

# **Statement of Need and Reasonableness**

**RADIATION SAFETY, MINNESOTA RULES, CHAPTER 4731**

**OCTOBER 2024**

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# Proposed Amendment to Rules Governing Radiation Safety, Minnesota Rules, 4731; Revisor's ID Number R-4793

The Minnesota Department of Health (MDH or department) proposes to amend Minnesota Rules, Chapter 4731, to reflect the U.S. Nuclear Regulatory Commission's (NRC) recent regulation changes. The proposed changes conform MDH's rules to NRC-mandated regulations. This rule is only one part of a multi-faceted compliance program.

## INTRODUCTION

NRC entered into an agreement with the State of Minnesota in March 2006, where regulatory authority of byproduct, source, and certain special nuclear materials was given to the state. These byproduct, source and special nuclear materials are radioactive materials used in research, medical, industrial, and manufacturing settings. This means that Minnesota now regulates radioactive material within the state.

The agreement does not cover nuclear power-plant regulation, radioactive material used at facilities under exclusive federal jurisdiction, exempt-quantities distribution, or evaluation of either sealed-sources or devices. NRC still performs these functions exclusively.

Minnesota and other states that have signed such agreements are known as "Agreement States." The agreement requires Minnesota to maintain rules that are compatible with NRC regulations. When NRC makes regulation changes, the Agreement States have a deadline to bring their rules likewise up to date. The deadline for the adoption of these rule revisions is September 8, 2024.<sup>1</sup>

NRC categorizes its regulations by level of compatibility required. Some categories require strict adherence while others allow states flexibility in their rules. The compatibility categories are A, B, C, and D. In addition, there are NRC and Health and safety (H&S) designations.

Compatibility A are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. These program elements should be essentially identical to those of NRC to provide uniformity in the regulation of agreement material on a nationwide basis.

Compatibility B are program elements that cross jurisdictional boundaries and have a particular impact on public health and safety. Like Compatibility A, these elements need to be adopted in an essentially identical manner to ensure uniformity of regulation on a nationwide basis.

Compatibility C are program elements important to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. The Agreement State program elements may be more restrictive than the NRC program elements provided that the essential objective is met, and the state requirements do not jeopardize an orderly pattern of regulation of agreement material on a nationwide basis.

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<sup>1</sup> See Review Summary Sheets for Regulation Amendments (RATS) 2021-1 through 2022-1 (available at [https://scp.nrc.gov/rss\\_regamendments.html](https://scp.nrc.gov/rss_regamendments.html)).

Compatibility D are not required for purpose of compatibility.

NRC also has designations of NRC and H&S. A designation of NRC address areas of regulation that cannot be discontinued when a state enters into an Agreement with NRC pursuant to the Atomic Energy Act or provisions of the Code of Federal Regulations (CFR). These are reserved for NRC, and we are not proposing rules designated as this category. Thus these do not show up further in the discussion.

H&S designations are not required for compatibility but do have particular health and safety significance. Although not required for compatibility, the state must adopt program elements in this category that embody the basic health and safety aspects of NRC's program elements because of particular health and safety considerations.

The proposed changes are described below in the Rule-by-Rule Analysis section. Any instances where MDH has the discretion and decided to deviate from NRC requirements for these federal regulation changes are also described in that section. A detailed summary and discussion of NRC changes are found in the Federal Register using the citations in the below paragraphs 1 through 6.<sup>2</sup>

1. **Condition of Licenses** – § 70.32(a)(9)(i)(B) and (C), 86 FR 43397 and 86 FR 47209.
2. **Reports of transactions involving nationally tracked sources** – § 20.2207(h), 86 FR 43397 and 86 FR 47209.
3. **Training for authorized nuclear pharmacist** – § 35.55(a)(1), 86 FR 43397 and 86 FR 47209.
4. **Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist**, § 35.57(b)(2), 86 FR 43397 and 86 FR 47209.
5. **Requirements for criminal history record checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material**, § 37.27(c)(1), 86 FR 43397.
6. **Category 1 and Category 2 Radioactive Materials**, Appendix A to Part 37, 86 FR 67839.

## ALTERNATIVE FORMAT

Upon request, this information can be made available in an alternative format, such as large print, braille, or audio. To make such a request, please contact:

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 625 Robert Street North  
 P.O. Box 64975  
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<sup>2</sup> [govinfo.gov | U.S. Government Publishing Office](http://www.gpo.gov/fdsys/search/submitcitation.action?publication=FR)

(<http://www.gpo.gov/fdsys/search/submitcitation.action?publication=FR>.)

[From the main page select the desired volume (number preceding FR), and enter the page number (number following FR)].

Phone: (651) 201-4526

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## **PUBLIC PARTICPATION AND ADDITIONAL NOTICE**

The Request for Comments (RFC) was published in the State Register on June 5, 2023. Copies of the RFC were sent to 237 email addresses belonging to licensee contacts or individuals who have requested to be on the agency rulemaking mailing list. The department did not convene an advisory committee for this rule revision because the changes are required by NRC and are not negotiable.

The department will provide all notices required by statute. The proposed rules and Notice of Intent to Adopt will be sent to everyone who received copies of the RFC as provided above, including those people who have registered to be on the department's rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a. We will also give notice to the Legislature per Minnesota Statutes, section 14.116.

Also, when the department publishes the Notice of Intent to Adopt in the State Register, the department will provide a copy of the Notice by US mail or email to the 139 facilities that have an MDH-specific radioactive materials license, and the 52 that have a general license that requires registration. The facilities that will receive a notice include medical facilities, colleges and universities, research facilities, and industrial users. The notice will also be posted on the Radioactive Materials page of the MDH website.

## **STATUTORY AUTHORITY**

Minnesota Statutes, section 144.1202, subdivision 1, authorizes the governor, on behalf of the state, to enter into an agreement with NRC to administer this program, and subdivision 2 establishes the department's lead role in pursuing the agreement and authorizes the department to adopt rules necessary for that purpose. Minnesota Statutes, sections 144.1201 through 144.1205, expand on the requirements of the state's program and the department's rulemaking authority related to it.

## **OVERARCHING NEED AND REASONABLENESS OF NRC-REQUIRED REVISIONS**

**NEED:** The department must make most of these revisions or lose its standing as an Agreement State. State administration of this program is more cost efficient resulting in lower license fees for most licensees. If Minnesota did not administer this program, efficiency would be lost and license fees would be higher.

**REASONABLENESS:** Revising the rule to incorporate these changes is a reasonable approach because it will allow Minnesota to remain an Agreement State and keep costs lower for licensees.

## RULE-BY-RULE ANALYSIS

As previously stated, NRC requires most proposed rule changes to meet the compatibility requirements with its regulations. NRC categorizes rules that the states adopt as A, B, C, D, or Health and Safety (H&S) compatibility. The following describes NRC's various categories:

A = Basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. The program elements adopted by an Agreement State should be essentially identical to those of NRC to provide uniformity in the regulation of agreement material on a nationwide basis.

B = These program elements apply to activities that cross jurisdictional boundaries. These program elements have a particular impact on public health and safety and need to be adopted in an essentially identical manner in order to ensure uniformity of regulation on a nationwide basis.

C = These program elements are important for an Agreement State to have in order to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. The Agreement State program elements may be more restrictive than the NRC program elements provided that the essential objective is met, and the state requirements do not jeopardize an orderly pattern of regulation of agreement material on a nationwide basis.

D = Not required for purposes of compatibility.

H&S = Program elements identified by H&S are not required for purposes of compatibility; however, they do have particular health and safety significance. Although not required for compatibility, the state must adopt program elements in this category, that embody the basic health and safety aspects of NRC's program elements because of particular health and safety considerations.<sup>3</sup>

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

The changes proposed in this rulemaking are H&S (where MDH had some discretion with regard to the updates and language used to make them) and Compatibility B regulations.

### **4731.0590, subpart 2 (NRC 10 CFR 70.32(a)(9)(i)(B) and (C))**

MDH is choosing to make this H&S change to maintain compatibility and be consistent with a federal regulation reference update to the United States Code regarding the filing of a voluntary or involuntary petition for bankruptcy under any chapter of United States Code, title 11.

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<sup>3</sup> See SA-200, Compatibility Categories, and Health and Safety Identification for NRC Regulations and Other Program Elements, Section V. Guidance (available at <https://www.nrc.gov/docs/ML2018/ML20183A325.pdf>).

**4731.2705, subpart 9 (NRC 10 CFR 20.2207(h))**

NRC removed an outdated reporting requirement that was previously required of Agreement States as a Category B regulation. In response, the department is repealing the counterpart to that requirement in its regulations, which is found at subpart 9.

**4731.3395, subpart 1 (NRC 10 CFR 32.72(a))**

The department is required to make this Category B change to the United States Code of Federal Regulations by replacing section “207.20(a)” with “207.17(a)” as directed by NRC.

**4731.4413, subpart 2 (NRC 10 CFR 35.55(a)(1))**

The department is required to make this Category B change by updating the name of the American Council on Pharmaceutical Education to the Accreditation Council for Pharmacy Education (ACPE).

**4731.4414, item E (NRC – 10 CFR 35.57(b)(2))**

The department is required to make this Category B change to item E to reflect NRC’s revision in its rule of the phrase “or a permit issued by a Commission master material license of broad scope on or before October 24, 2005,” to “or a permit issued in accordance with a Commission master material broad scope license on or before October 24, 2005 . . . .”

The department is also amending 12 instances where the modifier “on or” was omitted in reference to dates in which certain licensed professionals had to obtain their licensure were exempt from additional training requirements. This change is needed to maintain compatibility with NRC regulations.

**4731.8025, subpart 3, item A (NRC – 10 CFR 35.27(c)(1))**

The department is required to make this Category B change to item A to reflect an NRC revision of the mailstop number where licensees must submit their fingerprinting information for background checks.

**4731.8140, subpart 2, item B (NRC – 10 CFR 37, Appendix A)**

The department is required to make this Category B change to item B to reflect an NRC revision to its sum of fractions formula.

## **REGULATORY ANALYSIS**

The department is amending its rules to incorporate recent required NRC regulation changes. These changes maintain standards necessary to promote and protect the radiological health and safety of the public, employee health and safety, and the environment. The proposed rule changes establish requirements that are an integral element in the Agreement State process.

Minnesota Statutes, section 14.131 sets out eight factors for a regulatory analysis that must be included in the SONAR. Paragraphs (1) through (8) below quote these factors and then give the department’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 primarily affect MDH radioactive material licensees. Examples of businesses that use radioactive materials: hospitals and clinics, manufacturing facilities, engineering companies, and universities and colleges.

The proposed changes will affect a licensee minimally. The rule requirements will be clearer and there are no discernible costs to licensees other than reviewing the changes.

**“(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 proposed changes are minor and administrative in nature. The enforcement costs of these new requirements are negligible. The department will require no increase in license fees to implement these revisions and enforce these rules.

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

MDH has little or no discretion in considering methods that would be less restrictive to the regulated parties. The only real alternative to amending the rule to be in compliance with NRC is giving up Minnesota’s Agreement State status. If the department lost the program, one major impact would be higher federal license fees for Minnesota licensees.

**“(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”**

As stated above, rather than amending the rules to maintain compatibility with NRC and other Agreement States, the state could terminate its agreement, and NRC would resume regulatory responsibility for Minnesota. If that action were taken, MDH would no longer regulate radioactive material use in the state and the state’s licensees would pay significantly higher license fees, but to the federal government instead of the state.

**“(5) the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals”**

All of the proposed changes are minor and the department does not anticipate that the amendments to these rules will result in increased compliance costs for licensees. Even if there were additional compliance costs, these revisions are required by NRC. If MDH fails to adopt them, NRC could revoke Minnesota’s Agreement State status and enforce the revised requirements against all regulated parties in Minnesota without MDH’s involvement. Accordingly, any additional compliance costs of these revisions will exist regardless of MDH’s adoption of these revisions and are thus not technically a consequence of this rulemaking.

**“(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 department does not adopt the rule amendments, the rules would fail to meet NRC compatibility requirements. NRC may terminate Minnesota’s agreement, resume regulatory



control over radioactive material use in Minnesota, and impose its higher licensing fees on Minnesota companies, institutions, and not-for profits who need to be licensed.<sup>4</sup>

**“(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”**

Any differences between the proposed rule changes and the federal regulations are non-substantive formatting changes that are necessary to conform to Minnesota’s rulemaking format and Minnesota rule drafting requirement.

**“(8) an assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule. . . . ‘Cumulative effect’ means the impact that results from incremental impact of the proposed rule in addition to other rules, regardless of what state or federal agency has adopted the other rules. Cumulative effects can result from individually minor but collectively significant rules adopted over a period of time.”**

The department is not aware of any other regulations related to the specific purpose of the rule.

The proposed rules must be compatible with NRC’s regulation in the Code of Federal Regulations Chapter 10 (10 CFR). Though the proposed regulations are similar to corresponding regulations in 10 CFR, the effect is not cumulative. The material that falls under the agreement between NRC and Minnesota is covered by Minnesota rules and not NRC regulations, so licensees in the state follow Minnesota Rules Chapter 4731, not the corresponding parts of 10 CFR. For material not covered by the agreement (e.g. distribution of exempt material and the nuclear power plants) the opposite is true, they follow 10 CFR, not Chapter 4731.

## **PERFORMANCE-BASED RULES**

As stated above, the proposed rules are based on federal regulations that the department is contractually required to adopt. The department thus has little flexibility in designing these rules.

## **CONSULTATION WITH MMB ON LOCAL GOVERNMENT IMPACT**

As required by Minnesota Statutes, section 14.131, the department consulted with Minnesota Management and Budget (MMB). MDH did this by sending MMB copies of the proposed rule and SONAR before MDH published its Notice of Intent to Adopt. The department will submit a copy of the cover correspondence and any response received from MMB to the Office of Administrative Hearing (OAH) at the hearing or with the documents it submits for Administrative Law Judge (ALJ) review.

## **DETERMINATION ABOUT RULES REQUIRING LOCAL IMPLEMENTATION**

As required by Minnesota Statutes, section 14.128, subdivision 1, the agency has considered whether these proposed rules will require a local government to adopt or amend any ordinance

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<sup>4</sup> See 42 U.S.C. § 2021(j)(1).

or other regulation to comply with these rules. The agency has determined that they do not because these rules amend a regulatory framework for the department's oversight of radioactive materials under its agreement with NRC. All regulatory functions are performed within the Department of Health and do not require local government enforcement.

Furthermore, the affected licensees are parties such as hospitals and clinics, manufacturing facilities, engineering companies, and universities and colleges in Minnesota. These parties are almost exclusively privately owned entities or individuals. While there are publicly owned entities, any action required by these parties' governing boards would be administrative in nature and not require a local government to adopt or amend an ordinance or other regulation. During the rulemaking process, the department received no comments that suggested that the rule would be affected in such a way that would require local governments to adopt or amend any ordinance or other regulation.

### **COST OF COMPLYING FOR SMALL BUSINESS OR CITY**

As required by Minnesota Statutes, section 14.127, MDH 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. MDH has determined that it will not. This determination is based on the same analysis provided above regarding the probable costs of complying with the proposed rule, as described in the Regulatory Analysis section of this SONAR on page 4.

### **LIST OF EXHIBITS**

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

### **CONCLUSION**

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

11/1/2024

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Date

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**Exhibit 1****Cross Reference and Compatibility Table**

<b>MN Rule Part</b>	<b>Title</b>	<b>10 CFR</b>	<b>Compatibility</b>
<b>4731.0590</b>	<b>License Conditions</b>		
Subp. 2	Bankruptcy	70.32(a)(9)	H&S
<b>4731.2705</b>	<b>National Source Tracking Transaction Reporting</b>	<b>20.2207</b>	<b>B</b>
Subp. 9	Initial inventory	20.2207(h)	B
<b>4731.3395</b>	<b>Specific License; Radioactive Drugs For Medical Use; Manufacture, Preparation, Or Transfer</b>	<b>32.72</b>	<b>B</b>
Subp. 1	Approval criteria	32.72(a)	B
<b>4731.4413</b>	<b>Authorized Nuclear Pharmacist Training</b>	<b>35.55</b>	<b>B</b>
Subp. 2	Certification requirements	35.55(a)	B
<b>4731.4414</b>	<b>Training; Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist</b>	<b>35.57</b>	<b>B except D [(a)(4) &amp; (b)(3)]</b>
<b>4731.8025</b>	<b>Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access to Category 1 or Category 2 Quantities of Radioactive Material</b>	<b>37.27</b>	<b>B</b>
Subp. 3	Procedures for processing of fingerprint checks	37.27(c)	B
<b>4731.8140</b>	<b>Category 1 and Category 2 Radioactive Materials</b>	<b>37 Appendix</b>	<b>B</b>
Subp. 2	Calculations concerning multiple sources or multiple radionuclides	37 Appendix A	B

The NRC categorizes rules that are adopted by agreement states as A, B, C, D, or H&S. The following describes the NRC's various categories:

- A = Basic radiation protection standard or related definitions, signs, labels, or terms necessary for the common understanding of radiation protection principles. The state program element should be essentially identical to that of NRC.
- B = Program element with significant direct trans-boundary implications. The state program element should be essentially identical to that of 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 NRC, provided the essential objectives are met.
- D = Not required for purposes of compatibility.
- 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.