(c) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(d) The NRC normally evaluates a sealed source or a device using radiation safety criteria in

accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The NRC shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

(e) After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.

(f) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with--

(1) The statements and representations, including quality control program, contained in the request; and

(2) The provisions of the registration certificate.

[52 FR 27786, July 24, 1987, as amended at 60 FR 24551, May 9, 1995; 68 FR 58805, Oct. 10, 2003; 73 FR 5719, Jan. 31, 2008]

Subpart E--Violations

§ 32.301 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i)

of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55073, Nov. 24, 1992]

§ 32.303 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 32 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 32 that are not issued under subsections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 32.1, 32.2, 32.8, 32.11, 32.14, 32.18, 32.22, 32.23, 32.24, 32.26, 32.27, 32.28, 32.51, 32.53, 32.57, 32.61, 32.71, 32.74, 32.301, and 32.303.

[57 FR 55073, Nov. 24, 1992, as amended at 59 FR 61781, Dec. 2, 1994; 73 FR 42674, July 23, 2008]

CHAPTER 33.1-10-22
PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

Section
33.1-10-22-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 37

33.1-10-22-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 37.

10 Code of Federal Regulations 37.1, 37.3, 37.5, 37.11, 37.21, 37.23, 37.25, 37.27, 37.29, 37.31, 37.33, 37.41, 37.43, 37.45, 37.47, 37.49, 37.51, 37.53, 37.55, 37.57, 37.71, 37.73, 37.75, 37.77, 37.79, 37.81, 37.101, 37.103, 37.105, and appendix A to part 37 are adopted by reference as they exist on December 30, 2021, with the following exceptions:

1. Not adopted by reference is 10 Code of Federal Regulations (CFR) 37.11(b) and 37.43(d)(9).

2. All of the requirements in chapter 33.1-10-22 apply to both licensees and registrants. A reference in 10 CFR part 37 to "license" includes "registration", a reference to "licensee" includes "registrant", a reference to "licensed" includes "registered", a reference to "licensed material(s)" includes "registered source of radiation" and a reference to "licensed radioactive material" includes "registered source of radiation". "Registrant" means any person who is registered with the department and is legally obligated to register with the department pursuant to article 33.1-10 and North Dakota Century Code chapter 23.1-03. "Registration" means the notification of the department of environmental quality of possession of a source of radiation and the furnishing of information with respect thereto, in accordance with North Dakota Century Code chapter 23.1-02.

3. Where the word "NRC" appears in 10 CFR 37.31(d), 37.43(c)(3)(iii), 37.57(a), 37.57(c), 37.77 [with the exception of "the NRC's Web site" in 37.77(a)(1)], and 37.81(g), substitute the words "department of environmental quality".

4. Where the word "Commission" appears in 10 CFR 37.5 (definitions of "byproduct material" and "person"), 37.11(a), 37.43(a)(3), 37.43(c)(1)(ii), 37.101, 37.103, and 37.105, substitute the words "department of environmental quality".

5. Where the words "NRC regional office" appear in 10 CFR 37.41(a)(3) and 37.81, substitute the words "department of environmental quality".

6. Where the words "appropriate NRC regional office listed in § 30.6(a)(2) of this chapter" appear in 10 CFR 37.45(b), substitute the words "department of environmental quality".

7. Where the words "NRC's Operational Center (301-816-5100)" appear in 10 CFR 37.57(a), 37.57(b), and 37.81, substitute the words "department of environmental quality".

8. Where the words "NRC's Operational Center" appear in 10 CFR 37.81, substitute the words "department of environmental quality".

9. Where the words "NRC's Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001. The notification to the NRC may be made by email to RAMQC_SHIPMENTS@nrc.gov or by fax to 301-

816-5151" appear in 10 CFR 37.77(a)(1), substitute the words "department of environmental quality".

10. Where the words "NRC's Director of Nuclear Security, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001" appear in 10 CFR 37.77(c)(1), substitute the words "department of environmental quality".

11. Where the words "NRC's Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001" appear in 10 CFR 37.77(c)(2) and 37.77(d), substitute the words "department of environmental quality".

12. Where the words "Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001" appear in 10 CFR 37.81(g), substitute the words "department of environmental quality".

13. Requirements in 10 CFR part 37 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

14. "Act" includes North Dakota Century Code chapters 23.1-02 and 23.1-03.

History: Effective January 1, 2019; amended effective July 1, 2021.
General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-03-03, 23.1-03-04; S.L. 2017, ch. 199, § 18

PART 37—PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2

QUANTITIES OF RADIOACTIVE MATERIAL

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37.79 Requirements for physical protection of category 1 and category 2 quantities of radioactive material during shipment.

37.81 Reporting of events.

Subpart E—[Reserved]

Subpart F—Records

37.101 Form of records.

37.103 Record retention.

Subpart G—Enforcement

37.105 Inspections.

37.107 Violations.

37.109 Criminal penalties.

Appendix A to Part 37—Category 1 and Category 2 Radioactive Materials

Authority:

Atomic Energy Act of 1954, secs. 11, 53, 81, 103, 104, 147, 148, 149, 161, 182, 183, 223, 234, 274 (42 U.S.C. 2014, 2073, 2111, 2133, 2134, 2167, 2168, 2169, 2201, 2232, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

[78 FR 17007, Mar. 19, 2013; 80 FR 54234, Sep. 9, 2015]

Subpart A--General Provisions

§ 37.1 Purpose.

This part has been established to provide the requirements for the physical protection program for any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material listed in Appendix A to this part. These requirements provide reasonable assurance of the security of category 1 or category 2 quantities of radioactive material by protecting these materials from theft or diversion. Specific requirements for access to material, use of material, transfer of material, and transport of material are included. No provision of this part authorizes possession of licensed material.

[78 FR 17007, Mar. 19, 2013]

§ 37.3 Scope.

(a) Subparts B and C of this part apply to any person who, under the regulations in this chapter, possesses or uses at any site, an aggregated category 1 or category 2 quantity of radioactive material.

(b) Subpart D of this part applies to any person who, under the regulations of this chapter:

(1) Transports or delivers to a carrier for transport in a single shipment, a category 1 or category 2 quantity of radioactive material; or

(2) Imports or exports a category 1 or category 2 quantity of radioactive material; the provisions only apply to the domestic portion of the transport.

[78 FR 17007, Mar. 19, 2013]

§ 37.5 Definitions.

As used in this part:

Access control means a system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

Act means the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto.

Aggregated means accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a category 2 quantity of radioactive material.

Agreement State means any state with which the Atomic Energy Commission or the U.S. Nuclear Regulatory Commission has entered into an effective agreement under subsection 274b. of the Act. *Non-agreement State* means any other State.

*Approved individua*l means an individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with subpart B of this part and who has completed the training required by § 37.43(c).

Background investigation means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

Becquerel (Bq) means one disintegration per second.

Byproduct material means—

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(4) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

Carrier means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

Category 1 quantity of radioactive material means a quantity of radioactive material meeting or exceeding the category 1 threshold in Table 1 of Appendix A to this part. This is determined by calculating the ratio of the total activity of each radionuclide to the category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

Category 2 quantity of radioactive material means a quantity of radioactive material meeting or exceeding the category 2 threshold but less than the category 1 threshold in Table 1 of Appendix A to this part. This is determined by calculating the ratio of the total activity of each radionuclide to the category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

Commission means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

Curie means that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second.

Diversion means the unauthorized movement of radioactive material subject to this part to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.

Escorted access means accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.

Fingerprint orders means the orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by Agreement States that require fingerprints and criminal history records checks for individuals with unescorted access to category 1 and category 2 quantities of radioactive material or safeguards information-modified handling.

Government agency means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

License, except where otherwise specified, means a license for byproduct material issued pursuant to the regulations in parts 30 through 36 and 39 of this chapter;

License issuing authority means the licensing agency that issued the license, i.e. the U.S. Nuclear Regulatory Commission or the appropriate agency of an Agreement State;

Local law enforcement agency (LLEA) means a public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the

licensed category 1 or category 2 quantity of radioactive material is used, stored, or transported.

Lost or missing licensed material means licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

Mobile device means a piece of equipment containing licensed radioactive material that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting; or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

Movement control center means an operations center that is remote from transport activity and that maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.

No-later-than arrival time means the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival time may not be more than 6 hours after the estimated arrival time for shipments of category 2 quantities of radioactive material.

Person means—

(1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the DOE (except that the Department shall be considered a person within the meaning of the regulations in 10 CFR chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission under section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act of 1982 (96 Stat. 2201), and section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and

(2) Any legal successor, representative, agent, or agency of the foregoing.

Reviewing official means the individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the category 1 or category 2 quantities of radioactive materials that are possessed by the licensee.

Sabotage means deliberate damage, with malevolent intent, to a category 1 or category 2 quantity of radioactive material, a device that contains a category 1 or category 2 quantity of radioactive material, or the components of the security system.

Safe haven means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law enforcement authorities.

Security zone means any temporary or permanent area determined and established by the licensee for the physical protection of category 1 or category 2 quantities of radioactive material.

State means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Telemetric position monitoring system means a data transfer system that captures information by instrumentation and/or measuring devices about the location and status of a transport vehicle or package between the departure and destination locations.

Trustworthiness and reliability are characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to category 1 or category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

Unescorted access means solitary access to an aggregated category 1 or category 2 quantity of radioactive material or the devices that contain the material.

United States, when used in a geographical sense, includes Puerto Rico and all territories and possessions of the United States.

[78 FR 17007, Mar. 19, 2013]

§ 37.7 Communications.

Except where otherwise specified or covered under the regional licensing program as provided in § 30.6(b) of this chapter, all communications and reports concerning the regulations in this part may be sent as follows:

(a) By mail addressed to: ATTN: Document Control Desk; Director, Office of Nuclear Reactor Regulation; or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001;

(b) By hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland 20852;

(c) Where practicable, by electronic submission, for example, Electronic Information Exchange, or CD–ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html*; by email to *MSHD.Resource@nrc.gov*; or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information.

[78 FR 17009, Mar. 19, 2013; 79 FR 75739. Dec. 19, 2014; 83 FR 57231, Nov. 21, 2018; 84 FR 65639, Nov. 29, 2019; 84 FR 66561, Dec. 5, 2019]

§ 37.9 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretations of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized as binding upon the Commission.

[78 FR 17009, Mar. 19, 2013]

§ 37.11 Specific exemptions.

(a) The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security, and are otherwise in the public interest.

(b) Any licensee's NRC-licensed activities are exempt from the requirements of subparts B and C of this part to the extent that its activities are included in a security plan required by part 73 of this chapter.

(c) A licensee that possesses radioactive waste that contains category 1 or category 2 quantities of radioactive material is exempt from the requirements of subparts B, C, and D of this part. Except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of this part. The licensee shall implement the following requirements to secure the radioactive waste:

(1) Use continuous physical barriers that allow access to the radioactive waste only through established access control points;

(2) Use a locked door or gate with monitored alarm at the access control point;

(3) Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and

(4) Immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains category 1 or category 2 quantities of radioactive material.

[78 FR 17009, Mar. 19, 2013]

§ 37.13 Information collection requirements: OMB approval.

(a) The U.S. Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB has approved the information collection requirements contained in this part under control number 3150–0214.

(b) The approved information collection requirements contained in this part appear in §§ 37.11, 37.21, 37.23, 37.25, 37.27, 37.29, 37.31, 37.33, 37.41, 37.43, 37.45, 37.49, 37.51, 37.55, 37.57, 37.71, 37.75, 37.77, 37.79, and 37.81.

[78 FR 17009, Mar. 19, 2013]

Subpart B—Background Investigations and Access Control Program

§ 37.21 Personnel access authorization requirements for category 1 or category 2 quantities of radioactive material.

(a) *General.* (1) Each licensee that possesses an aggregated quantity of radioactive material at or above the category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements of this subpart.

(2) An applicant for a new license and each licensee that would become newly subject to the requirements of this subpart upon application for modification of its license shall implement the requirements of this subpart, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(3) Any licensee that has not previously implemented the Security Orders or been subject to the provisions of this subpart B shall implement the provisions of this subpart B before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(b) *General performance objective.* The licensee's access authorization program must ensure that the individuals specified in paragraph (c)(1) of this section are trustworthy and reliable.

(c) *Applicability.* (1) Licensees shall subject the following individuals to an access authorization program:

(i) Any individual whose assigned duties require unescorted access to category 1 or category 2 quantities of radioactive material or to any device that contains the radioactive material; and

(ii) Reviewing officials.

(2) Licensees need not subject the categories of individuals listed in § 37.29(a)(1) through (13) to the investigation elements of the access authorization program.

(3) Licensees shall approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material.

(4) Licensees may include individuals needing access to safeguards information-modified handling under part 73 of this chapter in the access authorization program under this subpart B.

[78 FR 17010, Mar. 19, 2013]

§ 37.23 Access authorization program requirements.

(a) *Granting unescorted access authorization.* (1) Licensees shall implement the requirements of this subpart for granting initial or reinstated unescorted access authorization.

(2) Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by § 37.43(c) before being allowed unescorted access to category 1 or category 2 quantities of radioactive material.

(b) *Reviewing officials.* (1) Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.

(2) Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Provide oath or affirmation certifications to the Manager, Radiation Control Program. The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with § 37.25(c).

(3) Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive materials or access to safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling.

(4) Reviewing officials cannot approve other individuals to act as reviewing officials.

(5) A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(i) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(ii) The individual is subject to a category listed in § 37.29(a).

(c) *Informed consent.* (1) Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of § 37.25(b). A signed consent must be obtained prior to any reinvestigation.

(2) The subject individual may withdraw his or her consent at any time. Licensees shall inform the individual that:

(i) If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his or her consent; and

(ii) The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

(d) *Personal history disclosure.* Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by this subpart is sufficient cause for denial or termination of unescorted access.

(e) *Determination basis.* (1) The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all of the information collected to meet the requirements of this subpart.

(2) The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all of the information collected to meet the requirements of this subpart and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.

(3) The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

(4) The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access authorization.

(5) Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall remove the person from the approved list as soon as possible, but no later than 7 working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

(f) *Procedures.* Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures must include provisions for the notification of individuals who are denied unescorted access. The procedures must include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures must contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

(g) *Right to correct and complete information.* (1) Prior to any final adverse determination, licensees shall provide each individual subject to this subpart with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation.

Confirmation of receipt by the individual of this notification must be maintained by the licensee for a period of 1 year from the date of the notification.

(2) If, after reviewing his or her criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D–2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data, and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. Licensees must provide at least 10 days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his or her review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

(h) *Records.* (1) The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

(2) The licensee shall retain a copy of the current access authorization program procedures as a record for 3 years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for 3 years after the record is superseded.

(3) The licensee shall retain the list of persons approved for unescorted access authorization for 3 years after the list is superseded or replaced.

[78 FR 17010, Mar. 19, 2013; 80 FR 45843, Aug. 3, 2015; 83 FR 30285, Jun. 28, 2018; 84 FR 63565, Nov. 18, 2019]

§ 37.25 Background investigations.

(a) *Initial investigation.* Before allowing an individual unescorted access to category 1 or category 2 quantities of radioactive material or to the devices that contain the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the 7 years preceding the date of the background investigation or since the individual's eighteenth birthday, whichever is shorter. The background investigation must include at a minimum:

(1) Fingerprinting and an FBI identification and criminal history records check in accordance with § 37.27;

(2) Verification of true identity. Licensees shall verify the true identity of the individual who is

applying for unescorted access authorization to ensure that the applicant is who he or she claims to be. A licensee shall review official identification documents (e.g., driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information. Licensees shall document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with § 37.31. Licensees shall certify in writing that the identification was properly reviewed, and shall maintain the certification and all related documents for review upon inspection;

(3) Employment history verification. Licensees shall complete an employment history verification, including military history. Licensees shall verify the individual's employment with each previous employer for the most recent 7 years before the date of application;

(4) Verification of education. Licensees shall verify that the individual participated in the education process during the claimed period;

(5) Character and reputation determination. Licensees shall complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this subpart must be limited to whether the individual has been and continues to be trustworthy and reliable;

(6) The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual (e.g., seek references not supplied by the individual); and

(7) If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at least after 10 business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation; and attempt to obtain the information from an alternate source.

(b) *Grandfathering.* (1) Individuals who have been determined to be trustworthy and reliable for unescorted access to category 1 or category 2 quantities of radioactive material under the Fingerprint Orders may continue to have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement.

(2) Individuals who have been determined to be trustworthy and reliable under the provisions of part 73 of this chapter or the security orders for access to safeguards information, safeguards information-modified handling, or risk-significant material may have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. The licensee shall document that the individual was determined to be trustworthy and reliable under the provisions of part 73 of this chapter or a security order. Security order, in this context, refers to any order that was issued by the NRC that required fingerprints and an FBI criminal history records check for access to safeguards information, safeguards information-modified handling,

or risk significant material such as special nuclear material or large quantities of uranium hexafluoride. These individuals shall be subject to the reinvestigation requirement.

(c) *Reinvestigations.* Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with § 37.27. The reinvestigations must be completed within 10 years of the date on which these elements were last completed.

[78 FR 17011, Mar. 19, 2013]

§ 37.27 Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material.

(a) *General performance objective and requirements.* (1) Except for those individuals listed in § 37.29 and those individuals grandfathered under § 37.25(b), each licensee subject to the provisions of this subpart shall fingerprint each individual who is to be permitted unescorted access to category 1 or category 2 quantities of radioactive material. Licensees shall transmit all collected fingerprints to the Commission for transmission to the FBI. The licensee shall use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to category 1 or category 2 quantities of radioactive materials for that individual.

(2) The licensee shall notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record, and shall inform him or her of the procedures for revising the record or adding explanations to the record.

(3) Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to category 1 or category 2 quantities of radioactive materials if:

(i) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his or her unescorted access authorization; and

(ii) The previous access was terminated under favorable conditions.

(4) Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted under this subpart, the Fingerprint Orders, or part 73 of this chapter. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of § 37.31(c).

(5) Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

(b) *Prohibitions.* (1) Licensees may not base a final determination to deny an individual

unescorted access authorization to category 1 or category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

(i) An arrest more than 1 year old for which there is no information of the disposition of the case; or

(ii) An arrest that resulted in dismissal of the charge or an acquittal.

(2) Licensees may not use information received from a criminal history records check obtained under this subpart in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

(c) *Procedures for processing of fingerprint checks.* (1) For the purposes of complying with this subpart, licensees shall use an appropriate method listed in § 37.7 to submit to the U.S. Nuclear Regulatory Commission, Director, Division of Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-07D04M, Rockville, MD 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at https://www.nrc.gov/security/chp.html.

(2) Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the Division of Physical and Cyber Security Policy by e-mailing Crimhist.Resource@nrc.gov.) Combined payment for multiple applications is acceptable. The Commission publishes the amount of the fingerprint check application fee on the NRC's public Web site. (To find the current fee amount, go to the Licensee Criminal History Records Checks & Firearms Background Check information page at https://www.nrc.gov/security/chp.html and see the link for How do I determine how much to pay for the request?).

(3) The Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

[78 FR 17012, Mar. 19, 2013; 84 FR 63565, Nov. 18, 2019; 86 FR 43397, Aug. 9, 2021; 86 FR 47209, Aug. 24, 2021 (corrected version)]

§ 37.29 Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials.

(a) Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to category 1 or category 2 quantities of radioactive materials:

(1) An employee of the Commission or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(2) A Member of Congress;

(3) An employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(4) The Governor of a State or his or her designated State employee representative;

(5) Federal, State, or local law enforcement personnel;

(6) State Radiation Control Program Directors and State Homeland Security Advisors or their designated State employee representatives;

(7) Agreement State employees conducting security inspections on behalf of the NRC under an agreement executed under section 274.i. of the Atomic Energy Act;

(8) Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;

(9) Emergency response personnel who are responding to an emergency;

(10) Commercial vehicle drivers for road shipments of category 1 and category 2 quantities of radioactive material;

(11) Package handlers at transportation facilities such as freight terminals and railroad yards;

(12) Any individual who has an active Federal security clearance, provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that granted the Federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material; and

(13) Any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to category 1 or category 2 quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee shall retain the documentation for a period of 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

(b) Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last 5 years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this

documentation for a period of 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material. These programs include, but are not limited to:

(1) National Agency Check;

(2) Transportation Worker Identification Credentials (TWIC) under 49 CFR part 1572;

(3) Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR part 555;

(4) Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR part 73;

(5) Hazardous Material security threat assessment for hazardous material endorsement to commercial drivers license under 49 CFR part 1572; and

(6) Customs and Border Protection's Free and Secure Trade (FAST) Program.

[78 FR 17013, Mar. 19, 2013; 79 FR 58671, Sept. 30, 2014]

§ 37.31 Protection of information.

(a) Each licensee who obtains background information on an individual under this subpart shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

(b) The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his or her representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

(c) The personal information obtained on an individual from a background investigation may be provided to another licensee:

(1) Upon the individual's written request to the licensee holding the data to disseminate the information contained in his or her file; and

(2) The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

(d) The licensee shall make background investigation records obtained under this subpart available for examination by an authorized representative of the NRC to determine compliance with the regulations and laws.

(e) The licensee shall retain all fingerprint and criminal history records (including data indicating

no record) received from the FBI, or a copy of these records if the individual's file has been transferred, on an individual for 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

[78 FR 17013, Mar. 19, 2013]

§ 37.33 Access authorization program review.

(a) Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of this subpart and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. Each licensee shall periodically (at least annually) review the access program content and implementation.

(b) The results of the reviews, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the access authorization program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(c) Review records must be maintained for 3 years.

[78 FR 17013, Mar. 19, 2013]

Subpart C—Physical Protection Requirements During Use

§ 37.41 Security program.

(a) *Applicability.* (1) Each licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this subpart.

(2) An applicant for a new license and each licensee that would become newly subject to the requirements of this subpart upon application for modification of its license shall implement the requirements of this subpart, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(3) Any licensee that has not previously implemented the Security Orders or been subject to the provisions of subpart C shall provide written notification to the NRC regional office specified in § 30.6 of this chapter at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(b) *General performance objective.* Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material.

(c) *Program features.* Each licensee's security program must include the program features, as appropriate, described in §§ 37.43, 37.45, 37.47, 37.49, 37.51, 37.53, and 37.55.

[78 FR 17014, Mar. 19, 2013]

§ 37.43 General security program requirements.

(a) *Security plan.* (1) Each licensee identified in § 37.41(a) shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this subpart. The security plan must, at a minimum:

(i) Describe the measures and strategies used to implement the requirements of this subpart; and

(ii) Identify the security resources, equipment, and technology used to satisfy the requirements of this subpart.

(2) The security plan must be reviewed and approved by the individual with overall responsibility for the security program.

(3) A licensee shall revise its security plan as necessary to ensure the effective implementation of Commission requirements. The licensee shall ensure that:

(i) The revision has been reviewed and approved by the individual with overall responsibility for the security program; and

(ii) The affected individuals are instructed on the revised plan before the changes are implemented.

(4) The licensee shall retain a copy of the current security plan as a record for 3 years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for 3 years after the record is superseded.

(b) *Implementing procedures.* (1) The licensee shall develop and maintain written procedures that document how the requirements of this subpart and the security plan will be met.

(2) The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall responsibility for the security program.

(3) The licensee shall retain a copy of the current procedure as a record for 3 years after the procedure is no longer needed. Superseded portions of the procedure must be retained for 3 years after the record is superseded.

(c) *Training.* (1) Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include instruction in:

(i) The licensee's security program and procedures to secure category 1 or category 2 quantities

of radioactive material, and in the purposes and functions of the security measures employed;

(ii) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of Commission requirements;

(iii) The responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material; and

(iv) The appropriate response to security alarms.

(2) In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of category 1 or category 2 quantities of radioactive material. The extent of the training must be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material.

(3) Refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training must include:

(i) Review of the training requirements of paragraph (c) of this section and any changes made to the security program since the last training;

(ii) Reports on any relevant security issues, problems, and lessons learned;

(iii) Relevant results of NRC inspections; and

(iv) Relevant results of the licensee's program review and testing and maintenance.

(4) The licensee shall maintain records of the initial and refresher training for 3 years from the date of the training. The training records must include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

(d) *Protection of information.* (1) Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

(2) Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

(3) Before granting an individual access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access, licensees shall:

(i) Evaluate an individual's need to know the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access; and

(ii) If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in § 37.25(a)(2) through (a)(7).

(4) Licensees need not subject the following individuals to the background investigation elements for protection of information:

(i) The categories of individuals listed in § 37.29(a)(1) through (13); or

(ii) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in § 37.25(a)(2) through (a)(7), has been provided by the security service provider.

(5) The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

(6) Licensees shall maintain a list of persons currently approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access, or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than 7 working days, and take prompt measures to ensure that the individual is unable to obtain the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

(7) When not in use, the licensee shall store its security plan, implementing procedures, and the list of individuals that have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

(8) The licensee shall retain as a record for 3 years after the document is no longer needed:

(i) A copy of the information protection procedures; and

(ii) The list of individuals approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

[78 FR 17014, Mar. 19, 2013; 79 FR 58671, Sept. 30, 2014; 83 FR 30285, Jun. 28, 2018]

§ 37.45 LLEA coordination.

(a) A licensee subject to this subpart shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:

(1) A description of the facilities and the category 1 and category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with this subpart; and

(2) A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material.

(b) The licensee shall notify the appropriate NRC regional office listed in § 30.6(b)(2) of this chapter within 3 business days if:

(1) The LLEA has not responded to the request for coordination within 60 days of the coordination request; or

(2) The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

(c) The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for 3 years.

(d) The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

[78 FR 17015, Mar. 19, 2013; 83 FR 30285, Jun. 28, 2018]

§ 37.47 Security zones.

(a) Licensees shall ensure that all aggregated category 1 and category 2 quantities of radioactive material are used or stored within licensee established security zones. Security zones may be permanent or temporary.

(b) Temporary security zones must be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

(c) Security zones must, at a minimum, allow unescorted access only to approved individuals through:

(1) Isolation of category 1 and category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the category 1 or category 2 quantities of radioactive material within a security zone; or

(2) Direct control of the security zone by approved individuals at all times; or

(3) A combination of continuous physical barriers and direct control.

(d) For category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

(e) Individuals not approved for unescorted access to category 1 or category 2 quantities of radioactive material must be escorted by an approved individual when in a security zone.

[78 FR 17015, Mar. 19, 2013]

§ 37.49 Monitoring, detection, and assessment.

(a) *Monitoring and detection.* (1) Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

(2) Monitoring and detection must be performed by:

(i) A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; or

(ii) Electronic devices for intrusion detection alarms that will alert nearby facility personnel; or

(iii) A monitored video surveillance system; or

(iv) Direct visual surveillance by approved individuals located within the security zone; or

(v) Direct visual surveillance by a licensee designated individual located outside the security zone.

(3) A licensee subject to this subpart shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:

(i) For category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability must be provided by:

(A) Electronic sensors linked to an alarm; or

(B) Continuous monitored video surveillance; or

(C) Direct visual surveillance.

(ii) For category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

(b) *Assessment.* Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

(c) *Personnel communications and data transmission.* For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessment systems, licensees shall:

(1) Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

(2) Provide an alternative communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmission systems may not be subject to the same failure modes as the primary systems.

(d) *Response.* Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

[78 FR 17015, Mar. 19, 2013]

§ 37.51 Maintenance and testing.

(a) Each licensee subject to this subpart shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this part must be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no suggested manufacturer's suggested frequency, the testing must be performed at least annually, not to exceed 12 months.

(b) The licensee shall maintain records on the maintenance and testing activities for 3 years.

[78 FR 17016, Mar. 19, 2013]

§ 37.53 Requirements for mobile devices.

Each licensee that possesses mobile devices containing category 1 or category 2 quantities of radioactive material must:

(a) Have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and

(b) For devices in or on a vehicle or trailer, unless the health and safety requirements for a site

prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

[78 FR 17016, Mar. 19, 2013]

§ 37.55 Security program review.

(a) Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of this subpart and that comprehensive actions are taken to correct any noncompliance that is identified. The review must include the radioactive material security program content and implementation. Each licensee shall periodically (at least annually) review the security program content and implementation.

(b) The results of the review, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the security program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(c) The licensee shall maintain the review documentation for 3 years.

[78 FR 17016, Mar. 19, 2013]

§ 37.57 Reporting of events.

(a) The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the NRC's Operations Center (301–816–5100). In no case shall the notification to the NRC be later than 4 hours after the discovery of any attempted or actual theft, sabotage, or diversion.

(b) The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than 4 hours after notifying the LLEA, the licensee shall notify the NRC's Operations Center (301–816–5100).

(c) The initial telephonic notification required by paragraph (a) of this section must be followed within a period of 30 days by a written report submitted to the NRC by an appropriate method listed in § 37.7. The report must include sufficient information for NRC analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

[78 FR 17016, Mar. 19, 2013]

Subpart D—Physical Protection in Transit

§ 37.71 Additional requirements for transfer of category 1 and category 2 quantities of radioactive material.

A licensee transferring a category 1 or category 2 quantity of radioactive material to a licensee of the Commission or an Agreement State shall meet the license verification provisions listed below instead of those listed in § 30.41(d) of this chapter:

(a) Any licensee transferring category 1 quantities of radioactive material to a licensee of the Commission or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(b) Any licensee transferring category 2 quantities of radioactive material to a licensee of the Commission or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(c) In an emergency where the licensee cannot reach the license issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification must include the license number, current revision number, issuing agency, expiration date, and for a category 1 shipment the authorized address. The licensee shall keep a copy of the certification. The certification must be confirmed by use of the NRC's license verification system or by contacting the license issuing authority by the end of the next business day.

(d) The transferor shall keep a copy of the verification documentation as a record for 3 years.

[78 FR 17016, Mar. 19, 2013]

§ 37.73 Applicability of physical protection of category 1 and category 2 quantities of radioactive material during transit.

(a) For shipments of category 1 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in §§ 37.75(a) and (e); 37.77; 37.79(a)(1), (b)(1), and (c); and 37.81(a), (c), (e), (g) and (h).

(b) For shipments of category 2 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in §§ 37.75(b) through (e); 37.79(a)(2), (a)(3), (b)(2), and (c); and 37.81(b), (d), (f), (g), and (h). For those shipments of category 2 quantities of radioactive material that meet the criteria of § 71.97(b) of this chapter, the shipping licensee shall also comply with the advance notification provisions of § 71.97 of

this chapter.

(c) The shipping licensee shall be responsible for meeting the requirements of this subpart unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under this subpart.

(d) Each licensee that imports or exports category 1 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in §§ 37.75(a)(2) and (e); 37.77; 37.79(a)(1), (b)(1), and (c); and 37.81(a), (c), (e), (g), and (h) for the domestic portion of the shipment.

(e) Each licensee that imports or exports category 2 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in §§ 37.79(a)(2), (a)(3), and (b)(2); and 37.81(b), (d), (f), (g), and (h) for the domestic portion of the shipment.

[78 FR 17017, Mar. 19, 2013]

§ 37.75 Preplanning and coordination of shipment of category 1 or category 2 quantities of radioactive material.

(a) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

(1) Preplan and coordinate shipment arrival and departure times with the receiving licensee;

(2) Preplan and coordinate shipment information with the governor or the governor's designee of any State through which the shipment will pass to:

(i) Discuss the State's intention to provide law enforcement escorts; and

(ii) Identify safe havens; and

(3) Document the preplanning and coordination activities.

(b) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

(c) Each licensee who receives a shipment of a category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

(d) Each licensee, who transports or plans to transport a shipment of a category 2 quantity of radioactive material, and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to paragraph (b) of this section, shall promptly notify the receiving licensee of the new no-later-than arrival time.

(e) The licensee shall retain a copy of the documentation for preplanning and coordination and any revision thereof, as a record for 3 years.

[78 FR 17017, Mar. 19, 2013]

§ 37.77 Advance notification of shipment of category 1 quantities of radioactive material.

As specified in paragraphs (a) and (b) of this section, each licensee shall provide advance notification to the NRC and the governor of a State, or the governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the State, before the transport, or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

(a) *Procedures for submitting advance notification*.

(1) The notification must be made to the NRC and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the NRC's Web site at *https://scp.nrc.gov/special/designee.pdf*. A list of the contact information is also available upon request from the Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Notifications to the NRC must be to the NRC's Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The notification to the NRC may be made by email to *RAMQC_SHIPMENTS@nrc.gov* or by fax to 301–816–5151.

(2) A notification delivered by mail must be postmarked at least 7 days before transport of the shipment commences at the shipping facility.

(3) A notification delivered by any means other than mail must reach NRC at least 4 days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least 4 days before transport of a shipment within or through the State.

(b) *Information to be furnished in advance notification of shipment*. Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

(2) The license numbers of the shipper and receiver;

(3) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(4) The point of origin of the shipment and the estimated time and date that shipment will commence;

(5) The estimated time and date that the shipment is expected to enter each State along the route;

(6) The estimated time and date of arrival of the shipment at the destination; and

(7) A point of contact, with a telephone number, for current shipment information.

(c) *Revision notice*. (1) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the State or the governor's designee and to the NRC's Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

(2) A licensee shall promptly notify the governor of the State or the governor's designee of any changes to the information provided in accordance with paragraphs (b) and (c)(1) of this section. The licensee shall also immediately notify the NRC's Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 of any such changes.

(d) *Cancellation notice*. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified and to the NRC's Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

(e) *Records*. The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for 3 years.

(f) *Protection of information*. State officials, State employees, and other individuals, whether or not licensees of the Commission or an Agreement State, who receive schedule information of the kind specified in § 37.77(b) shall protect that information against unauthorized disclosure as specified in § 37.43(d) of this part.

[78 FR 17017, Mar. 19, 2013; 78 FR 31821, May 28, 2013; 79 FR 75739, Dec. 19, 2014; 79 FR 58671, Sept. 30, 2014; 83 FR 30285, Jun. 28, 2018; 83 FR 57231, Nov. 21, 2018]

§ 37.79 Requirements for physical protection of category 1 and category 2 quantities of radioactive material during shipment.

(a) *Shipments by road.* (1) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(i) Ensure that movement control centers are established that maintain position information from a remote location. These control centers must monitor shipments 24 hours a day, 7 days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.

(ii) Ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.

(iii) Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center must provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

(iv) Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver.

(v) Develop written normal and contingency procedures to address:

(A) Notifications to the communication center and law enforcement agencies;

(B) Communication protocols. Communication protocols must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;

(C) Loss of communications; and

(D) Responses to an actual or attempted theft or diversion of a shipment.

(vi) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

(2) Each licensee that transports category 2 quantities of radioactive material shall maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

(3) Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(i) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

(ii) Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(iii) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(b) *Shipments by rail.* (1) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(i) Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

(ii) Ensure that periodic reports to the communications center are made at preset intervals.

(2) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(i) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

(ii) Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(iii) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(c) *Investigations.* Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

[78 FR 17018, Mar. 19, 2013]

§ 37.81 Reporting of events.

(a) The shipping licensee shall notify the appropriate LLEA and the NRC's Operations Center (301–816–5100) within 1 hour of its determination that a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by § 37.79(c), the shipping licensee will provide agreed upon updates to the NRC's Operations Center on the status of the investigation.

(b) The shipping licensee shall notify the NRC's Operations Center (301–816–5100) within 4 hours of its determination that a shipment of category 2 quantities of radioactive material is lost

or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the NRC's Operations Center.

(c) The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the NRC's Operations Center (301–816–5100) upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of category 1 radioactive material.

(d) The shipping licensee shall notify the NRC's Operations Center (301–816–5100) as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a category 2 quantity of radioactive material.

(e) The shipping licensee shall notify the NRC's Operations Center (301–816–5100) and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.

(f) The shipping licensee shall notify the NRC's Operations Center (301–816–5100) as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.

(g) The initial telephonic notification required by paragraphs (a) through (d) of this section must be followed within a period of 30 days by a written report submitted to the NRC by an appropriate method listed in § 37.7. A written report is not required for notifications on suspicious activities required by paragraphs (c) and (d) of this section. The report must set forth the following information:

(1) A description of the licensed material involved, including kind, quantity, and chemical and physical form;

(2) A description of the circumstances under which the loss or theft occurred;

(3) A statement of disposition, or probable disposition, of the licensed material involved;

(4) Actions that have been taken, or will be taken, to recover the material; and

(5) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

(h) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

[78 FR 17019, Mar. 19, 2013; 83 FR 57231, Nov. 21, 2018]

Subpart F—Records.

§ 37.101 Form of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[78 FR 17019, Mar. 19, 2013]

§ 37.103 Record retention.

Licensees shall maintain the records that are required by the regulations in this part for the period specified by the appropriate regulation. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the facility's license. All records related to this part may be destroyed upon Commission termination of the facility license.

[78 FR 17019, Mar. 19, 2013]

Subpart G—Enforcement.

§ 37.105 Inspections.

(a) Each licensee shall afford to the Commission at all reasonable times opportunity to inspect category 1 or category 2 quantities of radioactive material and the premises and facilities wherein the nuclear material is used, produced, or stored.

(b) Each licensee shall make available to the Commission for inspection, upon reasonable notice, records kept by the licensee pertaining to its receipt, possession, use, acquisition, import, export, or transfer of category 1 or category 2 quantities of radioactive material.

[78 FR 17019, Mar. 19, 2013]

§ 37.107 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under

section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended:

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

[78 FR 17019, Mar. 19, 2013]

§ 37.109 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in this part 37 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in this part 37 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 37.1, 37.3, 37.5, 37.7, 37.9, 37.11, 37.13, 37.107, and 37.109.

[78 FR 17020, Mar. 19, 2013]

Appendix A to Part 37—Category 1 and Category 2 Radioactive Materials

Table 1—Category 1 and Category 2 Threshold

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Americium-241	60	1,620	0.6	16.2
Americium-241/Be	60	1,620	0.6	16.2
Californium-252	20	540	0.2	5.40

Cobalt-60	30	810	0.3	8.10
Curium-244	50	1,350	0.5	13.5
Cesium-137	100	2,700	1	27.0
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,160	0.8	21.6
Plutonium-238	60	1,620	0.6	16.2
Plutonium-239/Be	60	1,620	0.6	16.2
Promethium-147	40,000	1,080,000	400	10,800
Radium-226	40	1,080	0.4	10.8
Selenium-75	200	5,400	2	54.0
Strontium-90	1,000	27,000	10	270
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81.0

Note: Calculations Concerning Multiple Sources or Multiple Radionuclides

The "sum of fractions" methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a location meets or exceeds the threshold and is thus subject to the requirements of this part.

I. If multiple sources of the same radionuclide and/or multiple radionuclides are aggregated at a location, the sum of the ratios of the total activity of each of the radionuclides must be determined to verify whether the activity at the location is less than the category 1 or category 2 thresholds of Table 1, as appropriate. If the calculated sum of the ratios, using the equation below, is greater than or equal to 1.0, then the applicable requirements of this part apply.

II. First determine the total activity for each radionuclide from Table 1. This is done by adding the activity of each individual source, material in any device, and any loose or bulk material that contains the radionuclide. Then use the equation below to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides from Table 1 in the numerator of the equation and the corresponding threshold activity from Table 1 in the denominator of the equation. Calculations must be performed in metric values (i.e., TBq) and the numerator and denominator values must be in the same units.

R_1 = total activity for radionuclide 1
R_2 = total activity for radionuclide 2
R_n = total activity for radionuclide n
AR_1 = activity threshold for radionuclide 1
AR_2 = activity threshold for radionuclide 2
AR_n = activity threshold for radionuclide n

$$\frac{R_1}{AR_1} + \frac{R_2}{AR_2} + \cdots + \frac{R_n}{AR_n} \geq 1.0$$

[78 FR 17020, Mar. 19, 2013; 86 FR 67839, Nov. 30, 2021]