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7-27-2007

MINNESOTA MDH DEPARTMENT OF HEALTH

*Protecting, maintaining and improving the health of all Minnesotans*

July 26, 2007

Legislative Reference Library
645 State Office Building
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St. Paul, Minnesota 55155

Re: In The Matter Of The Proposed Rules Of The State Department Of Health Governing Radioactive Materials; Governor's Tracking #AR310

Dear Librarian:

The Minnesota Department of Health intends to adopt rules governing radioactive materials. We plan to publish a Dual Notice in the July 30, 2007 State Register.

The Department has prepared a Statement of Need and Reasonableness. As required by Minnesota Statutes, sections 14.131 and 14.23, the Department is sending the Library a copy of the Statement of Need and Reasonableness at the time we are mailing our Notice of Intent to Adopt Rules.

If you have any questions, please contact me at 651-201-4530.

Yours very truly,

George F. Johns, Jr., Supervisor
Radiation Control
625 North Robert Street
P.O. Box 64975
St. Paul, Minnesota 55164-0975

Enclosure: Statement of Need and Reasonableness

**Minnesota Department of Health**
**Environmental Health Division**
**Indoor Environments and Radiation Section**

# STATEMENT OF NEED AND REASONABLENESS

## Proposed Amendment to Rules Governing Radioactive Materials, *Minnesota Rules*, Chapter 4731

The proposed rule changes pertain to regulations dealing with the transportation of radioactive material, security of portable gauges, the training and experience for medical users of radioactive material (authorized users, medical physicists, nuclear pharmacists, and radiation safety officers), and minor amendments. The proposed rule changes are necessary to meet compatibility requirements with US Nuclear Regulatory Commission (NRC) regulations. The rules do not pertain to areas of exclusive federal jurisdictions (such as Veteran's Administration facilities) or to radioactive material used for the production of nuclear power. In addition, there are a few changes proposed to address editorial issues in the current rule; these changes do not represent a substantive change to the regulatory requirements.

## INTRODUCTION

The Atomic Energy Act of 1954, as amended, gives authority to regulate byproduct, source, and special nuclear material to the NRC. Subsection 274b of the act allows the NRC to enter into agreements relinquishing regulatory control of these materials to states that request the authority for such programs and meet NRC criteria for assuming this responsibility. States that have been delegated regulatory oversight of this radioactive material are known as "agreement states." (Regulation of nuclear power plants and the use of byproduct material at facilities under exclusive federal jurisdiction cannot be transferred to states.) On March 31, 2006, Minnesota entered into this agreement, becoming the 34$^{th}$ Agreement State. As part of the agreement state process, the NRC requires states to adopt and update rules to be compatible with NRC regulations. In January of 2005, the Minnesota Department of Health adopted Chapter 4731, rules that govern the use of radioactive materials to meet this requirement, as a precursor to becoming an agreement state.

These rules also apply to the use of naturally occurring or accelerator produced radioactive material (NARM). Historically NARM was not included in the definition of byproduct material, and not under the jurisdiction of the NRC. The state had regulated NARM prior to becoming an agreement state under Chapter 4730. When Chapter 4731 was adopted, it included NARM to create uniformity in the standards for the use of radioactive material within the state. Subsequently, the Energy Policy Act (EPAct) of 2005 changed the definition of byproduct material to include much of what is classified as NARM. In a letter dated September 7, 2006, the governor certified to the NRC that the State of Minnesota has a program to regulate the material included in the new definition of byproduct materials that is adequate to protect the public health and safety.

Since the Minnesota Department of Health adopted Chapter 4731, the US Nuclear Regulatory Commission implemented changes to their regulations pertaining to the transportation of radioactive materials, security of portable gauges, the training and experience for medical users (authorized users, medical physicists, nuclear pharmacists, and radiation safety officers), and minor amendments. The proposed changes to Chapter 4731 are necessary to assure compatibility with the new federal requirements, which are crucial for Minnesota's agreement state status.

The following summarizes the four rulemaking efforts that have been implemented by the NRC since the Department promulgated Chapter 4731 rules.

I. Compatibility With IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments, published in the *Federal Register*, 69 FR 3697, with an effective date of October 1, 2004. This rule changed the requirements for packaging and transporting radioactive material to make the regulations compatible with the latest version of the International Atomic Energy Agency (IAEA) standards and codify other applicable requirements.

The NRC staff grouped the part compatibility changes into the following issues:

(1) changing to the International System of Units (SI) only;
(2) radionuclide exemption values;
(3) revision of A1 and A2;
(4) uranium hexafluoride (UF6) package requirements;
(5) introduction of the criticality safety index requirements;
(6) type C packages and low dispersible material;
(7) deep immersion test;
(8) grandfathering previously approved packages;
(9) changes to various definitions;
(10) crush test for fissile material package design; and
(11) fissile material package design for transport by aircraft.

Eight additional NRC-initiated issues were identified for incorporation in part 71. These NRC-initiated changes were:

(12) special package authorizations;
(13) expansion of Quality Assurance (QA) requirements to Certificate of Compliance (CoC) holders;
(14) adoption of the American Society of Mechanical Engineers (ASME) code;
(15) change authority for Dual-Purpose Package Certificate holders;
(16) fissile material exemptions and general license provisions;
(17) decision on petition for rulemaking on Double Containment of Plutonium;
(18) contamination limits as applied to Spent Fuel and High-Level Waste (HLW) packages; and
(19) modifications of event reporting requirements.

The rule changes were coordinated with the US Department of Transportation (DOT) to ensure that consistent regulatory standards are maintained between NRC and DOT

radioactive material transportation regulations and to ensure coordinated publication of the final rules by both agencies.

II. Security Requirements for Portable Gauges Containing Byproduct Material, published in the *Federal Register*, 70 FR 2001, with an effective date of July 11, 2005. This rule requires a portable gauge licensee to use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal whenever the portable gauges are not under the control and constant surveillance of the licensee.

Portable gauges are devices containing licensed material that are used to determine physical properties (such as density and moisture content of soil, concrete, and other materials) in a field setting. The most commonly used portable gauges contain two encapsulated sources of radioactive material. When not in use, portable gauges are generally stored in a permanent storage location within a licensed facility. Sometimes, portable gauges are stored at a jobsite, at a temporary storage location, or on a vehicle. When transporting a portable gauge in a vehicle, the gauge is often placed in a transportation case, and is secured in or onto the vehicle.

Existing rules addressed storage and control of licensed material. Licensees must secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. "Control of material not in storage" requires licensees to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. Despite these requirements, the theft of portable gauges continues at a rate of approximately 50 gauges per year with a less than 50-percent recovery rate. More than two-thirds of the stolen gauges were taken from vehicles parked outdoors. In most of these incidents, the gauge was in a U.S. Department of Transportation (DOT) "Type A" transportation case, which was then secured with a chain to the open bed of a pickup truck. Frequently, the chain was cut or the transportation case was broken, and the gauge was stolen. NRC has issued several notices to increase licensees' awareness of security concerns regarding portable gauges. However, the yearly number of reported incidents has not changed in response to these notices.

Although the amount of radioactive material used in a portable gauge is relatively small and the radioactive material is encapsulated in stainless steel, unauthorized removal of portable gauges still poses a potential public health and safety concern. A portable gauge that is not under the control of a licensee poses a potential radiation hazard to individuals that may come in close contact with the source. It also creates a concern if the portable gauge that is removed without authorization is abandoned, inadvertently recycled, or used inappropriately.

The primary intent of this rulemaking was to increase licensees' control of portable gauges to reduce the opportunity for unauthorized removal or theft.

III. Medical Use of Byproduct Material – Recognition of Specialty Boards, published in the *Federal Register*, 70 FR 16336, with an effective date of April 29, 2005. This rule changed the requirements for recognition of specialty boards whose certifications may be used to demonstrate the adequacy of the training and experience of individuals to serve as radiation safety officers, authorized medical physicists, authorized nuclear pharmacists, or authorized users. The final rule also revised the requirements for demonstrating the adequacy of training and experience for pathways other than the board certification pathway. This rulemaking was necessary to address the training and experience issue for recognition of specialty board certifications. Without this rulemaking, the issue of board recognition would not be addressed and there would be a potential shortage of individuals authorized to perform medical procedures involving the use of radioactive material.

IV. Minor Amendments – Parts 1, 13, 20, 30, 32, 35, 40, 55, 70, 73, 110, and 140, published in the *Federal Register*, 71 FR 15005, with an effective date of March 27, 2006. This rule corrected several miscellaneous errors in the Code of Federal Regulations.

The *Federal Register* pages listed above can be accessed online from the Government Printing Office, *Federal Register* website at http://www.gpoaccess.gov/fr/index.html. From the main page, perform a page number search; highlight the desired volume (number preceding FR), and enter the page number (number following FR).

In addition to the above, the department proposes several changes to address editorial issues, which are listed below in the rule-by-rule analysis section.

## ALTERNATIVE FORMAT

Upon request, this Statement of Need and Reasonableness can be made available in an alternative format, such as large print, Braille, or cassette tape. To make such a request, please contact:

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## STATUTORY AUTHORITY

This rulemaking is an amendment of rules and so *Minnesota Statutes*, section 14.125, does not apply.

The Department's statutory authority to adopt the rules is set forth in *Minnesota Statutes*, sections 144.1202 and 144.1203. Section 144.1202 provides that the commissioner may adopt rules to allow the state to assume regulatory authority under an agreement under this section, including the licensing and regulation of radioactive materials.

Section 144.1203 provides that the commissioner shall adopt rules to ensure that individuals handling or utilizing radioactive materials under the terms of a license issued by the commissioner under section 144.1202 have proper training and qualifications to do so.

## REGULATORY ANALYSIS

To reflect standards necessary to promote and protect the radiological health and safety of the public, employee's health and safety, and the safety of the environment, the department is promulgating rules concerning the transportation of radioactive materials, security of portable gauges, the training and experience for medical users, and minor amendments. The proposed rule changes establish requirements that are an integral element in the agreement state process.

*Minnesota Statutes*, section 14.131, sets out seven factors for a regulatory analysis that must be included in the SONAR. Paragraphs (1) through (7) below quote these factors and then provide the agency's response.

**"(1) a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule."**

The rules will affect persons who own, receive, possess, use, transfer, acquire, or dispose of radioactive material that requires a license from the MDH. The effect on the licensees will be minimal because they are currently required to meet the requirements in the proposed rule by conditions that were put into their license when MDH took over. All four of the NRC rule amendments took effect prior to Minnesota becoming an agreement state. Because of this, licensees in Minnesota had to meet these requirements when under regulatory control of the NRC. To keep the requirements in effect and ensure regulatory consistency, the MDH agreed to implement these requirements by license conditions for all applicable licensees as a temporary measure until the new rule can be put into place.

The types of licensees most affected by the proposed rules are:

- The rules governing the transportation of radioactive material cover all licensees currently regulated by the state. Licensees include academic, industrial, medical, and research users of these radioactive nuclides. The proposed transportation rule changes are consistent with current international and federal requirements for the transportation of radioactive material within the United States.

- The rules governing the use of radioactive material in specifically licensed portable gauges impacts engineering firms that utilize these devices to measure moisture or density of soil, concrete, and other materials in a field setting.

- The rules related to the training and experience for medical users will affect individuals serving as radiation safety officers, authorized medical physicists, authorized nuclear pharmacists, or authorized users for medical use.

The largest group affected by these rules is the general public within the State of Minnesota, as the purpose of the rules is to protect both licensees and the general public from unwanted or unsafe exposures to radioactive materials.

**"(2) the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues."**

The cost to enforce the proposed rules will be comparable to what is required to enforce the current rules. The cost of enforcement of the rules is funded through annual fees, which were established in the 2004 Minnesota Legislature Legislative Session and found in *Minnesota Statutes*, section 144.1205. The department will require no additional revenues to enforce these rules. There are no other agencies that will be involved in implementing or enforcing these rules, so there are no expected costs to other agencies.

**"(3) a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule."**

The proposed rules are necessary to meet the compatibility requirements with the NRC's regulations. MDH has little discretion in considering methods that would be less restrictive to the regulated parties.

**"(4) a description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule."**

To meet the compatibility requirements with the NRC's rule amendments, the department had little choice other than updating the existing Chapter 4731. No alternative methods were seriously considered.

**"(5) the probable costs of complying with the proposed rule."**

Given that the regulations, in the form of license conditions, currently apply to licensed facilities, there is no increased financial impact associated with adoption of these rules. Even without these

license conditions, the increased costs to comply with the rule changes would be negligible compared to the costs to comply with the existing rules.

**"(6) the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals."**

If the proposed rule changes are not adopted, the rules would not meet the compatibility requirements of the agreement with the NRC. The NRC could ultimately end the agreement and reclaim regulatory control. In this case, the state would lose the annual fees to the federal government and licensees would pay more; NRC annual fees are approximately 25% higher than the Minnesota fees.

**"(7) an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference."**

The only differences between the proposed rule changes and the federal regulations are those necessary to conform to Minnesota rulemaking format.

## PERFORMANCE-BASED RULES

As stated above, the proposed rules are based on federal regulations that the department is required to adopt to meet compatibility requirements as part of our agreement. The department has little flexibility in implementing performance-based rules when not adopted by the NRC.

## ADDITIONAL NOTICE

At the time of publishing the Dual Notice, the MDH intends to seek information by methods designed to reach persons or classes of persons who might be significantly affected by the proposed rules, in accordance with *Minnesota Statutes*, section 14.22, by:

1. Publishing the Dual Notice in the *State Register*.

2. Posting the Notice, proposed amendments to Chapter 4731, SONAR, and information on submitting comments on the Radioactive Materials website at: http://www.health.state.mn.us/divs/eh/radiation/radioactive/index.htm. In addition, links to the website highlighting the proposed rule changes will be posted on the MDH and Environmental Health home pages.

3. Mailing the Dual Notice to persons that are specifically licensed by MDH to use radioactive materials.

4. Mailing the Dual Notice to registered general licensees. These are persons that have generally licensed devices and are able to acquire, receive, possess, use, or transfer radioactive material in their device. These "general licensees" are then required to register their device with the MDH.

5. Mailing the Dual Notice to medical physicists on the Radiation Control Unit's mailing list. The proposed rules would change the training requirements for medical physicists, and medical physicists often serve as consultants to medical use licensees.

6. Mailing the Dual Notice to persons on the department's rulemaking mailing list established by Minnesota Statutes, section 14.14, subdivision 1a.

7. Mailing the Dual Notice to the chairs and ranking minority party members on the House Health Care and Human Services Finance Division Committee, House Health and Human Services Committee, Senate Finance Committee - Health and Human Services Budget Division, and Senate Health, Housing and Family Security Committee per Minnesota Statutes, section 14.116.

The department believes these measures are adequate to meet the statutory requirement of reaching affected people. The people who will have to meet these requirements are radioactive material licensees of the department. All licensees that were NRC licensees prior to Minnesota becoming an agreement state had to meet the requirements of the proposed rule changes when regulated by the NRC. To keep the requirements in effect and ensure regulatory consistency, the MDH has implemented these requirements by license conditions for all applicable licensees. There have not been any issues with these license conditions to date, and we do not anticipate any issues with making the requirements part of the rule. Non-licensees will be minimally impacted by the proposed rules.

## CONSULT WITH FINANCE ON LOCAL GOVERNMENT IMPACT

As required by *Minnesota Statutes*, section 14.131, the department has consulted with the Commissioner of Finance. The department did this by sending to the Commissioner of Finance copies of the documents sent to the Governor's Office for review and approval by the Governor's Office prior to the department publishing the Dual Notice. The department sent the copies on April 16, 2007. The documents included: the Governor's Office Proposed Rule and SONAR Form; almost final draft rules; and almost final SONAR. A response, dated May 9, 2007, states the proposed rule does not have a fiscal impact for local units of government.

## COST OF COMPLYING FOR SMALL BUSINESS OR CITY

As required by *Minnesota Statues*, section 14.127, the department has considered whether the cost of complying with the proposed rules in the first year after the rules take effect will exceed $25,000 for any small business or small city. The department has determined that the cost of

complying with the proposed rules in the first year after the rules take effect will not exceed $25,000 for any small business or small city.

The department has made this determination based on the probable costs of complying with the proposed rule, as described in the Regulatory Analysis section of this SONAR on pages 5 - 7.

**RULE-BY-RULE ANALYSIS**

Most of the changes reflected in the proposed rule are needed to meet compatibility requirements with changes to the federal regulations in the four NRC rule amendments stated above. These changes are reasonable because they mirror the current federal regulations that have gone through the federal rule making process. As previously indicated, the proposed rule changes are essentially those of the U.S. Nuclear Regulatory Commission. The NRC categorizes rules that are adopted by states as A, B, C, D, or Health and Safety (H&S). The following is a description of the various categories:

A = Basic radiation protection standard or related definitions, signs, labels, or terms necessary for the common understanding of radiation principles. The state program should be essentially identical to that of the NRC.

B = Program element with significant direct trans-boundary implications. The state program element should be essentially identical to that of the NRC.

C = Program element, the essential objectives of which should be adopted by the state to avoid conflicts, duplications, or gaps. The manner in which the essential objectives are addressed need not be the same as the NRC, provided the essential objectives are met.

D = Not required for compatibility purposes.

H&S = Program element with a particular health and safety significance. The state should adopt the essential objectives of such program elements in order to maintain an adequate program.

A table correlating the NRC rules to the proposed rule changes and indicating the compatibility level of each rule is included as Exhibit 1 of this SONAR.

The following changes are not NRC driven based on the four NRC amendments referred to above, but instead are editorial issues. All of these changes are needed to either, clarify existing requirements, or to meet compatibility issues that were errors in the initial rule. They are reasonable because the clarifying changes do not alter the sense, meaning, or effect of the rule, and the compatibility changes mirror the current federal regulations that have gone through the federal rule making process. These changes are:

| | |
|---|---|
| 4731.0100 | Subp. 224, Changed to be consistent with the rest of the rule that lists common units, with International System of Units (SI) in parentheses. |
| 4731.0200 | Changed to reflect Radiation Control's address change. |
| 4731.0280 | Incorporated 4731.0405 into this Part to keep all deliberate misconduct requirements in the same section. |
| 4731.0355 | Changed to reflect Radiation Control's address change. |
| 4731.0405 | This Part was moved to 4731.0280 to keep all deliberate misconduct requirements in the same section. |
| 4731.1010 | This Part was revised to remove an incorrect web address. |
| 4731.2600 | Corrected a misstated requirement. This is needed to meet the compatibility requirement, but not part of the NRC amendments referred to above. This was an error in the initial rule that was identified by staff. |
| 4731.2800 | Remove Subpart 3 B & C, which repeat what is stated in Subparts 1 & 2. |
| 4731.3080 | An error in the language was fixed to match NRC requirements. This is needed to meet the compatibility requirement, but not part of the NRC amendments referred to above. This was an error in the initial rule that was identified by staff. |
| 4731.3215 | The Subpart was separated to facilitate identification of generally licensed material requiring registration. |
| 4721.4423 | The change was to fix an incorrect rule reference. |

References to the affected sections were also changed but not noted separately here.

## LIST OF EXHIBITS

1. Correlation of Department Rules to NRC Regulations and Compatibility Classification

## CONCLUSION

Based on the foregoing, the proposed rule changes are both needed and reasonable.

1/11/07
Date

John Linc Stine, Director
Environmental Health Division

Exhibit 1
Correlation of Department Rules to NRC Regulations and Compatibility Classification

| MN Rule Part | Title | 10 CFR Reference | Compatibility |
|---|---|---|---|
| **4731.0100** | Definitions | | |
| subp. 22. | Authorized medical physicist | 35.2 | B |
| subp. 23. | Authorized nuclear pharmacist | 35.2 | B |
| subp. 24. | Authorized user | 35.2 | B |
| subp. 33a. | Certificate holder | 71.4 | B |
| subp. 33b. | Certificate of compliance | 71.4 | B |
| subp. 43a. | Consignment | 71.4 | B |
| subp. 44a. | Containment system | 71.4 | D |
| subp. 49a. | Conveyance | 71.4 | B |
| subp. 50a. | Criticality safety index | 71.4 | B |
| subp. 59a. | Deuterium | 71.4 | B |
| subp. 84. | Fissile material | 71.4 | B |
| subp. 90a. | Graphite | 71.4 | B |
| subp. 129. | Low specific activity material or LSA | 71.4 | B |
| subp. 130. | Low specific activity material group I | 71.4 | B |
| subp. 131. | Low specific activity material group II | 71.4 | B |
| subp. 132. | Low specific activity material group III | 71.4 | B |
| subp. 159. | Package | 71.4 | B |
| subp. 174. | Preceptor | 35.2 | B |
| subp. 193. | Radiation safety officer | 35.2 | B |
| subp. 224. | Special form radioactive material | 71.4 | B |
| subp. 235. | Surface contaminated object | 71.4 | B |
| subp. 246. | Transport index | 71.4 | B |
| subp. 253a. | Unirradiated uranium | 71.4 | B |
| **4731.0200** | General Applications | All CFR Parts | D |
| subp. 4. | Submissions | | |
| **4731.0280** | Deliberate Misconduct | 30.10, 71.8 | C |
| subp. 1. | Applicability | | |
| subp. 2. | Prohibition | | |
| subp. 3. | Enforcement | | |
| subp. 4. | Definition | | |
| **4731.0355** | Reciprocity | 150.20 | C |
| subp.1. | Application; recognition | | |
| **4731.0400** | Scope, enforcement notice | 71.0 | D |
| subp. 1. | Scope | | |
| subp. 2. | Application of law | | |
| subp. 3. | Applicability | | |
| subp. 4. | Enforcement notice | | |
| **4731.0401** | Requirement for license | 71.3 | D |
| **4731.0402** | Transporation of Licensed Material | 71.5 | B |
| subp. 1. | DOT regulations | | |
| **4731.0403** | Specifics Exemptions | | |
| subp. 1. | Physicians | 71.13 | B |
| subp. 1a. | Grounds | 71.12 | D |
| subp. 2. | Low-level materials | 71.14 | B |

Exhibit 1
Correlation of Department Rules to NRC Regulations and Compatibility Classification

| | | | |
|---|---|---|---|
| subp. 3. | Exemption from classification as fissile material | 71.15 | B |
| **4731.0405** | ***Combined with 4731.0280*** | | |
| **4731.0406** | General license: NRC-approved packages | 71.17 | B |
| subp. 2. | Approved quality assurance program | | |
| subp. 3. | Compliance with conditions | | |
| **4731.0408** | General license; DOT specification container | 71.20 | B |
| subp. 2. | Approved quality assurance program | | |
| subp. 4. | Use within United States | | |
| subp. 5. | Expiration date | | |
| **4731.0409** | General license; foreign-approved package | 71.21 | B |
| subp. 2. | Approved quality assurance program | | |
| subp. 4. | Certificate conditions | | |
| **4731.0410** | General license; fissile material | 71.22 | B |
| subp. 1. | License to transport or deliver fissile material | | |
| subp. 2. | Approved quality assurance program | | |
| subp. 3. | Type A quantity limits | | |
| subp. 4. | Fissile material labeled with a criticality safety index | | |
| subp. 7. | Criticality safety index values | | |
| subp. 8. | Mass limits for general license packages | | |
| subp. 9. | Mass limits for general license packages containing uranium-235 of known enrichment | | |
| **4731.0411** | General License; Plutonium-beryllium special form material | 71.23 | B |
| subp. 1. | Transport of plutonium-beryllium | | |
| subp. 2. | Approved quality assurance program | | |
| subp. 3. | Package contents | | |
| subp. 4. | Packages labeled with criticality safety index | | |
| subp. 5. | Criticality safety index | | |
| **4731.0415** | Routine determinations | 71.15 | B |
| **4731.0416** | Air Transport of Plutonium | 71.88 | B |
| subp. 1. | Limitations for plutonium transport | | |
| **4731.0419** | Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste | 71.97 | B |
| subp. 2. | Shipments requiring notice | | |
| subp. 3. | Procedures for submitting notification | | |
| subp. 4. | Information to be furnished in advance notification of shipment | | |
| subp. 5. | Revision notice | | |
| subp. 5a. | Record retained | | |
| subp. 6. | Cancellation notice | | |
| **4731.0421** | Quality Assurance Organization | 71.103 | D |
| subp. 8. | Access to management | | |
| **4731.0422** | $A_1$ and $A_2$ Values for Radionuclides | Appendix A | B |
| subp. 1a. | $A_1$ and $A_2$ values | | |
| subp. 2. | Specific activity | | |
| subp. 3. | Exempt material activity concentrations and exempt consignment activity limits | | |
| **4731.0423** | Determination of $A_1$ and $A_2$ | Appendix A | B |
| subp. 1. | Generally | | |

Exhibit 1
Correlation of Department Rules to NRC Regulations and Compatibility Classification

| | | | |
|---|---|---|---|
| subp. 2. | Individual radionuclides; not listed in part 4731.0422, subpart 1 | | |
| subp. 2a. | Individual radionuclides; not listed in part 4731.0422, subpart 3 | | |
| subp. 2b. | Prior approval | | |
| subp. 3. | Radioactive decay chain | | |
| subp. 4. | Radionuclide mixture | | |
| subp. 5. | Activities unknown | | |
| subp. 8. | General Values for $A_1$ and $A_2$ | | |
| **4731.0455** | Quality Assurance for Transportation Packages | 71.101 - 71.137 | D/C |
| **4731.0610** | Authorized Use of Special Nuclear Material | 70.41 | C |
| subp. 1. | Authority under license | | |
| **4731.0780** | Financial Assurance and Record Keeping for Decommissioning | 40.36 | DH&S |
| subp. 3. | Between ten mCi and 100 mCi | | |
| **4731.1010** | Posting Worker Notices | 19.11 | C |
| subp. 2. | Notice to employees | | |
| **4731.2600** | Reports; Theft or Loss of Licensed Material | 20.2201 | C |
| subp. 1. | Telephone reports | | |
| **4731.2800** | Quantities of Licensed Material Requiring Labeling | Appendix C Part 20 | A |
| subp. 3. | Quantities requiring labeling | | |
| **4731.3075** | Terms and Conditions of Licenses | 30.34 | C |
| subp. 3. | Scope of license | | |
| subp. 4. | Bankruptcy | | |
| subp. 8. | Security requirements for portable gauges | | |
| **4731.3080** | Financial Assurance and Record Keeping for Decommissioning | 30.35 | DH&S |
| subp. 1. | Decommissioning funding plan required | | |
| subp. 2. | Plan or financial assurance required | | |
| **4731.3215** | General License; Detecting, Measuring, Gauging, Controlling, and Other Devices | 31.35 | D |
| subp. 3. | Requirements | | |
| subp. 3a. | Registration of generally licensed devices | | |
| subp. 4. | Limitation | | |
| **4731.3330** | Specific License; Certain Devices Containing Radioactive Materials; Manufacture or Initial Transfer | 32.51 | B |
| subp. 1. | Approval criteria | | |
| subp. 4. | Transfer for use under general license; requirements | | |
| **4731.3395** | Specific License; Radioactive Drugs for Medical Use; Manufacture, Preparation, or Transfer | 32.72 | B |
| subp. 2. | Pharmacy licensees | | |
| **4731.3400** | Specific License; Sources or Devices for Medical Use; Manufacture and Distribution | 32.74 | B |
| subp. 1. | Approval criteria | | |
| **4731.4030** | Performance Requirements; Industrial Radiography Equipment | 34.20 | B |
| subp. 2. | Additional requirements | | |
| **4731.4110** | Labeling; Packaging; Security | 34.35 | B |

Exhibit 1
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| subp. 2. | Required packaging | | |
| **4731.4140** | Radiographer Training | 34.43 | B |
| subp. 1. | Requirements; radiographer | | |
| subp. 2. | Requirements; radiographer's assistant | | |
| **4731.4403** | Specific License; Medical Use of Radioactive Materials | | |
| subp. 3. | License amendments | 35.13 | D |
| subp. 4. | Notifications | 35.14 | D |
| **4731.4410** | Suppliers of Medical Use Sealed Sources or Devices | 35.49 | C |
| **4731.4411** | Radiation Safety Officer Training | 35.30 | B |
| subp. 1. | Training and education requirements | | |
| subp. 2. | Certification requirements | | |
| **4731.4412** | Authorized Medical Physicist Training | 35.51 | B |
| subp. 1. | Training and education requirements | | |
| subp. 2. | Certification requirements | | |
| **4731.4413** | Authorized Nuclear Pharmacist Training | 35.55 | B |
| subp. 1. | Training and education requirements | | |
| subp. 2. | Certification requirements | | |
| **4731.4414** | Training: Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist | 35.37 | B |
| **4731.4423** | Authorization for Calibration, Transmission, and Reference Use | 35.65 | D |
| **4731.4427** | Release of Individuals Containing Unsealed Radioactive Material or Implants | 35.75 | C/D |
| **4731.4432** | Unsealed Radioactive Material; Uptake, Dilution, and Excretion Studies; Written Directive Not Required | 35.100 | B |
| **4731.4433** | Uptake, Dilution, and Excretion Studies; Training | 35.190 | B |
| subp. 1. | Training and education requirements | | |
| subp. 2. | Certification requirements | | |
| **4731.4434** | Unsealed Radioactive Material; Imaging and Localization Studies; Written Directive Not Required | 35.200 | H&S |
| **4731.4436** | Imaging and Localization Studies; Training | 35.290 | B |
| subp. 1. | Training and education requirements | | |
| subp. 2. | Certification requirements | | |
| **4731.4443** | Unsealed Radioactive Material; Written Directive Required; Training | 35.390 | B |
| subp. 1. | Training and education requirements | | |
| subp. 2. | Certification requirements | | |
| **4731.4444** | Oral Administration of Sodium Iodide I-131; Quantities Less Than or Equal to 33 Millicuries (1.22 GBq); Written Directive Required: Training | 35.392 | B |
| **4731.4445** | Oral Administration of Sodium Iodide; Quantities Greater Than 33 Millicuries (1.2 GBq); Written Directive Required; Training | 35.394 | B |
| **4731.4446** | Parenteral Administration of Unsealed Radioactive Material; Written Directive Required; Training | 35.396 | B |
| **4731.4458** | Manual Brachytherapy Training | 35.490 | B |
| subp. 1. | Training and education | | |
| subp. 2. | Certification requirements | | |
| **4731.4459** | Ophthalmic Use of Strontium-90; Training | 35.491 | B |

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| **4731.4461** | Use of Sealed Sources for Diagnosis; Training | 35.590 | B |
| **4731.4479** | Remote Afterloader Units, Teletherapy Units, and Gamma Sterotactic Radiosurgery Units; Training | 35.690 | B |
| subp. 1. | Training and education requirements | | |
| subp. 2. | Certification requirements | | |
| **4731.7050** | Labels, Security, and Transportation Precautions | 35.690 | B |
| subp. 1. | Labeling | | |