

Testimony

to

Legislative Council's

Administrative Rules Committee

December 15, 2010

Good morning Mr. Chairman and members of the committee. My name is Dan Harman and I am with the Air Quality Division of the Health Department. I am here to address amendments to Article 33-10, Radiological Health (pages 124- 392).

1. Two components of the x-ray rule amendments were required by the 2005 Legislative assembly.
2. The restructuring to these rules are driven by changes the Nuclear Regulatory Commission has made to Title 10 of the Code of Federal Regulations. As an Agreement State, we are required to maintain compatibility with the applicable Nuclear Regulatory Commission rules. For this amendment cycle, the decision was made to adopt the applicable rules by reference.
3. The process for adopting amendments involved a review by the State Health Council for approval to proceed to public notice, a public hearing and comment period, response to comments, approval of final draft by the State Health Council and Attorney General. Public notice regarding the hearing for the rules and the public comment period was given by an abbreviated notice published once in all 53 official county papers, and an announcement on the Department's web site. The public hearing regarding amendments was held April 29, 2010.
4. No comments were received.
5. The approximate cost of giving public notice and holding the hearing on the proposed amendments was \$1700.
6. There are 12 updates to the radioactive materials part of the rules. These are required to maintain compatibility with the Nuclear Regulatory Commission rules. And, five significant changes to the x-ray part of the rules affect the Limited X-ray Machine Operator. Three changes add to the training requirements and the fourth adds to the list of acceptable exams. The fifth change prohibits Limited X-ray Machine Operators from operating Computed Tomography (CT) machines, even in emergency situations.
7. A regulatory analysis was required and prepared for both the radioactive materials and x-ray rules. However, no request was received.
8. An economic impact statement of impact on small entities was prepared for both the radioactive materials and x-ray rules. It is incorporated into the regulatory analysis.
9. A constitutional takings assessment was prepared for both the radioactive materials and x-ray rules. It is incorporated into the regulatory analysis.
10. These are not emergency rules.

If you have any questions, I would be happy to answer them at this time.

Rule Revision Analysis and Assessment

I NDCC 28-32-08

Regulatory Analysis for X-Ray Rules

Background

Section 38-32-08 of the North Dakota Century Code requires the Department to issue a regulatory analysis on any rule revision if a request for the analysis is filed by the Governor or a member of the Legislature within 20 days after the last published notice of the proposed rule hearing or if the proposed rule is expected to have an impact on the regulated community in excess of \$50,000.

These rules were developed to satisfy the provisions of Chapter 23-20 and 23-20.1.

The following analysis is prepared to comply with the requirements of that section, and is prepared for the following chapters of the Radiologic Health Rules under consideration:

Chapter 33-10-01 – General Provisions

Chapter 33-10-02 – Registration of Radiation Machine Facilities and Services

Chapter 33-10-06 – X-ray and Imaging Systems in the Healing Arts

Chapter 33-10-08 – Radiation Safety Requirements for Analytical X-ray Equipment

Chapter 33-10-09 – Radiation Safety for Particle Accelerators

Chapter 33-10-11 – Fees for Issuance of License and Registration Certificates and Inspections

Chapter 33-10-15 – Therapeutic Radiation Machines

Class of People Probably Affected

Proposed amendments to the Radiological Health Rules affect all X-ray registrants. The x-ray rule changes to Chapter 33-10-06 affect primarily the limited scope operators with changes to the training requirements and the new views added to the approved list. The changes to the fee schedule (33-10-11 Appendix B) will affect all registrants.

Probable Impact Including Economic Impact

The changes to the x-ray specific rules will have a positive impact on the regulated community. The most significant changes to the x-ray portions are the updating the views that limited scope x-ray operators may perform and adding the requirements for limited scope operator training. The limited scope operator training was required by the 2005 legislature.

Of all the changes, Chapter 11 has the significant impact on the regulated community. The decision was made to increase fees over a 6-year span to make the X-ray Program self-supporting. To calculate the projected operating cost, several assumptions were made. First, salaries would increase five percent in 2010 and 2011 and four percent per year the remaining four years, the overhead and indirect percentages would remain constant, and health insurance cost would increase \$1,000 each year for years two through six. Equipment expenses for the X-ray Program are projections based on replacing current old survey meters and purchasing new tools to evaluate new digital x-ray systems. Travel and training expenses are for travel to learn to use some of the new tools effectively as well as travel within the state to perform the inspections.

The projected net fee increases over the current fee schedule for the next 6 years increases from \$16,870 the first year up to \$30,462 the sixth year. The "Other Registration Fees and Services" fee calculations are based on the number of 2008 registered service providers. Since these fees are variable, only 50 percent of the calculated fees are added fee projections.

The therapeutic x-ray uses were removed from Chapter 6 and transferred to a new Chapter 15. Then Chapter 6 was updated to incorporate the limited scope x-ray operator training requirements mandated by the 2005 Legislature.

The estimated cost to the agency to implement and enforce these amendments is expected to be minimal. The verification that the rules are properly implemented is when each facility is inspected. There are no reasonable alternatives to these at present. If the rules were more stringent than proposed, the costs would increase to the agency and/or registrant. If the rule were less stringent than proposed there is an increased risk of over exposing the patients unnecessarily to radiation.

Small Entity Regulatory Analysis

- Q. Was establishment of less stringent compliance or reporting requirements for small entities considered? To what Result?
- A. No. The radiation exposures are to be as low as reasonably achievable. The rules as proposed are what are currently considered the reasonable radiation standards to protect the public from unnecessary radiation over-exposures.
- Q. Was establishment of less stringent schedules of deadlines for compliance or reporting requirements for small entities? To what result?
- A. No. The rules as proposed are the minimum standards that must be met to protect the public.
- Q. Was consolidation or simplification of compliance or reporting requirements for small entities considered? To what result?
- A. No. The rules as proposed implement no new reporting requirements.
- Q. Were performance standards established for small entities for replacement design or operation standards required in the proposed rule? To what result?
- A. No. The rules as proposed are the minimum that will protect the public from unnecessary radiation over-exposure.
- Q. Was any exemption of small entities from all or part of the requirements in the proposed rule considered? To what result?
- A. No. The rules as proposed are minimum required radiation standards to protect the public from unnecessary radiation over-exposure.

There are no regulatory means by which the department can give small business entities alternate rules. Because the rules are designed to protect the health of the users and the public and provide as safe of an environment as can be for x-ray equipment users. Therefore, no exemption can be given to the rules for any registrant.

Small Entity Economic Impact Analysis

- Q. Which small entities are subject to the proposed rule?
- A. There may be registrants that may qualify as a small entity. An example of a small entity could be a dental office with only five employees. However, the department has chosen not to extend small entity discounts to x-ray facilities.
- Q. What are the administrative and other costs required for compliance with the proposed rules?
- A. The tri-annual fees for registering x-ray producing devices are the only direct compliance cost. The Limited Scope Operator part of the rules does have some administrative requirements relating to documenting the Limited Scope Operator's hands-on training. There is also a direct cost to the person taking the Limited Scope Operator classroom training.
- Q. What is the probable cost and benefit to private persons and consumers who are affected by the proposed rule?

A. There is a direct benefit to private citizens that use medical facilities that cannot afford to cost of employing radiologic technologists. These proposed rules update the training requirements for limited scope x-ray operators typically used in smaller medical facilities.

Q. What is the probable effect of the proposed rule on the state revenues?

A. The intent of the fee increase is to increase fees collected to cover actual x-ray program operating costs.

Q. Is there any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule?

A. Considering the fee increase purpose, if small entities were given reduced fees, the burden would be passed on to the other registrants. The current fees are already less than neighboring states for the service provided.

The X-ray rules as proposed do not have any takings proposed or expected.

Rule Revision Analysis and Assessment

I NDCC 28-32-08

Regulatory Analysis for Radioactive Materials Rules

Background

Section 38-32-08 of the North Dakota Century Code requires the Department to issue a regulatory analysis on any rule revision if a request for the analysis is filed by the Governor or a member of the Legislature within 20 days after the last published notice of the proposed rule hearing, if the proposed rule is expected to have an impact on the regulated community in excess of \$50,000.

The following analysis is prepared to comply with the requirements of that section, and is prepared for the following chapters of the Radiologic Health Rules under consideration:

Chapter 33-10-01 – General Provisions

Chapter 33-10-03.1 – Rules of General Applicability to Domestic Licensing of Byproduct Material

Chapter 33-10-04.2 – Standards for Protection Against Radiation

Chapter 33-10-05.1 – Radiation Safety Requirements for Industrial Radiographic Operations

Chapter 33-10-07.2 – Medical Use of Byproduct Material

Chapter 33-10-09 – Radiation Safety for Particle Accelerators

Chapter 33-10-10.1 – Notices, Instructions and Reports to Workers: Inspections and Investigations

Chapter 33-10-11 – Fees for Issuance of License and Registration Certificates and Inspections

Chapter 33-10-12.1 – Licenses and Radiation Safety Requirements for Well Logging

Chapter 33-10-13.1 – Packaging and Transportation of Radioactive Material

Chapter 33-10-14.1 – Licenses and Radiation Safety Requirements for Irradiators

Chapter 33-10-16 – Domestic Licensing of Source Material

Chapter 33-10-17 – Domestic Licensing of Special Nuclear material

Chapter 33-10-18 – General Domestic Licenses for Byproduct Material

Chapter 33-10-19 – Reciprocal Recognition of Licenses

Chapter 33-10-20 – Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material

Chapter 33-10-21 – Specific Domestic Licenses of Broad Scope for Byproduct Material

To implement the Nuclear Regulatory Commission rules adoption by reference, it was necessary to amend existing Chapter 33-10-01, and repeal Chapters 33-10-03, 04.1, 05, 7.1, 10, 12, 13, and 14. New chapters, as shown above are added to accommodate the rules adoption by reference. Chapter 33-10-11 is amended to change the fee structure and include fee increases.

Class of People Probably Affected

Proposed amendments to the Radiological Health Rules affect the radioactive material licensees. The required Nuclear Regulatory Commission's (NRC) rules are adopted by reference to update the Radiologic Health Rules to meet the rule compatibility requirement. The changes to the fee schedule will affect all licensees.

Probable Impact Including Economic Impact

The current rules meet compatibility and Health & Safety requirements except for 12 new NRC amendments. Table 1 identifies the 12 specific new NRC rules applied to this proposed rule amendment. It should be noted that one of the new NRC amendments is significant and was required to be implemented by a license condition. Those licensees affected have already complied with this this amendment.

Table 1. NRC Rule Changes since Radiological Health Rules 2003 Amendments

RATS ID*	NRC Chronology Identification	NRC Rule Parts Affected
2003-1	Financial Assurance for Materials Licensees	Parts 30, 40, 70, 68
2004-1	Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments	Parts 71, 69
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material	Parts 30, 70
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards	Part 35
2006-1	Minor Amendments	Parts 20, 30, 32, 35, 40, 70
2006-2	National Source Tracking System - Serialization Requirements, Part 32 with reference to Part 20 Appendix E	Part 32 with reference to Part 20 Appendix E
2006-3	National Source Tracking System Part 20	Part 20
2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications	Parts 32 and 35
2007-2	Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements	Parts 30, 31, 32, 150
2007-3	Requirements for Expanded Definition of Byproduct Material	Parts 20, 30, 31, 32, 33, 35, 61, 150
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent	Parts 19, 20
2009-1	Medical Use of Byproduct Material – Authorized User Clarification	Part 35

*Regulatory Analysis Tracking System Identificaion

The Nuclear Regulatory Commission rules are federally mandated. By agreement between the Nuclear Regulatory Commission and the Sate, the State adopts, as a minimum, the applicable federal rules.

Of all the changes, Chapter 11 has the significant impact on the regulated community. The decision was made to increase fees over a 6-year span to make the Radioactive Materials Program self-supporting. To calculate the projected operating cost, several assumptions were made. First, salaries would increase five percent in 2010 and 2011 and four percent per year the remaining four years, the overhead and indirect percentages would remain constant, and health insurance cost would increase \$1,000 pre full time employee each year for years two through six. Equipment expenses for Radioactive Materials Program are projections based on replacing current old survey meters or adding new survey meters. The Radioactive Materials Program travel and training are based on in-state inspections and specialty training not paid for by the Nuclear Regulatory Commission.

Small Entity Regulatory Analysis

- Q. Was establishment of less stringent compliance or reporting requirements for small entities considered? To what Result?
- A. No. The rules promulgated by NRC are the minimum requirements the state may adopt to meet the NRC rules compatibility requirements. The small entity must meet the same radioactive materials safety requirements as other licensees for that type.
- Q. Was establishment of less stringent schedules of deadlines for compliance or reporting requirements for small entities? To what result?
- A. No. The rules promulgated by NRC are the minimum requirements the state may adopt to meet the NRC rules compatibility requirements. The small entity must meet the same radioactive materials safety requirements as other licensees for that type.
- Q. Was consolidation of simplification of compliance or reporting requirements for small entities considered? To what result?
- A. No. The rules promulgated by NRC are the minimum requirements the state may adopt to meet the NRC rules compatibility requirements. The small entity must meet the same radioactive materials safety requirements as other licensees for that type.
- Q. Were performance standards established for small entities for replacement design or operation standards required in the proposed rule? To what result?
- A. No. The rules promulgated by NRC are the minimum requirements the state may adopt to meet the NRC rules compatibility requirements. The small entity must meet the same radioactive materials safety requirements as other licensees for that type.
- Q. Was any exemption of small entities from all or part of the requirements in the proposed rule considered? To what result?
- A. No. The rules promulgated by NRC are the minimum requirements the state may adopt to meet the NRC rules compatibility requirements. The small entity must meet the same radioactive materials safety requirements as other licensees for that type.

There are no regulatory means by which the department can give small business entities alternate rules. The agreement between the Nuclear Regulatory Commission and the State requires the state to adopt rules that are at least as stringent as the applicable NRC rules in 10 CFR. The minimum rules the State must adopt are listed at http://nrc-stp.ornl.gov/regsumsheets_newregs.html. The links on that page lead to documents that, among other things, provide the "Compatibility Category." This link: <http://nrc-stp.ornl.gov/procedures/sa200.pdf> on pages 7 and 8 define the compatibility definitions.

Because the rules are designed to protect the health of the users and the public and provide as safe of an environment as can be for the radioactive materials users. Therefore, no exemption can be given to the rules for any licensee.

Small Entity Economic Impact Analysis

- Q. Which small entities are subject to the proposed rule?
- A. Any business that meets the definition (see 33-10-11-04.6) of a "Small Entity" and provides the required certification, may pay the reduced annual fee.
- Q. What are the administrative and other costs required for compliance with the proposed rules?
- A. The only fees are for a new license, the annual license fee and amendment fee.
- Q. What is the probable cost and benefit to private persons and consumers who are affected by the proposed rule?
- A. There are no direct benefits to private citizens. The consumers of the services benefit because of the lower cost for the services offered by these businesses classed as a "Small Entity."
- Q. What is the probable effect of the proposed rule on the state revenues?
- A. The state revenues will not be affected by adopting the NRC rules by reference. The increased radioactive materials fees will provide additional fee-based funding, using less of general funds revenue.

Q. Is there any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule?

A. The only alternative to the State is for the rules is to be more restrictive, which could increase the cost to the certified small entity licensees.