CHAPTER 61-02-07.1
PHARMACY TECHNICIAN

61-02-07.1-03. Educational preparation.

1. To be eligible to be registered by the board of pharmacy as a pharmacy technician the person must have completed one of the following requirements:
   a. Successful completion of an American Society of Health Systems Pharmacists accredited academic program ~~approved by the board of pharmacy~~;
   b. An American Society of Health Systems Pharmacists accredited on-the-job training program ~~that is directed by the pharmacist-in-charge and approved by the board of pharmacy~~; ~~or~~
   ~~c. Employment in a pharmacy as clerical personnel or pharmacy technician for at least one year. This provision will expire one year after the approval of this rule and will require a request in writing by a pharmacist-in-charge of a North Dakota pharmacy.~~

2. Technician certification: ~~A record of pharmacy technician education must be maintained by the pharmacist-in-charge or designated staff pharmacist which contains:~~
   ~~a. The name of the pharmacy technician receiving the education;~~
   ~~b. The date of the educational program;~~
   ~~c. A general description of the topic covered; and~~
   ~~d. The name of the presenter if not conducted by the pharmacist-in-charge~~.

   a. An applicant for registration as a pharmacy technician must have obtained certification by a national certification body approved by the Board of Pharmacy.
   b. A technician registered after August 1, 1995 must obtain and maintain certification by a national certification body approved by the Board of Pharmacy.
   c. A registered technician who does not hold certification on April 1, 2011 will have until March 1, 2014 to obtain that certification.
   d. A copy of a current certification certificate will serve as proof of the technicians continuing education requirement upon renewal or a continuing education audit.
   e. The Pharmacy Technician Certification Board (PTCB) is an approved certification body.

History: Effective October 1, 1993.
General Authority: NDCC 28-32-02, 43-15-10(12)(14)(19)
Law Implemented: NDCC ~~28-32-02,~~ 43-15-10(12)(14)(19)

Correcting missed "Brand Medically Necessary" additions

Originally Senate Bill #2122 and the May 2011 NDAC 61-04-05-03 Computer transmission of prescriptions rule changes of the addition of "Medically" to the required legend "Brand Medically Necessary" to the Board of Pharmacy Rules & Laws

61-04-06-02. Requirements of a prescription order for noncontrolled drugs. The patient hard copy prescription form for noncontrolled drugs must contain the following:

1. The name and address of the patient;
2. The date of issuance;
3. The name of the drug;
4. The quantity;
5. The strength;
6. Adequate directions for use;
7. The prescriber's name, either printed or stamped;
8. The prescriber's indication of refill authorization;
9. A reminder legend in at least six-point uppercase print stating, "In order to require that a brand name product be dispensed, the practitioner must hand write the words 'brand medically necessary'"; and
10. The signature of the prescriber, unless an oral or telephoned prescription.

History: Effective October 1, 1993.
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14)
Law Implemented: NDCC ~~28-32-02,~~ 43-15-10(9)(12)(14)

61-04-06-03. Requirements of prescription order for controlled drugs. The patient hard copy prescription form for controlled drugs must contain the following:

1. The name address of the patient;
2. The date of issuance;
3. The name of the drug;
4. The quantity;
5. The strength;
6. Adequate directions for use;
7. The prescriber's name, either printed or stamped;
8. The prescriber's indication of refill authorization;
9. A reminder legend in at least six-point uppercase print stating, "In order to require that a brand name product be dispensed, the practitioner must hand write the words 'brand medically necessary'";
10. The DEA number of the prescriber; and
10. The signature of the prescriber.

History: Effective October 1, 1993.
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14)
Law Implemented: NDCC ~~28-32-02,~~ 43-15-10(9)(12)(14)

ARTICLE 61-05
RADIOPHARMACEUTICAL SERVICES

CHAPTER 61-05-01
RADIOPHARMACEUTICAL SERVICES

61-05-01-01. Purpose and scope. It is unlawful to receive, possess, or transfer radioactive drugs, except in accordance with North Dakota Century Code chapter 43-15, this Article and the North Dakota Radiological Health Rules in Article 33-10. It is also unlawful for any person to provide radiopharmaceutical services unless that person is a pharmacist meeting the qualifications of North Dakota Administrative Code Section 61-05-01-04, or a person acting under the direct supervision of a pharmacist meeting those qualifications and acting in accordance with North Dakota Century Code chapter 43-15, ~~and~~ state board of pharmacy regulations and ~~regulations of~~ the North Dakota Radiological Health rules, in Article 33-10~~department of health~~, with the exception of a medical practitioner, who is listed as an authorized user on a radioactive materials license, for administration to the practitioner's patients. No person may receive, acquire, possess, use, transfer, or dispose of any radioactive material except in accordance with the conditions of ~~any~~ radioactive material license on which the person is an authorized user, as required by the North Dakota department of health pursuant to North Dakota ~~Century~~ Administrative Code ~~chapters 23-20 and 23-20.1~~ article 33-10. The requirements of this chapter are in addition to, and not in substitution for, other applicable provisions of regulations of the state board of pharmacy and the North Dakota department of health.

History: Effective August 1, 1983.
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36
Law Implemented: NDCC~~28-32-02,~~ 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14),43-15-36

61-05-01-02. Definitions.

1. "Authentication of product history" includes identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

2. "Internal test assessment" includes conducting those tests of a quality assurance necessary to ensure the integrity of the test.

3. "Radiopharmaceutical quality assurance" includes the performance of appropriate chemical, biological, and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history, and the keeping of proper records.

4. "Radiopharmaceutical service" includes the compounding, dispensing, labeling, and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards, and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of radiopharmaceuticals.

History: Effective August 1, 1983.
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36
Law Implemented: NDCC~~28-32-02,~~ 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36

61-05-01-03. General requirements for pharmacies providing radiopharmaceutical services.

1. A nuclear pharmacy providing radiopharmaceutical services shall only be managed by a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of the nuclear pharmacist. The nuclear pharmacist is responsible for all operations of the licensed area and shall be ~~in personal attendance~~ physically present at all times that the pharmacy is open for business. In emergency situations, in the nuclear pharmacist's absence, the nuclear pharmacist may designate one or more other qualified licensed professionals, who are authorized users, listed by name, on a radioactive materials license, to have access to the licensed area. These individuals may obtain single doses of radiopharmaceuticals, only if the single dose is already prepared by a qualified nuclear pharmacist, for the immediate emergency and must document such withdrawals in the control system.

2. Nuclear ~~P~~pharmacies providing radiopharmaceuticals shall have adequate space, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the state. The area shall be separate from the pharmacy areas for nonradioactive drugs and shall be secured from unauthorized personnel. All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area, occupying at least twenty-five square feet [2.32 square meters] of space, separate from and exclusive of the hot laboratory, compounding, dispensing, quality assurance, and office area. A pharmacy handling radioactive drugs exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the state board of pharmacy. Detailed floor plans shall be submitted to the state board of pharmacy before approval of the license.

3. Nuclear ~~P~~pharmacies providing radiopharmaceutical services shall only dispense radiopharmaceuticals which comply with acceptable standards of radiopharmaceutical quality assurance.

4. Nuclear ~~P~~pharmacies providing radiopharmaceutical services shall maintain records of acquisition and disposition of all radioactive drugs and byproduct material for the duration of the license.

5. Nuclear ~~P~~pharmacies providing radiopharmaceutical services shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs.

6. Radioactive drugs are to be dispensed only upon a ~~prescription~~ request from a licensee~~medical practitioner~~ authorized to possess, use, and administer radiopharmaceuticals. A pharmacist providing radiopharmaceutical services may transfer to authorized persons radioactive materials not intended for drug use, in accordance with North Dakota rules and regulations pertaining to radiation control.

7. A ~~prescription for a~~ radiopharmaceutical ~~shall be for an individual patient~~ may be provided only to a facility licensed under North Dakota Administrative Code article 33-10, with an authorized user for the radioactive drug requested. A nuclear pharmacy must have on file a copy of the current radioactive materials license for the licensed facility requesting any radioactive drug before the radioactive drug is permitted to be dispensed to that facility. The radioactive drug must be delivered to the authorized address in the license for receipt, logging in, testing for contamination, determining the current activity and then the dose is available to be administered to a patient. ~~A pharmacy may furnish radiopharmaceuticals for office use only to medical practitioners authorized to possess, use, and administer radiopharmaceuticals for an individual patient.~~

8. In addition to any labeling requirements of the state board of pharmacy for nonradioactive drugs, the immediate outer container of a radioactive drug to be dispensed shall also be labeled with:
   (a) the standard radiation symbol;
   (b) the words "Caution–Radioactive Material";
   (c) the radionuclide;
   (d) the chemical form;
   (e) the amount of radioactive material contained, in millicuries or microcuries;
   (f) if a liquid, the volume in ~~cubic centimeters~~ milliliters;
   (g) the requested calibration time for the amount of radioactivity contained.

9. The immediate container shall be labeled with:
   (a) the standard radiation symbol;
   (b) the words "Caution–Radioactive Material";
   (c) the name, address, and telephone number of the pharmacy; and
   (d) the prescription number.

10. The amount of radioactivity shall be determined by dose calibrator or other appropriate radiometric methods for each individual dose immediately prior to dispensing.

11. ~~P~~Nuclear pharmacies may redistribute national food and drug administration approved radioactive drugs if the pharmacy does not process the radioactive drugs in any manner nor violate the product packaging.

History: Effective August 1, 1983.
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36
Law Implemented: NDCC ~~28-32-02,~~43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36

61-05-01-04. General requirements for nuclear pharmacists to manage a nuclear pharmacy providing radiopharmaceutical services. A qualified nuclear pharmacist shall:

1. Meet minimal standards of training for medical uses of radioactive material.

2. ~~Be a currently licensed pharmacist~~ Hold a current, active license to practice pharmacy,in this state.

3. Have ~~received~~ completed a minimum of seven hundred contact hours in a structured educational program consisting of didactic instruction in nuclear pharmacy and clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing nuclear pharmacy services, or in a structured clinical nuclear pharmacy training program ~~from an accredited college of pharmacy~~, with emphasis 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
   f. Shipping, receiving and performing related radiation surveys
   g. 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
   h. Calculating, assaying and safely preparing dosages for patients or human research subjects
   i. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures

4. ~~Attain a minimum of one hundred sixty~~ hundred hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing nuclear pharmacy services, or in a structured clinical nuclear pharmacy training program in an accredited college of pharmacy. Obtain written attestation, signed by an authorized nuclear pharmacist stating that the pharmacist has completed the requirements of this section and has achieved a level of competence sufficient to function independently as an authorized nuclear pharmacist and submit that to the Board of Pharmacy, or;

5. Submit evidence ~~an affidavit of experience and training~~ to the state board of pharmacy that the pharmacist is certified by a specialty board whose certification has been recognized under 10 CFR 35.55(a).

History: Effective August 1, 1983.
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36
Law Implemented: NDCC ~~28-32-02~~,43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36

61-05-01-05. Library. Each nuclear pharmacy providing radiopharmaceutical services shall have current editions or revisions of:

1. United States Pharmacopoeia National Formulary, with supplements.

   ~~National Formulary, with supplements.~~
2. Current issues of the Journal of Nuclear Medicine or online access
3. State laws and regulations relating to pharmacy.
4. State and federal regulations governing the use of applicable radioactive materials, including North Dakota Radiological Health Rules, Article 33-10.
5. ~~United States public health service, Radiological Health Handbook.~~
   Nuclear Medicine; The requisites – by Thrall and Ziessman
6. ~~Nuclear Medicine by Blahd.~~
   Principles and Practice of Nuclear Medicine – by Early and Sodee
7. ~~Medical Radiation Physical by Hendree.~~
   Nuclear pharmacy – by Chilton and Witcofski
8. ~~Medical Radiation Biology by Pizzarello and Wetcofske.~~

   Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine – by Kowalski and Phelan

~~9. P.D.R. for Radiology and Nuclear Medicine.~~

~~10. Principles of Radiosotope Methodology by Chase and Rabinwotz.~~

~~11. Current issues of Journal of Nuclear Medicine.~~

The board of pharmacy recognizes that the library needed will depend on the type of radiopharmaceutical services offered. Variations in the required library may be granted by the board of pharmacy.

History: Effective August 1, 1983.
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36
Law Implemented: NDCC ~~28-32-02,~~43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36

61-05-01-06. Minimum equipment requirements. Each pharmacy providing radiopharmaceutical services shall have the following equipment:

1. ~~R~~Area radiation ~~laboratory~~ monitor ~~(a~~ which is stationary ~~one~~ and away from other activity~~)~~.
2. ~~Gamma counter~~ Dose calibrator and well counter.
3. Portable ~~ionization chamber~~ survey meter, capable of measuring up to 2000 mR/hr ~~(to~~ for determineing contamination and for other physic procedures~~)~~
4. Sufficient quantity of lead bricks, lead plates, leaded glass of high density, and leaded or tungsten syringe shields.
5. Refrigerator with freezer with temperature monitoring capabilities.
6. Class A prescription balance or balance of greater sensitivity.
7. Single, or multi-channel scintillation counter.
8. ~~Pyrogen oven.~~Sink with hot and cold running water.

9. ~~Portable radiation survey meter~~ Wipe test counter capable of detecting 0.005 microcuries of the radionuclides in question.

10. Chromatographic equipment.

11. ~~Fumer~~ Annually calibrated fume hood, if handling volatile radioactive materials.

12. Chemical exhaust hood, if handling large quantities of chemicals .

13. Electronic balance, or Class A prescription balance.

14. Lighted microscope /hemocytometer.

15. ~~Auto clave for steam sterilization.~~ ISO Class 5 Laminar flow dispensing hood.

16. ~~Dry heat oven (for heat sterilization and to dry glassware).~~ Forceps / tongs for remote handling of material.

17. Hotplate and/or heat block.

18. ~~Lead shielded water bath.~~ Class II Bio-safety cabinet for handling blood samples for labeling.

19. Glassware.

20. Other equipment necessary for radiopharmaceutical services provided as required by the board of pharmacy.

The board of pharmacy recognizes that the equipment needed will depend on the type of radiopharmaceutical services offered. Variations for required equipment may be granted by the board of pharmacy.

History: Effective August 1, 1983.
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36
Law Implemented: NDCC ~~28-32-02,~~ 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13),43-15-10(14), 43-15-36

ARTICLE 61-07
HOSPITAL PHARMACY

Chapter
61-07-01 Hospital Pharmacy

CHAPTER 61-07-01
HOSPITAL PHARMACY

Section
61-07-01-01 Definitions
61-07-01-02 Applicability
61-07-01-03 Registration
61-07-01-04 Personnel
61-07-01-05 Absence of Pharmacist
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61-07-01-14 Pharmacist First Dose Review

61-07-01-14 Pharmacist First Dose Review

1. A hospital pharmacy must have a pharmacist review all medication orders prior to the first dose being administered to the patient. Policies and procedures should be put into place to ensure compliance.

2. Either a pharmacist on-site or the use of hospital telepharmacy services will be sufficient to comply with the requirement.

3. This provision does not apply to the following situations.
   a. When the physician controls the ordering, dispensing, and administration of the drug, such as in the operating room, endoscopy suite, or emergency room.
   b. When time does not permit the pharmacist's review, such as with "stat" orders or when the clinical status of the patient would be significantly compromised by the delay resulting from the pharmacist's review of the order.

4. Each hospital pharmacy must be in compliance with this rule by June 30, 2013

History: Effective April 1, 1988 amended_____
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(14)
Law Implemented: NDCC 43-15-10(9), 43-15-10(14)

ARTICLE 61-09
PRESCRIPTION DRUG INVENTORY OF AMBULANCE SERVICES

CHAPTER 61-09-01
PRESCRIPTION DRUG INVENTORY OF AMBULANCE SERVICES

61-09-01-01. Prescription drug safeguard and control policy. Each ambulance service shall adopt a written prescription drug safeguard policy which, as a condition precedent to obtaining prescription drugs for ambulance service purposes, at a minimum, must include the following requirements:

1. All prescription drugs must be obtained from a North Dakota licensed pharmacy ~~or registered pharmacist~~, wholesaler or authorized prescriber ~~which may include a hospital pharmacy~~, at the request of the ambulance service's medical director or designee. The prescription drugs must be the property of the pharmacy or ~~pharmacist~~ medical director and not the property of the ambulance service.

2. The initial inventory of prescription drugs must be obtained by an ambulance service only upon the written authorization of the ambulance service's medical director who must be a "practitioner" as defined by subsection 17 of North Dakota Century Code section 43-15-01.

3. The pharmacist-in-charge of the licensed pharmacy, ~~or the~~ a ~~registered~~ licensed pharmacist, or the medical director must be responsible for the security and accountability of the prescription drug inventory obtained by an ambulance service.

4. Dispensing or administration of all prescription drugs must be pursuant to a standing order, oral instructions, or prescription of a practitioner.

5. All medications administered must be promptly documented on a ~~written prescription~~ patient care report, ~~signed~~ reviewed by the ~~prescribing practitioner or the advanced life support~~ ambulance service's medical director on a monthly basis either directly or indirectly through a quality assurance process approved by the medical director.

6. ~~All replacement~~ Replenishment of prescription drugs must be requested by a responsible individual. If obtained from a pharmacy the request must be documented on an administration record justifying the order ~~written prescription and signed by a practitioner~~. If obtained by, or on behalf of, the medical director, drugs must be obtained from a North Dakota licensed pharmacy, wholesaler, or an authorized prescriber.

7. Expired, damaged, or unused prescription drugs must be returned to the ~~a~~ licensed pharmacy where obtained ~~or pharmacist~~ or disposed of by the medical director or their designee, according to a written protocol established for this purpose. ~~The pharmacist, on a monthly basis, shall either check the drug box or review a perpetual inventory for expired drugs.~~

8. ~~Replacement of~~ I Lost, stolen, or misused prescription drugs ~~requires written authorization of~~ must be reported to the ambulance service's medical director or the pharmacy where they were obtained.

9. ~~At the beginning of each shift, ambulance (advanced life support) personnel shall conduct a checklist procedure to verify that the drug boxes contain all the required items and that the controlled substances are intact. The checklist procedure is not complete until it is signed by the individuals responsible for possible use of the drug boxes.~~ The licensed ambulance service must have a process, approved by the ambulance service's medical director, or pharmacist-in-charge where the drugs were obtained that accounts for all scheduled II – III – IV controlled substances, at least daily. The daily accounting of schedule II controlled substances must balance and be documented on a daily log.

10. Controlled substances must be sealed in a double lock secure system. A record separate from the other prescription drugs is to be kept for schedule II controlled substances. ~~Documentation on a duplicate form should include:~~ A system approved by the ambulance service's medical director to account for the use and waste of schedule II, III and IV controlled substances must be used. The system must include:
    a. Patient's name and address (if available);
    b. Medication and strength or amount given and amount wasted (if any) ;
    c. Date;
    d. Physician's name; and
    e. The signature of the individual administering the controlled substance.

11. Any unused portion of a prescription drug must be ~~returned for disposal or destruction to the emergency room where the patient is being brought for care. The return of the unused prescription drug should be documented in writing at the emergency room by the ambulance personnel and cosigned by a registered pharmacist or registered nurse as a witness~~ disposed of in a manner that it cannot be collected or recovered. The disposal of all controlled substances must be witnessed and co-signed by another person legally qualified to administer controlled substances.

12. ~~When a controlled substance needs replacement, a copy of the completed form with the necessary documentation is to be given to the licensed pharmacy or registered pharmacist, preferably the same facility where the original supply was obtained. This will ensure better control of the dispensing of these controlled substances. A form with serial and unit numbers must create an audit trail to account for all drugs and control sheets dispensed.~~

History: Effective July 1, 1990.
General Authority: NDCC 28-32-02, 43-15-10(12), 43-15-10(14)
Law Implemented: NDCC 28-32-03, 43-15-10(12), 43-15-10(14)

61-09-01-02. Requirement of pharmacy supplier of ambulance service drugs.
The pharmacist-in-charge of the licensed pharmacy or the pharmacist supplying prescription drugs to an ambulance service, prior to supplying said drugs, shall review the written prescription drug safeguard policy of the ambulance service to determine that all of section 61-09-01-01 requirements are contained therein and that the ambulance service is complying with those requirements. No prescription drugs may be supplied to an ambulance service if

the requirements of section 61-09-01-01 are not contained in the written prescription drug safeguard policy or if the ambulance service is not in compliance with these requirements.

History: Effective July 1, 1990.
General Authority: NDCC 28-32-02, 43-15-10(12), 43-15-10(14)
Law Implemented: NDCC 28-32-03, 43-15-10(12), 43-15-10(14)