DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

October 6, 2021

Delivered Electronically

Legislative Reference Library
645 State Office Building
100 Rev. Dr. Martin Luther King Jr. Blvd.
Saint Paul, MN 55155
sonars@lrl.leg.mn

Re: In The Matter of the Proposed Rules of the Department of Health Governing Radioactive Materials; Revisor's ID Number 4671

Dear Librarian:

The Minnesota Department of Health intends to adopt rules governing radioactive materials. We plan to publish a Notice of Intent to Adopt Rules Without A Public Hearing in the October 11, 2021 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 an electronic copy of the Statement of Need and Reasonableness at the same time we are mailing our Notice of Intent to Adopt Rules.

If you have questions, please contact me at 651-201-4526.

Your very truly,

/s/ Brandon Juran
Industrial Hygienist 3

Enclosure: Statement of Need and Reasonableness

STATEMENT OF NEED AND REASONABLENESS

Proposed Amendment to Rules Governing Radioactive Materials, Minnesota Rules, 4731; Revisor's ID Number R-4671; OAH Docket No. 82-9000-37774

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. The proposed changes also include MDH-initiated changes to clarify existing requirements and to correct editorial issues. 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 the 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 December 21, 2021.[1]

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 the 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

[1] *See* Review Summary Sheets for Regulation Amendments (RATS) 2018-1 through 2020-3 (available at https://scp.nrc.gov/rss_regamendents.html).

program elements if the essential objective is met and the State requirements do not jeopardize an orderly pattern of regulation of agreement material on a nationwide basis.

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 the NRC pursuant to the Atomic Energy Act or provisions of the Code of Federal Regulations (CFR). Since these are reserved for NRC, we are not proposing rules designated as this category and 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 the NRC's program elements because of particular health and safety considerations.

The following summaries explain NRC's eight federal regulation changes that MDH proposes to incorporate into its rules. Any instances where MDH has the discretion and decided to deviate from NRC requirements for these federal regulation changes are described below in the Rule-by-Rule Analysis section.

1. **Medical Use of Byproduct Material –** Medical Event Definitions, Training and Experience, and Clarifying Amendments, 10 CFR Parts 30, 32, and 35, 83 FR 33046. To maintain compatibility and be consistent with these federal regulation changes, MDH is making the following changes:

    - Changing the requirements for generator use by adding a reporting requirement for breakthrough of molybdenum-99 in molybdenum-99/technetium-99m generators and contamination of strontium-82 and strontium-85 in strontium-82/rubidium-82 generators; requires that molybdenum-99 breakthrough testing for molybdenum-99/technetium-99m generators be performed for each eluate.[2]
    - Updating the qualification requirements for medical use of radioactive materials by removing the preceptor requirement for radiation safety officers, authorized users, authorized nuclear pharmacists, and authorized medical physicists who are board certified by a recognized board; modifying the written attestation statement for people not certified by a recognized board;
    - Allowing a residency program director to sign the written attestation for authorized users, except for use of strontium-90 for ophthalmic use; allows experienced radiation safety officers, authorized users, authorized nuclear pharmacists, and authorized medical physicists to continue use of radioactive material without meeting the new training requirements;
    - Adding definitions, duties, and qualification requirements for the new positions of associate radiation safety officer and ophthalmic physicist;

[2] Eluate is a solution obtained by extracting one material from another, usually be means of a solvent. (American Heritage Dictionary Entry: elution (ahdictionary.com) (https://ahdictionary.com/word/search.html?q=elution)

- Adding a definition for preceptor; reducing the number of subcategories for authorization to use unsealed radioactive material requiring a written directive from four to three by combining the two parenteral authorizations.
- Distinguishing the use of sealed sources for diagnostic use not in medical devices from sealed sources for diagnostic use in medical devices and specifying the requirements for both types.
- Clarifying that licensees who manufacture, prepare, or transfer for commercial distribution radioactive drugs must follow the labeling requirement they committed to in their application.
- Allowing the use of brachytherapy sources from a different manufacturer, or different model number than what is listed on the license, if the source is listed in the sealed source and device registry and in a quantity and for an isotope authorized on the license.
- Requiring procedures for a written directive to include determining if a medical event has occurred.
- Modifying the written directive requirements for permanent implant brachytherapy; requiring a post-implant verification for permanent implant brachytherapy; and revising the medical event reporting requirements for permanent implant brachytherapy.
- Restricting the use of check, calibration, transmission, and reference material to non-medical use, except in accordance with 4731.4460; clarifying that the check, calibration, transmission, and reference material that are listed in this rule part are not required to be listed on the license.
- Requiring manufacturer training for operators of new or upgraded therapy devices; clarifying what is required in a full inspection for certain therapy devices; and extending the allowable full-inspection servicing interval from five years to seven years for gamma stereotactic radiosurgery units.
- Clarifying record keeping requirements for radiation safety officers and safety instruction records.
- Revising the medical event reporting requirements for permanent implant brachytherapy.

2. **Organizational Changes**, 10 CFR Parts 37, 40, 70, and 71, 83 FR 58721. NRC made recent organizational changes. MDH is updating NRC office information where referenced in the rules.

3. **Miscellaneous Corrections,** 10 CFR Parts 1, 2, 34, 37, 50, 71, 73, and 140, 83 FR 30285. To maintain compatibility with these NRC changes, MDH is making the following changes:
   - updating where to submit the certification of reviewing officials for licensees requiring enhanced security;
   - clarifying what is required to protect the list of individuals that are approved for unescorted access; and
   - updating references to reflect NRC organizational changes.

4. **Finger Print Cards,** 10 CFR Parts 2, 21, 31, 50, 52, 73, and 110, 84 FR 63565. These changes update the process to submit fingerprint cards to NRC for processing. MDH

licensees must submit fingerprint cards to NRC. MDH is amending its rules accordingly to reflect this new process. MDH has no discretion over these changes.

5. **Organizational Changes and Conforming Amendments**, 10 CFR Parts 1, 2, 37, 40, 50, 51, 52, 55, 71, 72, 73, 74, 100, 140, and 150, 84 FR 65639. These miscellaneous housekeeping changes relate to organizational changes within the NRC. MDH is amending its rules to reflect the organizational changes where referenced.

6. **Individual (Personnel) Monitoring Devices**, 10 CFR Parts 34, 36, and 39, 85 FR 15347. These changes modify the personnel monitoring requirements for radiography, well logging, and irradiator licensees to allow for direct reading personnel monitoring devices that do not need to be returned and processed for evaluation. MDH is amending its rules accordingly to maintain compatibility with NRC regulations.

7. **Social Security Number Fraud Prevention**, 10 CFR Parts 9 and 35, 85 FR 33527 and 85 FR 44685. NRC changes now prioritize the use of identification numbers that are not social security numbers when identifying patients to comply with the Social Security Number Fraud Prevention Act of 2017. MDH is amending its rules to comply with these changes.

8. **Miscellaneous Corrections**, 10 CFR Parts 1, 2, 19, 20, 21, 30, 34, 35, 40, 50, 51, 52, 60, 61, 62, 63, 70, 71, 72, 73, 74, 75, 76, 110, and 140, 85 FR 65656. NRC updated their regulations to redesignate footnotes, correct references, typographical errors, nomenclature, titles, email addresses, and contact information. MDH amendments include correcting the name for the Council on Postdoctoral Training of the American Osteopathic Association and correcting the specific activity for Samarium-147.

Detailed summaries and discussions of NRC changes are found in the Federal Register using the citations in paragraphs 1 through 8.[3]

In addition to the above, the department proposes changes that clarify existing requirements and make editorial corrections. Those proposed changes are listed below in the Rule-by-Rule Analysis section.

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:

Brandon Juran
Minnesota Department of Health
625 Robert Street North
P.O. Box 64975
St. Paul, Minnesota 55164-0975

[3] govinfo.gov | U.S. Government Publishing Office
(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
FAX: (651) 201-4606

STATUTORY AUTHORITY

Minnesota Statutes, sections 144.1201 through 144.1205, authorize the department to enter into an agreement with NRC to assume regulatory authority over certain nuclear materials. These sections also authorize rulemaking to allow Minnesota to assume regulatory authority under the agreement with the NRC. Minnesota Statutes, section 144.1202, subdivision 1, authorizes the governor to enter into an agreement with NRC or administer this program, and subdivision 2 authorizes rulemaking.

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. MDH also is correcting some errors in the rule.

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 extent to which the proposed changes will affect a licensee will depend on the type of license and the material the licensee possesses. Examples of costs to licensees: increased breakthrough testing of molybdenum-99/technetium-99m generators, updating written directive procedures, reporting to MDH and distributers if molybdenum-99/technetium-99m generators fail a breakthrough test. Medical users will be most affected.

Ultimately, the largest group affected by these rules is the Minnesota general public since the purpose of the rules is to protect both licensees and the general public from unwanted or unsafe exposures to radioactive materials. A major focus of this rule is minimizing worker exposures.

"(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"

Increased cost of enforcement of these new requirements is small. Examples of the small costs to the department are training inspectors on the updated requirements, updating medical training forms for changes in preceptor requirements, and answering questions about the rule changes

from licensees. The enforcement costs are funded through annual license fees. 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 the NRC is giving up Minnesota's Agreement State status. If the department lost the program, one major impact would be higher license fees.

"(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 department 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"

Most 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.

"(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.[4]

"(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 majority of the 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. Any exceptions are described in further detail in the Rule-By-Rule analysis section below.

"(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

[4] *See* 42 U.S.C. § 2021(j)(1).

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 the 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 the NRC and Minnesota is covered by Minnesota rules and not the 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. These rule parts are performance based: 4731.4409, 4731.4405 subpart 1, 4731.4477, 4731.4456 item B.

PUBLIC PARTICPATION AND ADDITIONAL NOTICE

The Request for Comments was published in the State Register on May 17, 2021. The notice was sent to 251 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 has 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 147 facilities that have an MDH-specific radioactive materials license, and the 50 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.

CONSULTATION WITH MMB ON LOCAL GOVERNMENT IMPACT

As required by Minnesota Statutes, section 14.131, the Department has consulted with Minnesota Management and Budget (MMB). We did this by sending MMB copies of the proposed rules and the SONAR on September 10, 2021, before publishing the Notice of Intent to Adopt Rules Without a Hearing. In a Memorandum to MDH dated September 16, 2021, MMB

concluded that these proposed rule amendments would have immaterial costs to local units of government. A copy of MMB's response is attached as Exhibit 2.

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 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 the 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 administerial 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 Statues, 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 mirrors the probable costs of complying with the proposed rule, as described in the Regulatory Analysis section of this SONAR at item 5.

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. Even where NRC gives some discretion to MDH regarding the Compatibility C and D requirements, the rules regarding training and qualifications of individuals handling or utilizing radioactive materials "must be at least as stringent as" NRC regulations of these areas.[5] The need and reasonableness of the NCR D category items and any instances where the department went beyond the essential program elements for NRC C category items are discussed below.

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

RULE-BY-RULE ANALYSIS

[5] *See* Minn. Stat. § 144.1203

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 H&S compatibility. The following describes the 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 the 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 H&S significance. Although not required for compatibility, the State must adopt program elements in this category, that embody the basic H&S aspects of the NRC's program elements because of particular H&S considerations.[6]

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 following changes are Compatibility C or D regulations where MDH had some discretion with regard to the updates and language used to make them. In addition, these changes include amendments to ensure consistency within the rule in light of other required changes.

4731.0100, subpart 174 (NRC – 10 CFR 35.2)

MDH is adding associate radiation safety officer to the definition of preceptor. During the regulation change in 2019, NRC added the position of associate radiation safety officer. 10 CFR 35.24 (compatibility H&S) adds the ability for medical licensees to appoint associate radiation safety officers in addition to radiation safety officers. The same regulation change 35.50 (compatibility B) adds the required training for associate radiation safety officer to the training for radiation safety officer. In this change the regulations allow an associate radiation safety

[6] *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).

officer to act as a preceptor for proposed radiation safety officers and associate radiation safety officers. Since MDH needs to add associate radiation safety officers to the rule to meet compatibility requirements and the associate radiation safety officer is able to act as preceptor, for accuracy of the definition it is needed and reasonable to add associate radiation safety officer to the definition.

4731.2750 Annual Limits on Intake and Derived Air Concentrations

The department is fixing a typo in the listing in the table for Barium-133m where the "m" is missing from the listing. This correction is needed to clearly identify the nuclide by its correct name, and it is reasonable to do it in the rule part that incorrectly identifies it.

4731.3330, subpart 4, item B

The department is correcting an incorrect rule reference. This is needed to clearly identify the rule reference, and it is reasonable to do it in the rule part that contains the incorrect reference.

4731.4403 Specific License; Medical Use of Radioactive Materials

4731.4403, subpart 2 (NRC – 10 CFR 35.12)

The department is removing the requirement to submit a copy of a renewal or amendment application for a medical use license under items B and C. MDH license reviewers do not need a duplicate copy of the application to do the review and do not keep two copies of the application. There is no practical reason to have the extra copy submitted and it wastes time for the applicant to create a copy and MDH staff time to dispose of the extra copy, therefore this change is needed and reasonable.

The department is adding to item B a requirement to submit with a medical use license application the training and experience qualifications for associate radiation safety officers and ophthalmic physicists. These new positions must be added to other parts of the rule to meet compatibility requirements. The people in these positions have important health and safety roles and will be specifically listed on the license, indicating they have met the qualifications. Once listed on the license these people will be considered qualified for the use of the material. They can then use the MDH license to demonstrate their qualifications when seeking to be added to licenses issued by other agreement states or NRC.7 An applicant for a medical use license is required to submit documentation of the other named positions associated with a medical use license (i.e., radiation safety officer, authorized users, authorized medical physicist, and authorized nuclear pharmacists). MDH needs to verify these peoples' qualifications prior to adding them to the radioactive materials license. Therefore it is needed and reasonable to require that this documentation be submitted with a license application.

The department is specifying in item C that if a licensee submits a letter requesting an amendment or renewal to their license instead of using the prescribed form, the licensee needs to submit the information included in the application form. This clarifies what information needs to be submitted if a licensee is requesting an amendment or renewal. This is needed and reasonable so licensees know what to submit with their amendment or renewal request.

7 *See, e.g.*, 10 C.F.R. 35.13(b).

At item D, the department is adding that, if a licensee's part 4731.4404 use (i.e., other medical uses not specifically addressed in parts 4731.4432 to 4731.4479) differs from certain listed rule parts, the licensee needs to describe how the use is different. This is already required where the use is not addressed in the listed parts. A use that is different from what is addressed in a rule part is logically equivalent to one that is not addressed. It is necessary and reasonable to clarify this concept in the rule part so that licensees can understand its requirements.

The department is also adding parts 4731.4500 to 4731.4528 (records and reports) to the list of rule parts cited in item D that can invoke the description requirement. The department is also requiring applicants for 4731.4404 uses to identify and commit to following applicable radiation safety program requirements for the applicable medical uses. The medical use specified in 4731.4404 allows medical licensees to use radioactive materials in emerging technologies where there are not specific regulations for the new type of use. These changes are needed and reasonable to allow MDH to review medical uses under part 4731.4404 in order to evaluate if the material will be used safely prior to being approved on a license.

4731.4403, subpart 3 (NRC – 10 CFR 35.13)

The department is adding the new ophthalmic physicist position to item B's list of users who generally may not work under a license without a license amendment. The ophthalmic physicist is a new type of user under a medical use license that is named on the license. To approve these new users and add them to the license, MDH needs the licensee to submit an amendment request so we can review and approve the changes. It is reasonable to place this requirement in the rule.

The department is also specifying in subitems (1) and (2) to item B that a separate license or permit issued by the commissioner satisfies the exception allowing users to use material before being listed on the subject license. Minnesota is an agreement state, so this would be allowed since a license issued by an agreement state is currently in rule. The rule change just makes it more clear.

The department is also adding an additional exception to the item B requirement for users who are authorized on licenses issued by commercial pharmacies that are authorized to identify authorized nuclear pharmacists. This addition is reasonable, as it is consistent with the other exceptions to item B because, like those, it only applies to individuals who are authorized users under NRC-approved requirements. This change is needed so that licensees can let those people work prior to being listed on their licenses.

At item D, the department is adding the newly created position of associate radiation safety officer to the list of positions that cannot work under a license without an amendment adding them to the license. Pursuant to other proposed additions to the rule, associate radiation safety officers must be identified on a license for the types of uses for which they have been assigned.[8] This change to item D is thus needed and reasonable because, in order to approve an associate radiation safety officer and add them to the license, MDH needs the licensee to submit an amendment request.

The department is also adding the allowance at item I for medical licensees to receive sealed brachytherapy sources from a different manufacturer or a different model number for the same

8 *See, e.g.*, Proposed Part 4731.0100, subp. 19a.

type of source approved on their license. This is a Compatibility D change that was made by the NRC to allow licensees to get needed brachytherapy sources to treat patients, even if their usual supplier is having supply issues. For this allowance, the NRC requires the licensee to notify them within 30 days. Instead of a notification within 30 days, the department is requiring an amendment to add the new sources to the license be submitted within 30 days. This gives licensees the flexibility to use sources for needed medical procedures without having to wait for an amendment, but allows the department to amend the license to reflect the current use of materials. This is needed and reasonable to allow important patient treatment even if there is a brachytherapy source supply issue.

4731.4403, subpart 4 (NRC – 10 CFR 35.14)

The department is adding associate radiation safety officer and ophthalmic physicist to the list of user types that require notification if there is a name change. These people are listed on the license, and, if they have a name change, the license needs to be updated so they are correctly listed on the license. This is needed and reasonable to make sure users are accurately listed on the license.

The department is also requiring notification within 30 days if the licensee is allowing someone to work under subpart 3, item B as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist without being listed on the license. This requirement is needed and reasonable to allow the department to verify the person is qualified for the use of the material while still allowing the licensee to use the person prior to being listed on the license.

4731.4403 subpart 5 (NRC – 10 CFR 35.15)

Adds ophthalmic physicist to the list of people for whom Type A broad scope licensees are not required to give notice to MDH if the person has a name change. Like other medical user types, Type A broad scope licensees will be able to verify the qualifications of ophthalmic physicists under their licenses, and these people are not listed on the licenses. Since these people are not listed on the license and the records of their qualifications are kept with the licensee, there is no need for MDH to be notified if these people have a name change. This is needed and reasonable to continue to allow Type A broad scope licensees to manage their own users.

4731.4405, Subpart 1 (NRC – 10 CFR 35.24)

For item C the department is deleting an authorized user as a person who can fill in as a radiation safety officer. Anyone filling in as a radiation safety officer should be qualified for that position. Authorized users can fill this role if they have the additional training in radiation safety, regulatory issues, and emergency procedures. This is a Compatibility D requirement and is needed and reasonable to make sure the licensee has a qualified person overseeing the radiation protection program at all times.

4731.4423 subpart 2 (NRC – 10 CFR 35.65(b))

In item A, the department is specifying that the radioactive material in sources authorized under this part can only be used for medical use subject to the requirements of 4731.4460 (use of sealed sources for diagnosis), which subjects the use to supervision pursuant to part 4731.4461. This clarifies that all radioactive material for medical use must be under the supervision of an

authorized user. This part still allows the use of those sources without being specifically listed on the license, but if the source is used for medical use, it is considered a use under 4731.4460. This is needed and reasonable to make sure radioactive material used for medical use is done under the supervision of an authorized user.

The department is also adding an item B that prohibits bundling of sources under this part to create a source that has a higher activity than is allowed under this part. This part allows some sources with limited activity to be used by a medical use license without being specifically listed on the license. This part was not intended to allow sources to be bundled to essentially create sources that would not otherwise be allowed under this part. If the licensee needs sources exceeding the activity allowed under this part, they can request authorization and have the material specifically listed on the license. This is needed and reasonable to ensure that sources exceeding the allowance under this part are licensed appropriately.

4731.4423 subpart 3 (NRC – 10 CFR 35.65(c))

This subpart clarifies that the sources used under this part do not need to be listed on the license. The allowance in subpart 1, implies that these sources are allowed to be possessed and used without being listed on the license and that is the current practice. This subpart explicitly states that practice to make it clear that this is allowed. It is needed and reasonable to make the rule more clear.

4731.4500 subpart 1 (NRC – 10 CFR 35.2024)

This subpart requires a record to be kept of the appointing of the associate radiation safety officer. This requirement is similar to that required for the radiation safety officer. This is needed and reasonable so there is a record for the licensee, associate radiation safety officer, and MDH to review to determine the duties that were assigned to the associate radiation safety officer.

4731.4510 (NRC – 10 CFR 35.2310)

The proposed addition to this part clarifies that the operational instructions required by part 4731.4466 must be maintained in addition to the safety instructions. Required changes to part 4731.4466 use the term “operational and safety instructions” to refer to these items. This proposed revision to part 4731.4510 makes the terms consistent between the two parts. This is needed and reasonable to make it more clear what must be maintained in the record.

4731.4524 (NRC – 10 CFR 35.2655): This record keeping change is being made to maintain consistency between this part’s inspection record requirement and part 4731.4477’s newly modified inspection requirements. The modifications to the inspection requirements extend the time between certain inspections to seven years while retaining the five-year interval for others. The reference in this part to a record of the five-year inspections is thus no longer accurate. This rule is needed and reasonable to ensure consistency with the other rule changes.

LIST OF EXHIBITS

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

2. MMB Memorandum re Review of Proposed Amendment to Rules Governing Radioactive Materials

CONCLUSION

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

October 4, 2021

Jan K. Malcolm
Commissioner of Health

DEPARTMENT OF HEALTH

Exhibit 1: Cross Reference and Compatibility Table

MN Rule Part	Title	10 CFR	Compatibility
4731.0100	**Definitions**		
Subp. 19a	Associate radiation safety officer	35.2	B
Subp. 157a	Ophthalmic physicist	35.2	B
Subp. 174	Preceptor	35.2	D
4731.0406	**General license; NRC-approved package**	**71.17**	**B**
Subp. 3	Compliance with conditions	71.17(c)	B
4731.0419	**Advance Notification of Shipment of Irradiated Fuel and Nuclear Waste**	**71.97**	**B**
Subp. 3	Procedures for submitting notification	71.97(c)	B
Subp. 6	Cancellation notice	71.97(f)	B
4731.0422	**A1 and A2 Values for Radionuclides**	**Part 71 Appendix A**	**B**
Subp. 2	Specific Activity	Part 71 Appendix A	B
4731.2750	**Annual Limits on Intake and Derived Air Concentrations**	**Part 20 Appendix B**	**A**
Subp. 7	Table of ALIs and DACs	Part 20 Appendix B	A
4731.3075	**Terms and conditions of licenses**	**30.34**	**Various**
Subp. 7	Molybdenum-99 requirement	30.34(g)	B
4731.3330	**Specific License; Certain Devices Containing Radioactive Materials; Manufacture or Initial Transfer**	**32.51 – 32.51a**	**B**
Subp. 4	Transfer for use under general license; requirements	32.51a(a)	B
4731.3395	**Specific License; Radioactive Drugs for Medical Use; Manufacture, Preparation, or Transfer**	**32.72**	**B**
Subp. 1	Approval criteria	32.72(a)	B
Subp. 2	Pharmacy license	32.72(b)	B
Subp. 3a	Labeling requirements	32.72(d)	B
4731.4170	**Personnel Monitoring**	**34.47**	**C**
Subp. 1	Monitoring Requirements	34.47(a)	C
Subp. 4	High Readings	34.47(d)	C
Subp. 6	Report Retention	34.47(f)	C
4731.4310	**Records; Personnel Monitoring**	**34.83**	**C**
4731.4403	**Specific License; Medical Use of Radioactive Materials**	**35.11 – 35.19**	**Various**

MN Rule Part	Title	10 CFR	Compatibility
Subp. 2	Application for license, amendment, or renewal	35.12	D
Subp. 3	License amendments	35.13	D
Subp. 4	Notifications of changes	35.14	D
Subp. 5	Exemptions; broad scope license	35.15	D
4731.4405	**Radiation Protection Program**	**35.24 – 35.26**	**Various**
Subp. 1	Authority and responsibilities	35.24	D [(a), (c), (d), (e), (f), & (h)] H&S [(b) & (g)]
4731.4408	**Written Directives**	**35.40**	**Various**
Subp. 2	Content requirements	35.40(b)	H&S
4731.4409	**Procedures for Administrations Requiring Written Directive**	**35.41**	**H&S [(a) & (b)] D[1] [(c)]**
4731.4411	**Radiation Safety Officer and Associate Radiation Safety Officer Training**	**35.50**	**B**
Subp. 1	Training and education 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		
4731.4414	**Training; Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist**	**35.57**	**B except D [(a)(4) & (b)(3)]**
4731.4423	**Authorization for Calibration, Transmission, and Reference Use**	**35.65**	**D**
Subp. 1	Check, calibration, transmission, and reference use	35.65(a)	D
Subp. 2	Restriction of use	35.65(b)	D
Subp. 3	Listing on license	35.65(c)	D

[1] This column identifies NRC compatibility categories for the entire referenced rule part, not just the provisions being changed per this proposed rule revision. For details about the compatibility requirement for the particular provisions that MDH proposes to modify via this rulemaking, one must review the RATS themselves alongside the summary and discussion of the most recent NRC changes contained in in the Federal Register for the respective regulation. *See*, RATS 2018-1 through 2020-3 (available at https://scp.nrc.gov/rss_regamendents.html); U.S. Government Publishing Office, https://www.govinfo.gov/#citation?csh={%22collection%22:%22FR%22,%22searchCriteria%22:[],%22selectOptions%22:[]}.

MN Rule Part	Title	10 CFR	Compatibility
4731.4433	**Uptake, Dilution, and Excretion Studies; Training**	**35.190**	**B**
Subp. 1	Training and education requirements		
4731.4435	**Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentration**	**35.204**	**H&S [(a), (b), & (e)] D [(c) & (d)]**
4731.4436	**Imaging and Localization Studies; Training**	**35.290**	**B**
Subp. 1	Training and education requirements		
Subp. 2	Certification requirements		
4731.4440	**Unsealed Radioactive Material; Written Directive Required**	**35.300**	**B**
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 (1.22 GBq); Written Directive Required; Training**	**35.394**	**B**
4731.4446	**Parenteral Administration of Unsealed Radioactive Material; Written Directive Required; Training**	**35.396**	**B**
4731.4450	**Use of Brachytherapy Sources**	**35.400**	**[C]**
4731.4456	**Decay of Strontium-90 Sources for Ophthalmic Treatments**	**35.433**	**B [(a)] H&S [(b)] D [(c)]**
4731.4458	**Manual Brachytherapy Training**	**35.490**	**B**
Subp. 1	Training and education requirements		
Subp. 2	Certification requirements		
4731.4459	**Ophthalmic Use of Strontium-90; Training**	**35.491**	**B**
4731.4460	**Use of Sealed Sources and Medical Devices for Diagnosis**	**35.500**	**C**
4731.4461	**Use of Sealed Sources for Diagnosis; Training**	**35.590**	**B**
4731.4463	**Use of a Sealed Source; Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit**	**35.600**	**C**

MN Rule Part	Title	10 CFR	Compatibility
4731.4466	**Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units; Safety Procedures and Instructions**	**35.610**	**H&S [(a), (b), (c), (d), (e), & (g)] D [(f)]**
4731.4477	**Teletherapy and Gamma Stereotactic Radiosurgery Units; Full-inspection Servicing**	**35.655**	**H&S [(a) & (b)] D [(c)]**
Subp. 1	Inspection and servicing required	35.655(a)	H&S
Subp. 2	Qualified inspectors	35.655(b)	H&S
4731.4479	**Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units; Training**	**35.690**	**B**
Subp. 1	Training and education requirements		
Subp. 2	Certification requirements		
4731.4500	**Radiation Protection Program Records**	**35.2024 – 35.2026**	**D**
Subp. 1	Records of authority and responsibilities; radiation protection programs	35.2024	D
4731.4510	**Safety Instruction Records**	**35.2310**	**D**
4731.4524	**Full-inspection Servicing Records; Teletherapy and Gamma Stereotactic Radiosurgery Units**	**35.2655**	**D**
4731.4525	**Medical Event; Report and Notification**	**35.3045**	**C**
Subp. 1	Report required	35.3045(a)	C
Subp. 7	Individual identification	35.3045(g)	C
4731.4526	**Dose to an Embryo/Fetus or Child; Report and Notification**	**35.3047**	**C**
Subp. 6	Individual identification	35.3047(f)	C
4731.4528	**Report and Notification for and Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations**	**35.3204**	**C**
Subp. 1	Telephone notification	35.3204(a)	C
Subp. 2	Written report	35.3204(b)	C
4731.6180	**Personnel Monitoring**	**36.55**	**H&S**
Subp. 1	Irradiator Operations	36.55(a)	H&S
4731.7220	**Personnel Monitoring**	**39.65**	**C**
4731.8015	**Access Authorization Program Requirements**	**37.23**	**B (except as noted)**

MN Rule Part	Title	10 CFR	Compatibility
Subp. 2	Reviewing Officials	37.23(b)	B [(b)(1), (b)(2), (b)(4), (b)(5)] C [(b)(3)]
4731.8025	**Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access to Category 1 or Category 2 Quantities of Radioactive Material**	**37.27**	**B**
Subp. 3	Procedures for processing of fingerprint checks	37.27(c)	B
4731.8055	**General Security Program Requirements**	**37.43**	**B (except as noted)**
Subp. 4	Protection of information	37.43(d)	C
4731.8115	**Advance Notification of Shipment of Category 1 Quantities of Radioactive Material**	**37.77**	**B (except as noted)**
Subp. 2	Procedures for submitting advance notification	37.77(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 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 the 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 H&S significance. Although not required for compatibility, the State must adopt program elements in this category, that embody

the basic H&S aspects of the NRC's program elements because of particular H&S considerations.

Radioactive Materials Unit
Minnesota Department of Health
PO Box 64975
St. Paul, MN 55164-0975
651-201-4400
health.ram@state.mn.us
www.health.state.mn.us

08/30/2021

To obtain this information in a different format, call: 651-201-4400. Printed on recycled paper.

Office Memorandum

Date: 9/16/2021

To: Josh Skaar
Attorney, Legal Unit
Minnesota Department of Health

From: Lindsay Dean
Executive Budget Officer
Minnesota Management & Budget

Subject: M.S. 14.131 Review of Proposed Amendment to Rules Governing Radioactive Materials, Minnesota Rules, 4731; Revisor's ID Number R-4671

Background

The Minnesota Department of Health (MDH) 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. The proposed changes also include MDH-initiated changes to clarify existing requirements and to correct editorial issues. Pursuant to Minnesota Statutes 14.131, MDH has requested Minnesota Management and Budget evaluate the proposed amendments for fiscal impact and benefits on units of local government.

Evaluation

On behalf of the Commissioner of Minnesota Management and Budget, I have reviewed the proposed changes and the draft of the SONAR to explore the potential fiscal impact these changes may have on local governments.

MDH is amending its rules to incorporate recent required NRC regulation changes and correcting some errors in the rule. The rules primarily affect MDH radioactive material licensees, such as hospitals and clinics, manufacturing facilities, engineering companies, and universities and colleges. The extent to which the proposed changes will affect a licensee will depend on the type of license and the material the licensee possesses. While there are some publicly owned entities, most of the proposed changes are minor and MDH does not anticipate that the amendments to these rules will result in increased compliance costs for licensees.

The proposed rules do not require a local government to adopt or amend any ordinance or other regulation to comply with these rules. These rules amend a regulatory framework for MDH's oversight

of radioactive materials under its agreement with the NRC. All regulatory functions are performed within MDH and do not require local government enforcement.

Based upon this information and consultation with agency staff, I believe the rule amendments proposed will have immaterial costs to local units of government.

Sincerely,

Lindsay Dean
Executive Budget Officer

cc: Angela Vogt, Executive Budget Coordinator, Minnesota Management and Budget