OAH 82-9000-37774
Revisor R-4671

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of Proposed Rules Governing Radioactive Materials, Minnesota Rules, Chapter 4731	**ORDER ON REVIEW OF RULES UNDER MINN. STAT. § 14.26**

The Minnesota Department of Health (Department) seeks review and approval of the above-entitled rules, which the Department adopted pursuant to Minn. Stat. § 14.26 (2020). On December 14, 2021, the Department filed with the Office of Administrative Hearings all documents required by Minn. Stat. § 14.26 and Minn. R. 1400.2310 (2021).

Based upon a review of the written submissions and filings, Minnesota Statutes, and Minnesota Rules,

IT IS HEREBY DETERMINED:

1. The Department has the statutory authority to adopt the rules.

2. The rules were adopted in compliance with the procedural requirements of Minnesota Statutes §§ 14.001 – 14.70 (2020), and Minnesota Rules Chapter 1400.0200 – 1400.8613 (2021).

3. The record demonstrates the rules are needed and reasonable.

IT IS HEREBY ORDERED THAT:

The rules are **APPROVED**.

Dated: December 16, 2021

BARBARA J. CASE
Administrative Law Judge

[168275]

Rule Filing Checklist for Rules Adopted Without a Public Hearing
Minn. Stat. 14.26; Minn. R. 1400.2310

Date of submission to OAH must be within **180 days of close of public comment period** (Minn. Stat. § 14.26, subd. 1)

Agency and Title of Rules: Department of Health Radiation Safety

OAH Docket Number: 82-9000-37774

Revisor's Number: 4671

Received: 12/15/21

Due 14 Calendar Days After Receipt: 12/29/21

The agency must file the following documents with the office:

_x_ **A. Request for Comments published in State Register**.
(published on 5/17/21)

_x_ 1. Description of subject matter of the proposal

_x_ 2. Types of groups and individuals likely to be affected

_x_ 3. Indicates where, when, and how person may comment

_x_ 4. Whether and how drafts of any proposal may be obtained from agency

_x_ 5. Published in State Register at least **60 days** before publication of Notice of Intent to Adopt or Notice of Hearing

_x_ 6. Notice of Intent to Adopt/Notice of Hearing published on 10/11/21

___ 7. Published within **60 days** of effective date of any new or amendatory law requiring rules to be adopted (§ 14.101)

___ **B. Petition for rulemaking, if rule is proposed in response to it**.

_x_ **C. Proposed rule with Revisor's approval**. *Dated:* 8/16/21

[168313/1]

_x__ **D. SONAR**. *Dated:* 10/4/21 draft; 10/11/21 (final)

General Requirements (1400.2070)

__x_ 1. Citations to manuals or treatises the agency anticipates relying on

__x_ 2. Citations to statutes or case law the agency anticipates relying on

___ 3. If hearing scheduled, list of any anticipated nonagency witnesses and summary of testimony

_x__ 4. Citation to agency's grant of statutory authority to adopt the rule and effective date of statutory authority if grant made after January 1, 1996.

_x__ 5. Date SONAR available for public review

Specific Requirements (14.131)

_x__ 1. Description of classes of persons affected, including those who will bear costs and those who will benefit

_x__ 2. Probable costs to the agency to implement and enforce rule

_x__ 3. Whether there are less costly / less intrusive methods

_x__ 4. Description of alternative methods seriously considered and why rejected

_x__ 5. Probable cost of complying with proposed rule

_x__ 6. Probable costs or consequences of not adopting the proposed rule

_x_ 7. Assessment of any difference between proposed rule and existing federal regulations and analysis of need and reasonableness of each difference

_x_ 8. Assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule

_x__9. Statement of how agency considered and implemented performance-based review (*See* § 14.002)

_x__ 10. Agency's efforts to provide additional notice to affected persons

_x_ 11. Consultation with Minnesota Management and Budget regarding fiscal impact on units of local government

_x 12. Notice sent to Legislative Reference Library when notice of hearing mailed

_x_ 13. Analysis under Minn. Stat. § 14.127 (small businesses and small towns)

_x_ 14. Analysis under Minn. Stat. § 14.128 (adopt or amend local ordinance)

_x__15. Any other information required by law or rule

_x__ **E. Notice of intent to adopt rules as mailed and published in State Register**

Notice must be **published** at least **30 days** before end of comment period and **mailed** at least **33 days** before end of comment period. (1400.2080 subp. 3, 6)

Notice must also be published within **18 months** of effective date of specific law authorizing rulemaking if not relying on general rulemaking authority (14.125)

Published on: 10/11/21

Dated: 10/11/21

30 day comment period ended on: 11/10/21

Mailed on: 10/5/21 (emailed 10/6/21)

Contents of all notices (1400.2080, subp. 2)

_x__ 1. Agency intends to adopt rule; identifies statute and rules to be followed

_x__ 2. Cites specific statutory authority for rule

_x__ 3. Proposed rule is attached to notice, or description of rule and how to obtain free copy from agency

___ 4. Cite to entire rule being repealed (if applicable)

_x__ 5. SONAR available to public; it summarizes rule, who affected and probable cost, and how to obtain copy of SONAR

_x__ 6. Proposed rule can be modified if modifications supported by record and do not make rule substantially different

_x__ 7. Persons may request to be on agency's mailing list

_x__ 8. Any other information required by law or rule to be included in notice

_x__ 9. Signature of authorized person and date person signed notice

Additional contents for notice without hearing and dual notice (1400.2080, subps. 3 and 6)

_x__ 1. Notice that public may comment and comment is encouraged

_x_ 2. Calendar date that comment period ends, which must be at least **30 days** after date of publication

_x__ 3. Notice that comments should identify the part of rule addressed, any change proposed, and reason for suggested change

_x__ 4. Notice that if 25 or more persons submit written request for a hearing during comment period, a hearing must be held unless sufficient number later withdraw request in writing

_x_ 5. Notice that any person requesting a hearing must include his or her name and address, and identify portion of rule objected to, otherwise request invalid and will not count when determining whether a hearing must be held

_x__ 6. Notice that any person requesting a hearing is encouraged to propose changes to the rule

_x__ 7. Explanation of how to submit comments or requests for hearing

_x_ 8. Notice that if hearing is held, agency must proceed under 14.131 to 14.20

_x__ 9. Notice that if no hearing is held, agency must submit rule and supporting documents to OAH for review for legality

_x_10. Notice that persons who wish to comment on the legality of the rule must do so during the 30-day comment period

_x__ 11. Notice that persons may request to be notified of the date the rule is submitted to OAH for review

_x__ 12. Notice must be mailed at least **33 days** before the end of comment period or start of hearing and must be published in State Register at least **30 days** before end of comment period

_x__ **F. Copy of OAH's authorization** to omit from notice published in State Register the text of proposed rule (if applicable)

_x__ **G. Certificate of mailing notice of intent to adopt rules and certificate of mailing list**

Dated: _____ *Mailed on:* 10/5/21 (emailed 10/6/21)

_x__ **H. Certificate of additional notice if given**

For Requests for Comments, dated: _____

For Notice of Intent to Adopt:

_X___ *Notice Plan Received Earlier Approval, Dated:* 8/30/21

_X___ *Additional Notice Matches Plan in SONAR*

_x_ **I. Copy of transmittal letter or certificate showing agency sent copy of SONAR to Legislative Reference Library**.

_x__ **J. All written comments and submissions on the proposed rule; requests for hearing and withdrawals of requests**

___ **K. Notice of withdrawal of hearing requests,** evidence that notice sent to all persons who requested a hearing and comments received (if required by 14.25)

_x__ **L**. **A copy of adopted rule,** showing any modifications and Revisor's approval

___ **M. If substantially different rule adopted under 1400.2110,** a copy of the notice sent to persons who commented and evidence that notice sent to those persons.

_x__ **N. A copy of Order adopting rule that complies with 1400.2090.**

___ If any changes were made to the proposed rule in the adopted rule, a description of the changes and an explanation of the reasons for the changes and why they do not make the rule substantially different; or a statement that the agency followed the procedures in 1400.2110 before adopting changes;

_x__ A statement that the agency has complied with all notice and procedural requirements (for multimember agencies order must include authorization);

_x__ If no public hearing held, the number of persons who requested a hearing, and the number of persons who withdrew their request;

_x__ The number of persons who requested notice when rule submitted to OAH;

_x__ A statement that the rule is needed and reasonable;

_x__ A statement that the rule is adopted by the agency

___ The signature of the person authorized to adopt the rule or sign the order and the date the person signed the order.

___ **O. Notice of submission of the rule to OAH**, if anyone requested this notice, and a copy of the transmittal letter or certificate showing agency sent notice.

___ **P. Any other documents or evidence showing compliance** with any other rule or law. Letter to and/or response from Commissioner of Management and Budget per Minn. Stat. § 14.131; Notice to Dept. of Agriculture, if applicable.

Review: Rule must meet the standards of 1400.2100 (*See* 1400.2300, subp. 3) (rationally related to agency's objective; not substantially different; doesn't grant undue discretion etc.)

MINNESOTA

December 14, 2021

The Honorable Barbara J. Case
Administrative Law Judge
Office of Administrative Hearings
600 North Robert Street
P.O. Box 64620
Saint Paul, Minnesota 55164-0620

Re: In the Matter of Minn. R. 4731, Possible Amendment to Rules Governing Radiation Safety, Revisor's ID No. R-4671; OAH 82-9000-37774

Dear Judge Case:

The Minnesota Department of Health requests that the Office of Administrative Hearings review and approve its rules governing radiation safety for legality and form according to Minnesota Statutes, section 14.26. Upon receipt of OAH approval, the Department will adopt the rules. Enclosed for your review are the documents required by Office of Administrative Hearings Rules, part 1400.2310, items A to P. Paragraphs A to P of this letter are keyed to items A to P of part 1400.2310. Each paragraph states whether the document is enclosed and, if the document is not enclosed, the reason that the document is not applicable.

A. Enclosed: the Request for Comments as published in the State Register.

B. Not enclosed: a petition for rulemaking. This is not enclosed because no petition was filed regarding these rules.

C. Enclosed: the proposed rule with the Revisor's certificate of approval.

D. Enclosed: the Statement of Need and Reasonableness.

E. Enclosed: the Notice of Intent to Adopt Rules as mailed and as published in the State Register.

F. Enclosed: the Order from the Chief Administrative Law Judge authorizing the Department to omit the text of the proposed rules from the Notice of Intent to Adopt Rules published in the State Register.

G. Enclosed: the Certificates of Mailing[1] the Notice of Intent to Adopt Rules and the Certificate of Accuracy of the Mailing List.

H. Enclosed: the Certificate of Additional Notice and Certificate of Giving Additional Notice to Correct an Incorrect Link.

[1] Please note that certificates of mailing enclosed with this letter include redactions to avoid disclosure of personal contact and online account information under Minnesota Statutes section 13.356.

I. Enclosed: the Certificate of Mailing the Statement of Need and Reasonableness to the Legislative Reference Library and a copy of the transmittal letter.

J. Enclosed: all written comments and submissions on the proposed rules that the Department received during the comment period, requests for hearing and withdrawals of requests for hearing, except those that only requested copies of documents.

K. Not enclosed: a notice of withdrawal of hearing request, evidence that the Department sent its notice of withdrawal to all persons who requested a hearing, and any responsive comments received. These are not enclosed because Minnesota Statutes, section 14.25, subdivision 2, did not require the Department to send a notice of withdrawal of hearing request.

L. Enclosed: There were no modifications to the proposed rule. Accordingly, a copy of the adopted rule is enclosed according to item C.

M. Not enclosed: a notice of adopting substantially different rules that was sent to persons or groups who commented during the comment period and evidence that the notice was sent to those persons or groups. This is not enclosed because the Department did not adopt substantially different rules.

N. Enclosed: the unsigned Order Adopting Rules that complies with the requirements in part 1400.2090.

O. Not enclosed: a notice of submission of rules to the Office of Administrative Hearings and a copy of a transmittal letter or certificate of mailing the notice of submission of rules to the Office of Administrative Hearings. No persons requested notification of the submission of the rules to the Office of Administrative Hearings.

P. Enclosed: the Certificate of No Impact on Farming Operations.

If you have questions or wish to discuss anything with me, please contact me at *josh.skaar@state.mn.us* or (651) 274-5310.

Regards,

/s/ *Josh Skaar*
Josh Skaar, MDH Rulemaking Coordinator
Minnesota Department of Health
625 Robert Street North
P.O. Box 64975
Saint Paul, MN 55164-0975

Notices, including any instructions for public access to the meetings, will be posted at the SBI office and on the SBI Website at *http://mn.gov/sbi*. For more information, the State Board of Investment can be reached at *minn.sbi@state.mn.us*.

Some members of the Executive Council, State Board of Investment and Land Exchange Board also may participate in the meeting electronically. If a Board Member calls in, in accordance with Minnesota Statutes, section 13D.015, subd. 4, the Executive Council, State Board of Investment and Land Exchange Board shall, to the extent practical, allow a person to monitor the meeting electronically from a remote location. The person making a connection may be required to pay for documented marginal costs that the entity incurs as a result of the additional connection.

Minnesota Department of Health (MDH)

Division of Environmental Health

REQUEST FOR COMMENT for Possible Amendment to Rules Governing Radiation Safety, *Minnesota Rules*, Chapter 4731, Revisor's ID Number RD4671

Subject of Rules. The Minnesota Department of Health requests comments on its possible amendment to rules governing radiation materials. The Department is considering rule amendments that incorporate requirements to maintain compatibility with U.S. Nuclear Regulatory Commission (NRC) regulations as required by our agreement. The Department is also considering minor editorial changes.

Persons Affected. The amendment to the rules would likely affect persons who are licensed by the Department to manufacture, produce, transfer, receive, acquire, own, possess, or use radioactive material.

Statutory Authority. *Minnesota Statutes*, sections 144.1202 and 144.1203, authorize the Department to adopt rules that allow the State to assume regulatory authority under an agreement with the NRC, including licensing and regulation of radioactive materials, and to ensure that individuals handling or using radioactive materials have proper training and qualifications.

Public Comment. Interested persons or groups may submit comments or information on these possible rules in writing until further notice is published in the *State Register* that the Department intends to adopt or withdraw the rules. The Department will not publish a notice of intent to adopt the rules until more than 60 days have elapsed from the date of this request for comments. The Department does not plan to appoint an Advisory Committee to comment on the possible rules.

Rules Drafts. The Department has drafted the possible rule amendments that are available on its website at *https://www.health.state.mn.us/communities/environment/radiation/monitor/rule/index.html*

Agency Contact Person. Written comments, questions, requests to receive a draft of the rules, and requests for more information on these possible rules should be directed to: Brandon Juran at Minnesota Department of Health, P.O. Box 64975, St. Paul, MN 55164-0975, Phone: (651) 201-4526, Fax: (651) 201-4606, and email *brandon.juran@state.mn.us*.

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 the agency contact person at the address or telephone number listed above.

NOTE: Comments received in response to this notice will not necessarily be included in the formal rulemaking record submitted to the Administrative Law Judge if and when a proceeding to adopt rules is started. The agency is required to submit to the Judge only those written comments received in response to the rules after they are proposed. If you submit comments during the development of the rules and you want to ensure that the Administrative Law Judge reviews those comments, you should resubmit the comments after the rules are formally proposed.

May 6, 2021

Steven Diaz
Environmental Health Assistant Division Director

Department of Health

Proposed Permanent Rules Relating to Radioactive Materials

4731.0100 DEFINITIONS.

[For text of subparts 1 to 19, see Minnesota Rules]

Subp. 19a. **Associate radiation safety officer.** "Associate radiation safety officer" means an individual who:

A. meets the requirements in parts 4731.4411 and 4731.4415; and

B. is currently identified as an associate radiation safety officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the radiation safety officer on:

(1) a specific medical use license issued by the commissioner, NRC, or an agreement state; or

(2) a medical use permit issued by an NRC master material licensee.

[For text of subparts 20 to 157, see Minnesota Rules]

Subp. 157a. **Ophthalmic physicist.** "Ophthalmic physicist" means an individual who:

A. meets the requirements in parts 4731.4456, item A, subitem (2), and 4731.4415; and

B. is identified as an ophthalmic physicist on a:

(1) specific medical use license issued by the commissioner, NRC, or an agreement state;

(2) permit issued by a commissioner, NRC, or agreement state broad scope medical use licensee;

(3) medical use permit issued by an NRC master material licensee; or

(4) permit issued by an NRC master material licensee broad scope medical use permittee.

[For text of subparts 158 to 173, see Minnesota Rules]

Subp. 174. **Preceptor.** "Preceptor" means an individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, ~~an~~ authorized medical physicist, ~~an~~ authorized nuclear pharmacist, ~~or~~ a radiation safety officer, or an associate radiation safety officer.

[For text of subparts 175 to 269, see Minnesota Rules]

4731.0406 GENERAL LICENSE; NRC-APPROVED PACKAGE.

[For text of subparts 1 and 2, see Minnesota Rules]

Subp. 3. **Compliance with conditions.** Each licensee issued a general license under subpart 1 must:

[For text of items A and B, see Minnesota Rules]

C. submit in writing to the NRC, before the licensee's first use of the package, the licensee's name and license number and the package identification number specified in the package approval. For the submittal to the NRC, the licensee must use an approved method listed in the Code of Federal Regulations, title 10, section 71.1(a), addressed to: ATTN: Document Control Desk, Director, Division of ~~Spent~~ Fuel ~~Storage and Transportation~~ Management, Office of Nuclear Material Safety and Safeguards.

[For text of subparts 4 and 5, see Minnesota Rules]

4731.0419 ADVANCE NOTIFICATION OF SHIPMENT OF IRRADIATED REACTOR FUEL AND NUCLEAR WASTE.

[For text of subparts 1 and 2, see Minnesota Rules]

Subp. 3. **Procedures for submitting notification.**

A. The notification required under this part must:

(1) be made in writing to the commissioner, the office of each appropriate state governor or governor's designee, the office of each appropriate Tribal official or Tribal official's designee, and to the director ~~of the Division of Security Policy~~, Office of Nuclear Security and Incident Response, NRC;

[For text of subitems (2) and (3), see Minnesota Rules]

B. Contact information, including telephone and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on the NRC website at: https://scp.nrc.gov/special/designee.pdf. The information is also available on request from the Director, Division of ~~Material~~ Materials Safety, Security, State, and Tribal~~, and Rulemaking~~ Programs, Office of Nuclear Material Safety and Safeguards, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

[For text of item C, see Minnesota Rules]

[For text of subparts 4 to 5a, see Minnesota Rules]

Subp. 6. **Cancellation notice.**

A. A licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent must send a cancellation notice to the commissioner, the governor of each state or the governor's designee previously notified, each Tribal official or the Tribal official's designee previously notified, and the director ~~of the Division of Security Policy~~, Office of Nuclear Security and Incident Response, NRC.

[For text of items B and C, see Minnesota Rules]

4731.0422 A_1 AND A_2 VALUES FOR RADIONUCLIDES.

Subpart 1. [Repealed, 32 SR 831]

[For text of subpart 1a, see Minnesota Rules]

Subp. 2. **Specific activity.** This subpart specifies specific activity for individual radionuclides.

Element and Atomic Number and Symbol of Radionuclide	Specific Activity (TBq/g)	Specific Activity (Ci/g)

[For text of Actinium (89) to Silicon (14), see Minnesota Rules]

Samarium (62)		
Sm-145	9.8×10^{1}	2.6×10^{3}
	~~8.5×10^{-1}~~	
Sm-147	8.5×10^{-10}	2.3×10^{-8}
Sm-151	9.7×10^{-1}	2.6×10^{1}
Sm-153	1.6×10^{4}	4.4×10^{5}

[For text of Tin (50) to Zirconium (40), see Minnesota Rules]

[For text of subpart 3, see Minnesota Rules]

4731.2750 ANNUAL LIMITS ON INTAKE AND DERIVED AIR CONCENTRATIONS.

[For text of subparts 1 to 6, see Minnesota Rules]

Subp. 7. **Table of ALIs and DACs.**

	Table 1			Table 2		Table 3
Atomic Number (AN), Radionuclide, and Class	1	2	3	1	2	

[For text of Atomic Numbers 1 to 55 (AN 1 to AN 55), see Minnesota Rules]

AN 56

Barium-126[2]

5.1	D, all compounds	6E+3	2E+4	6E-6	2E-8	8E-5	8E-4
5.2	Barium-128						
5.3	D, all compounds	5E+2	2E+3	7E-7	2E-9	7E-6	7E-5
5.4	Barium-131m[2]						
5.5	D, all compounds	4E+5	1E+6	6E-4	2E-6	---	---
5.6 5.7		Stom (5E+5)	---	---	---	7E-3	7E-2
5.8	Barium-131						
5.9	D, all compounds	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
5.10	~~Barium-133~~ Barium-133m						
5.11	D, all compounds	2E+3	9E+3	4E-6	1E-8	---	---
5.12 5.13		LLI (3E+3)	---	---	---	4E-5	4E-4
5.14	Barium-133						
5.15	D, all compounds	2E+3	7E+2	3E-7	9E-10	2E-5	2E-4
5.16	Barium-135m						
5.17	D, all compounds	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
5.18	Barium-139[2]						
5.19	D, all compounds	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
5.20	Barium-140						
5.21	D, all compounds	5E+2	1E+3	6E-7	2E-9	---	---
5.22 5.23		LLI (6E+2)	---	---	---	8E-6	8E-5
5.24	Barium-141[2]						

D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
Barium-142[2]						
D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3

[For text of Atomic Numbers 57 to 101 (AN 57 to AN 101), see Minnesota Rules]

FOOTNOTES:

[1] "Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

[2] These radionuclides have radiological half-lives of less than two hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do not include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 μCi/ml for the listed DAC to account for the submersion dose prospectively, but must use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits according to part 4731.2040.

[3] For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor according to part 4731.2020, subpart 5. If the percent by weight (enrichment) of U-235 is not greater than five, the concentration value for a 40-hour work week is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour work week must not exceed 8E-3 (SA) μCi-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, is:

SA = 3.6E-7 curies/gram U U-depleted

SA = [0.4 + 0.38 (enrichment) + 0.0034 (enrichment) ^{2}] E-6, enrichment > 0.72

where enrichment is the percentage by weight of U-235, expressed as percent.

[For text of subpart 8, see Minnesota Rules]

4731.3075 TERMS AND CONDITIONS OF LICENSES.

[For text of subparts 1 to 6, see Minnesota Rules]

Subp. 7. ~~**Molybdenum-99 requirement**~~ **Generator testing.** A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99 ~~or~~ / technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators must test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, according to part 4731.4435. The licensee must record the results of each test and retain each record for three years after the record is made. The licensee must report the results of any test that exceeds the permissible concentration listed in part 4731.4435, item A, at the time of generator elution, in accordance with part 4731.4528.

[For text of subparts 8 and 9, see Minnesota Rules]

4731.3330 SPECIFIC LICENSE; CERTAIN DEVICES CONTAINING RADIOACTIVE MATERIALS; MANUFACTURE OR INITIAL TRANSFER.

[For text of subparts 1 to 3, see Minnesota Rules]

Subp. 4. **Transfer for use under general license; requirements.** If a device containing radioactive material is to be transferred for use under a general license issued under part 4731.3215, a person that is licensed under this part must provide the information specified in this subpart to each person to whom a device is to be transferred. The information must be provided before the device may be transferred. In case of a transfer through an intermediate person, the information must also be provided to the intended user before the initial transfer to the intermediate person. The required information includes:

[For text of item A, see Minnesota Rules]

B. a copy of parts 4731.2600, 4731.2610, 4731.3115, and ~~4731.3205~~ 4731.3200, item B;

[For text of items C to E, see Minnesota Rules]

[For text of subparts 5 to 11, see Minnesota Rules]

4731.3395 SPECIFIC LICENSE; RADIOACTIVE DRUGS FOR MEDICAL USE; MANUFACTURE, PREPARATION, OR TRANSFER.

Subpart 1. **Approval criteria.** An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized according to parts 4731.4400 to 4731.4527 shall be approved if the applicant:

[For text of items A to C, see Minnesota Rules]

D. ~~satisfies~~ commits to the following labeling requirements:

[For text of subitems (1) and (2), see Minnesota Rules]

Subp. 2. **Pharmacy licensees.**

[For text of items A to C, see Minnesota Rules]

D. No later than 30 days after the date that a licensee described in subpart 1, item B, subitem (3) or (4), allows an individual to work as an authorized nuclear pharmacist under item A, subitem (2), unit (a) or (c), the licensee must provide to the commissioner a copy of:

(1) the individual's certification by a specialty board whose certification process has been recognized as specified in part 4731.4413, subpart 1~~, with the written attestation signed by a preceptor as required by part 4731.4413, subpart 1~~; or

[For text of subitems (2) to (4), see Minnesota Rules]

[For text of subpart 3, see Minnesota Rules]

Subp. 3a. **Labeling requirements.** A licensee must satisfy the labeling requirements of subpart 1, item D.

[For text of subpart 4, see Minnesota Rules]

4731.4170 PERSONNEL MONITORING.

Subpart 1. **Monitoring requirements.**

A. A licensee may not permit an individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of direct reading dosimeter, an operating alarm ratemeter, and a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~.

[For text of items B to D, see Minnesota Rules]

E. Film badges must be replaced at periods not to exceed one month and other personnel dosimeters ~~processed and evaluated by an accredited NVLAP processor~~ that require replacement must be replaced at periods not to exceed three months. All personnel dosimeters must be evaluated at periods not to exceed three months or promptly after replacement, whichever is more frequent.

~~F. After replacement, each personnel dosimeter must be processed as soon as possible.~~

[For text of subparts 2 and 3, see Minnesota Rules]

Subp. 4. **High readings.** If an individual's pocket chamber is found to be off-scale, or if the individual's electronic personal dosimeter reads greater than 200 millirems (2 mSv), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter that requires processing must be sent for processing and evaluation within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within 24 hours. The individual may not resume work associated with licensed material use until a determination of the individual's radiation exposure has been made. The determination must be made by the radiation safety officer or the radiation

safety officer's designee. The results of the determination must be included in the records maintained according to part 4731.4310.

[For text of subpart 5, see Minnesota Rules]

Subp. 6. **Report retention.** Dosimetry ~~reports received from the accredited NVLAP personnel dosimeter processor~~ results must be retained according to part 4731.4310.

[For text of subpart 7, see Minnesota Rules]

4731.4310 RECORDS; PERSONNEL MONITORING.

According to part 4731.4170, a licensee must maintain records of:

[For text of items A and B, see Minnesota Rules]

C. personnel dosimeter results ~~received from the accredited NVLAP processor~~ until the commissioner terminates the license; and

[For text of item D, see Minnesota Rules]

4731.4403 SPECIFIC LICENSE; MEDICAL USE OF RADIOACTIVE MATERIALS.

[For text of subpart 1, see Minnesota Rules]

Subp. 2. **Application for license, amendment, or renewal.**

[For text of item A, see Minnesota Rules]

B. An application for a license for medical use of radioactive materials as described in parts 4731.4404, 4731.4432, 4731.4434, 4731.4440, 4731.4450, 4731.4460, and 4731.4463 must include:

(1) an original ~~and one copy of an~~ application for radioactive material license form prescribed by the commissioner that includes the facility diagram, equipment, and training and experience qualifications of the radiation safety officer, associate radiation

safety officers, authorized users, authorized medical physicists, ophthalmic physicists, and authorized nuclear pharmacists; and

[For text of subitem (2), see Minnesota Rules]

C. A request for a license amendment or renewal must include:

(1) an original ~~and one copy~~ of the form prescribed by the commissioner under item B or ~~of~~ a letter requesting the amendment or renewal containing all the information in the form prescribed by the commissioner under item B; and

[For text of subitem (2), see Minnesota Rules]

D. In addition to the requirements under items B and C, an application for a license or amendment for medical use of radioactive material under part 4731.4404 must include:

(1) information regarding any radiation safety aspects of the medical use of the material that is not addressed in, or differs from, parts 4731.4400 to 4731.4427~~. The applicant must provide~~ and 4731.4500 to 4731.4528;

(2) identification of and commitment to follow the applicable radiation safety program requirements in parts 4731.4432 to 4731.4479 that are appropriate for the specific medical use;

(3) any additional specific information on:

~~(1)~~ (a) radiation safety precautions and instructions;

~~(2)~~ (b) methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

~~(3)~~ (c) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(4) any other information requested by the commissioner for review of the application.

[For text of item E, see Minnesota Rules]

Subp. 3. **License amendments.** A licensee must apply for and receive a license amendment:

[For text of item A, see Minnesota Rules]

B. before the licensee permits anyone to work as an authorized user, authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or ophthalmic physicist under the license, except that the licensee may permit an individual to work as an authorized user, ~~an~~ authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or ophthalmic physicist for 60 days before being authorized on a license if the individual is an authorized user, authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or ophthalmic physicist for the same type of use:

(1) on a license issued by the commissioner, the NRC, or an agreement state or on an equivalent permit or license recognized by the commissioner, the NRC, or an agreement state that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(2) on a permit issued by ~~an~~ a commissioner, NRC, or agreement state specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; ~~or~~

(3) on a permit issued by an NRC master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

(4) by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists;

[For text of item C, see Minnesota Rules]

D. before the licensee permits anyone to work as an associate radiation safety officer, or before the radiation safety officer assigns duties and tasks to an associate radiation safety officer that differ from those for which this individual is authorized on the license;

~~D.~~ E. before the licensee receives radioactive material in excess of the amount or in a form different than authorized in the license or before the licensee receives a radionuclide that is different than the radionuclide authorized in the license;

~~E.~~ F. before the licensee adds or changes the areas of use identified in the application or in the license, except for areas of use where radioactive material is used only according to part 4731.4432 or 4731.4434;

~~F.~~ G. before the licensee changes an address identified in the application or on the license; ~~and~~

~~G.~~ H. before the licensee revises procedures required under parts 4731.4466 and 4731.4472 to 4731.4474, as applicable, when the revision reduces radiation safety~~.~~; and

I. before the licensee receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license. If a licensee obtains a sealed source in accordance with this item, the licensee must submit an amendment request to add the sealed source to their radioactive materials license within 30 days after receiving the source.

Subp. 4. **Notifications of changes.**

A. A licensee must notify the commissioner by letter no later than 30 days after:

(1) an authorized user, ~~an~~ authorized nuclear pharmacist, ~~a~~ radiation safety officer, ~~or an~~ associate radiation officer, authorized medical physicist, or ophthalmic physicist has a name change;

[For text of subitems (2) and (3), see Minnesota Rules]

(4) the licensee has added to or changed the areas of use identified in the application or license where radioactive material is used according to part 4731.4432 or 4731.4434; ~~or~~

(5) the licensee permits ~~an authorized user or~~ an individual qualified to be a radiation safety officer under parts 4731.4411 and 4731.4415, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer as described under part 4731.4405, subpart 1, item C~~.~~; or

(6) the licensee permits an individual to work under the provisions of subpart 3, item B, as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist prior to being added to the license. The notification must include a copy of the commissioner, NRC, or agreement state license, the permit issued by an NRC master material licensee, the permit issued by a commissioner, NRC, or agreement state licensee of broad scope, or the permit issued by an NRC master material license broad scope permittee.

[For text of item B, see Minnesota Rules]

Subp. 5. **Exemptions; broad scope license.** A licensee possessing a Type A specific license of broad scope for medical use, issued under parts 4731.3500 to 4731.3580, is exempt from:

[For text of items A and B, see Minnesota Rules]

C. subpart 3, item ~~E~~ F, regarding additions to or changes in the areas of use at the addresses identified in the application or license;

D. subpart 4, item A, subitem (1), for an authorized user, ~~an~~ authorized nuclear pharmacist, ~~or an~~ authorized medical physicist, or ophthalmic physicist;

[For text of items E and F, see Minnesota Rules]

[For text of subparts 6 and 7, see Minnesota Rules]

4731.4405 RADIATION PROTECTION PROGRAM.

Subpart 1. **Authority and responsibilities.**

[For text of item A, see Minnesota Rules]

B. A licensee's management must appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety officer, must ensure that radiation safety activities are being performed according to licensee-approved procedures and this chapter. A licensee's management may appoint, in writing, one or more associate radiation safety officers to support the radiation safety officer. The radiation safety officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each associate radiation safety officer. These duties and tasks are restricted to the types of use for which the associate radiation safety officer is listed on a license. The radiation safety officer may delegate duties and tasks to the associate radiation safety officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

C. For up to 60 days each year, a licensee may permit ~~an authorized user or~~ an individual qualified to be a radiation safety officer under parts 4731.4411 and 4731.4415 to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer, as provided in item G, if the licensee takes the actions required by items B, E, G, and H, and notifies the commissioner according to part 4731.4403, subpart 4, item ~~B~~ A.

[For text of items D to H, see Minnesota Rules]

[For text of subpart 2, see Minnesota Rules]

4731.4408 WRITTEN DIRECTIVES.

[For text of subpart 1, see Minnesota Rules]

Subp. 2. **Content requirements.** The written directive under subpart 1 must contain the patient or human research subject's name and:

[For text of items A to D, see Minnesota Rules]

E. for high dose-rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; ~~or~~

F. for permanent implant brachytherapy:

(1) before implantation: the treatment site, radionuclide, and total source strength; and

(2) after implantation but before the patient leaves the post-treatment recovery area: the treatment site, number of sources implanted, total source strength implanted, and date; or

~~F.~~ G. for all other brachytherapy, including low, medium, and pulsed dose-rate remote afterloaders:

(1) before implantation~~,~~: the treatment site, radionuclide, and dose; and

(2) after implantation but before completion of the procedure~~,~~: the radionuclide, treatment site, number of sources, ~~and~~ total source strength and exposure time or the total dose, and date.

[For text of subparts 3 and 4, see Minnesota Rules]

4731.4409 PROCEDURES FOR ADMINISTRATIONS REQUIRING WRITTEN DIRECTIVE.

[For text of item A, see Minnesota Rules]

B. At a minimum, the procedures required by item A must address the following that are applicable to the licensee's use of radioactive material:

[For text of subitems (1) and (2), see Minnesota Rules]

(3) checking both manual and computer-generated dose calculations; ~~and~~

(4) verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized under part 4731.4404 or 4731.4463~~.~~;

(5) determining if a medical event, as defined in part 4731.4525, has occurred; and

(6) determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

[For text of item C, see Minnesota Rules]

4731.4411 RADIATION SAFETY OFFICER AND ASSOCIATE RADIATION SAFETY OFFICER TRAINING.

Subpart 1. **Training and education requirements.** Except as provided under part 4731.4414, a licensee must require an individual fulfilling the responsibilities of a radiation safety officer or an individual assigned duties and tasks as an associate radiation safety officer as provided under part 4731.4405, subpart 1, to be an individual who:

A. (1) is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; and:

~~(1) has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in this item and subpart 2 and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and~~

(2) has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, associate radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval;

B. (1) has completed a structured educational program consisting of both:

[For text of unit (a), see Minnesota Rules]

(b) one year of full-time radiation safety experience under the supervision of an individual identified as the radiation safety officer on an NRC or agreement state license or permit issued by an NRC master material licensee that authorizes similar types of uses of radioactive material ~~involving~~. An associate radiation safety officer may provide supervision for those areas for which the associate radiation safety officer is authorized on an NRC or agreement state license or permit issued by an NRC master material licensee. The full-time radiation safety experience must involve:

[For text of subunits i to vii, see Minnesota Rules]

(2) has obtained written attestation, signed by a preceptor radiation safety officer~~,~~ or associate radiation safety officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a radiation safety officer or an associate radiation safety officer. The written attestation must state that the individual has satisfactorily completed the requirements in this item and ~~has achieved a level of radiation safety knowledge sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as a radiation safety officer or as an associate radiation safety officer for a medical use licensee; and

(3) has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, associate radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval;

C. (1) is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC or an agreement state under part 4731.4412 ~~and~~, has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking approval of the individual as radiation safety officer or associate radiation safety officer; and~~:~~

~~(1) has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in this item and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and~~

(2) has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer,

associate radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval; ~~or~~

D. (1) is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on ~~the licensee's license and~~ an NRC or agreement state license, a permit issued by an NRC master material licensee, a permit issued by an NRC or agreement state licensee of broad scope, or a permit issued by an NRC master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities; and~~:~~

~~(1) has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in this item and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and~~

(2) has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, associate radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval~~.~~; or

E. has experience with the radiation safety aspects of the types of use for which the individual is seeking simultaneous approval both as the radiation safety officer and the authorized user on the same new medical use license, and has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, associate radiation safety officer, authorized medical physicist,

authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval.

[For text of subpart 2, see Minnesota Rules]

4731.4412 AUTHORIZED MEDICAL PHYSICIST TRAINING.

Subpart 1. **Training and education requirements.** Except as provided in part 4731.4414, a licensee must require an authorized medical physicist to be an individual who:

A. (1) is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; and~~:~~

~~(1) has obtained written attestation that the individual has satisfactorily completed the requirements in this item and subpart 2 and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in this part, part 4731.4414, or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and~~

[For text of subitem (2), see Minnesota Rules]

B. (1) holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university, and:

(a) has completed one year of full-time training in medical physics; and

[For text of unit (b), see Minnesota Rules]

(2) has obtained written attestation that the individual has satisfactorily completed the requirements in this item and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in this part, part 4731.4414, or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

[For text of subitem (3), see Minnesota Rules]

Subp. 2. **Certification requirements.** A specialty board under subpart 1, item A, shall require all candidates for certification to:

[For text of item A, see Minnesota Rules]

B. have two years of full-time practical training or supervised experience in medical physics:

(1) under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by ~~the commissioner,~~ the NRC~~,~~ or an agreement state; or

[For text of subitem (2), see Minnesota Rules]

[For text of item C, see Minnesota Rules]

4731.4413 AUTHORIZED NUCLEAR PHARMACIST TRAINING.

Subpart 1. **Training and education requirements.** Except as provided in part 4731.4414, a licensee must require an authorized nuclear pharmacist to be a pharmacist who:

A. is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state ~~and has obtained written attestation signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subpart 2 and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist~~. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; or

B. (1) has completed 700 hours in a structured educational program consisting of both:

(a) 200 hours of classroom and laboratory training in the following areas:

i. radiation physics and instrumentation;

ii. radiation protection;

iii. mathematics pertaining to the use and measurement of radioactivity;

iv. chemistry of radioactive material for medical use; and

v. radiation biology; and

[For text of unit (b), see Minnesota Rules]

(2) has obtained written attestation signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in this item and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

[For text of subpart 2, see Minnesota Rules]

4731.4414 TRAINING; EXPERIENCED RADIATION SAFETY OFFICER, TELETHERAPY OR MEDICAL PHYSICIST, AUTHORIZED USER, AND NUCLEAR PHARMACIST.

A. An individual identified as a radiation safety officer, a teletherapy or medical physicist, or a nuclear pharmacist on a license issued by the NRC or an agreement state; a permit issued by an NRC or agreement state broad scope licensee; a master material license permit; or a permit issued by a master material license permittee of broad scope before ~~October 24, 2002~~ January 14, 2019, need not comply with the training requirements under parts 4731.4411, 4731.4412, or 4731.4413, respectively, except a radiation safety officer or authorized medical physicist identified in this item must meet the training requirements in part 4731.4411, subpart 1, item A, subitem (2), or 4731.4412, subpart 1, item A, subitem (2), as appropriate, for any material or uses for which they were not authorized prior to this date.

~~B. An individual identified as a radiation safety officer, an authorized medical physicist, or an authorized nuclear pharmacist on an NRC or agreement state license; a permit issued by an NRC or agreement state broad scope licensee; an NRC or agreement state master material license permit; or a permit issued by a master material license permittee of broad scope between October 24, 2002, and April 29, 2005, need not comply with the training requirements of part 4731.4411, 4731.4412, or 4731.4413.~~

B. An individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine before October 24, 2005, need not comply with the training requirements of part 4731.4411 to be identified as a radiation safety officer or as an associate radiation safety officer on a

commission or an agreement state license or commission master material license permit for those materials and uses that these individuals performed before October 24, 2005.

C. An individual certified by the American Board of Radiology in therapeutic radiological physics, roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics before October 24, 2005, need not comply with the training requirements for an authorized medical physicist in part 4731.4412 for those materials and uses that these individuals performed before October 24, 2005.

~~C.~~ D. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or an agreement state; a permit issued by an NRC master material licensee; a permit issued by an NRC or agreement state broad scope licensee; or a permit issued by an NRC master material license broad scope permittee before ~~October 24, 2002~~ January 14, 2019, who perform only those medical uses for which they were authorized on that date, need not comply with the training requirements of parts 4731.4432 to 4731.4479.

~~D. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the commissioner, the NRC, or an agreement state; a permit issued by an NRC master material licensee; a permit issued by an NRC or agreement state broad scope licensee; or a permit issued by an NRC master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002, and April 29, 2005, need not comply with the training requirements of parts 4731.4432 to 4731.4479.~~

E. Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the NRC or an agreement state, a permit issued by an NRC master material licensee, a permit issued by an NRC or agreement state broad scope licensee, or a permit issued by an NRC master material license broad

scope permittee before October 24, 2005, need not comply with the training requirements of parts 4731.4432 to 4731.4479 for those materials and uses that these individuals performed before October 24, 2005, as follows:

(1) for uses authorized under part 4731.4432 or 4731.4434, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine, diagnostic radiology by the American Board of Radiology, diagnostic radiology or radiology by the American Osteopathic Board of Radiology, nuclear medicine by the Royal College of Physicians and Surgeons of Canada, or the American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(2) for uses authorized under part 4731.4440, a physician who was certified before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(3) for uses authorized under part 4731.4450 or 4731.4463, a physician who was certified before October 24, 2005, in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(4) for uses authorized under part 4731.4460, a physician who was certified before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic

Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

~~E.~~ F. Individuals who need not comply with training requirements described in this part may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses issued under this chapter for the same uses for which these individuals are authorized.

4731.4423 AUTHORIZATION FOR CHECK, CALIBRATION, TRANSMISSION, AND REFERENCE USE.

Subpart 1. **Check, calibration, transmission, and reference use.** A person authorized under part 4731.4403, subpart 1, for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, transmission, and reference use:

[For text of items A to E, see Minnesota Rules]

Subp. 2. **Restriction of use.** Radioactive material in sealed sources authorized by this part must not be:

A. used for medical use as defined in part 4731.0100 except in accordance with the requirements in part 4731.4460; or

B. combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this part.

Subp. 3. **Listing on license.** A licensee using calibration, transmission, and reference sources in accordance with subpart 1 or 2 need not list these sources on a specific medical use license.

4731.4433 UPTAKE, DILUTION, AND EXCRETION STUDIES; TRAINING.

Subpart 1. **Training and education requirements.** Except as provided under part 4731.4414, a licensee must require the authorized user of unsealed radioactive material for the uses authorized under part 4731.4432 to be a physician who:

A. is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state ~~and has obtained written attestation, signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, 4731.4436, or 4731.4443, or equivalent requirements of the NRC or an agreement state, that the individual has satisfactorily completed the requirements in subpart 2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under part 4731.4432~~. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page;

[For text of item B, see Minnesota Rules]

C. has:

[For text of subitem (1), see Minnesota Rules]

(2) obtained written attestation~~, signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, 4731.4436, or 4731.4443, or equivalent requirements of the NRC or an agreement state,~~ that the individual has satisfactorily completed the requirements in this item and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under part 4731.4432. The attestation must be obtained from either:

(a) a preceptor authorized user who meets the requirements in part 4731.4414, 4731.4433, 4731.4436, or 4731.4443, or equivalent requirements of the NRC or an agreement state; or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in part 4731.4414, 4731.4433, 4731.4436, or 4731.4443, or equivalent requirements of the NRC or an agreement state, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in this item.

[For text of subpart 2, see Minnesota Rules]

4731.4435 PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82, AND STRONTIUM-85 CONCENTRATION.

A. A licensee may not administer to humans a radiopharmaceutical that contains:

(1) more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m); ~~or~~

[For text of subitems (2) and (3), see Minnesota Rules]

B. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical must measure the molybdenum-99 concentration ~~of the first eluate after receipt of~~ in each eluate from a generator to demonstrate compliance with item A.

[For text of items C and D, see Minnesota Rules]

E. The licensee must report any measurement that exceeds the limits in item A at the time of generator elution, in accordance with part 4731.4528.

4731.4436 IMAGING AND LOCALIZATION STUDIES; TRAINING.

Subpart 1. **Training and education requirements.** Except as provided under part 4731.4414, a licensee must require an authorized user of unsealed radioactive material for the uses authorized under part 4731.4434 to be a physician who ~~is qualified as follows under item A, B, or C~~:

A. ~~The physician must:~~

~~(1)~~ ~~be~~ is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certification that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; ~~and~~

~~(2) must also have obtained written attestation that the individual physician has satisfactorily completed the requirements in subpart 2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under parts 4731.4432 and 4731.4434. The attestation must be signed by a preceptor authorized user who meets:~~

~~(a) the requirements in this part;~~

~~(b) the requirements in item C, subitem (1), unit (b), subunit vii, and part 4731.4443;~~

~~(c) the requirements in part 4731.4414; or~~

~~(d) equivalent requirements of the NRC or an agreement state.~~

B. ~~The physician must be~~ is an authorized user under part 4731.4443 and ~~meet~~ meets the requirements in item C, subitem (1), unit (b), subunit vii, or equivalent requirements of the NRC or an agreement state; or

C. ~~The physician must have~~ has:

(1) completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

[For text of unit (a), see Minnesota Rules]

(b) work experience, under the supervision of an authorized user who meets the requirements in this part, part 4731.4414, or in subunit vii and part 4731.4443, or equivalent requirements of the NRC or an agreement state~~, involving~~. An authorized nuclear pharmacist who meets the requirements in part 4731.4413 or 4731.4414 may provide the supervised work experience for subunit vii. Work experience must involve:

[For text of subunits i to vii, see Minnesota Rules]

(2) obtained written attestation that the individual physician has satisfactorily completed the requirements in this item and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under parts 4731.4432 and 4731.4434. The attestation must be ~~signed by a preceptor authorized user who meets~~ obtained from either:

(a) ~~the requirements in this part~~ a preceptor authorized user who meets the requirements in this part, part 4731.4414, or in subitem (1), unit (b), subunit vii, and part 4731.4443, or equivalent requirements of the NRC or an agreement state; or

(b) ~~the requirements in subitem (1), unit (b), subunit vii, and part 4731.4443;~~ a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this part, part 4731.4414, or in subitem (1), unit (b), subunit vii, and part 4731.4443, or equivalent requirements of the NRC or an agreement state, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in this item.

~~(c) the requirements in part 4731.4414; or~~

~~(d) equivalent requirements of the NRC or an agreement state.~~

Subp. 2. **Certification requirements.** A specialty board under subpart 1, item A, shall require all candidates for certification to:

[For text of items A and B, see Minnesota Rules]

4731.4440 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE REQUIRED.

A licensee may use any unsealed radioactive material identified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi, prepared for medical use and for which a written directive is required that is:

[For text of items A to D, see Minnesota Rules]

4731.4443 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE REQUIRED; TRAINING.

Subpart 1. **Training and education requirements.** Except as provided under part 4731.4414, a licensee must require an authorized user of unsealed radioactive material for the uses authorized under part 4731.4440 to be a physician who:

A. is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state, and meets the requirements in item B, subitem (1), unit (b), subunit vi~~, and has obtained written attestation that the individual has satisfactorily completed the requirements in this item and subpart 2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under part 4731.4440. The written attestation must be signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state. A preceptor authorized user who meets the requirements in item B must also have experience in administering dosages in the same dosage category or categories under item B, subitem (1), unit (b), subunit vi, as the individual requesting authorized user status~~. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; or

B. has:

(1) completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

[For text of unit (a), see Minnesota Rules]

(b) work experience, under the supervision of an authorized user who meets the requirements in this part, part 4731.4414, or equivalent requirements of the NRC

or an agreement state. A supervising authorized user who meets the requirements in this item must also have experience in administering dosages in the same dosage category or categories under subunit vi as the individual requesting authorized user status. The work experience must involve:

i. ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

[For text of subunits ii to v, see Minnesota Rules]

vi. administering dosages of radioactive drugs to patients or human research subjects ~~involving~~ from the three categories in this subunit. Radioactive drugs containing radionuclides in categories not included in this subunit are regulated under part 4731.4404. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status: oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide (I-131) for which a written directive is required; oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide (I-131) (experience with at least three cases also satisfies the requirement of oral administration of less than or equal to 33 millicuries of I-131); parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta ~~emitter~~ radiation characteristics, alpha radiation characteristics, or a ~~photon-emitting radionuclide with a~~ photon energy of less than 150 kilo electron volts for which a written directive is required; ~~or parenteral administration of any other radionuclide for which a written directive is required~~; and

(2) obtained written attestation that the individual has satisfactorily completed the requirements in this item and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under part 4731.4440~~. The written attestation~~

~~must be signed by~~ for which the individual is requesting authorized user status. The attestation must be obtained from either:

(a) a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state~~. A preceptor authorized user who meets the requirements in this item must also have~~ and has experience in administering dosages in the same dosage category or categories ~~under subitem (1), unit (b), subunit vi,~~ as the individual requesting authorized user status~~.~~; or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state; has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subitem (1).

Subp. 2. **Certification requirements.** A specialty board under subpart 1, item A, shall require all candidates for certification to:

A. successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in subpart 1, item B, subitem (1), units (a) and (b), subunits i to v. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the

~~Committee on Postgraduate Training~~ Council on Postdoctoral Training of the American Osteopathic Association; and

[For text of item B, see Minnesota Rules]

4731.4444 ORAL ADMINISTRATION OF SODIUM IODIDE I-131; QUANTITIES LESS THAN OR EQUAL TO 33 MILLICURIES (1.22 GBq); WRITTEN DIRECTIVE REQUIRED; TRAINING.

Except as provided under part 4731.4414, a licensee must require an authorized user for the oral administration of sodium iodide (I-131) requiring a written directive in quantities less than or equal to 33 millicuries (1.22 GBq) to be a physician who:

A. is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and includes all of the requirements of item C, subitems (1) and (2)~~, and who has obtained written attestation that the individual has satisfactorily completed the requirements of item C, subitems (1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under part 4731.4440. The written attestation must be signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, 4731.4443, or 4731.4445, or equivalent requirements of the NRC or an agreement state. A preceptor authorized user who meets the requirement in part 4731.4443, subpart 1, item B, must also have experience in oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide (I-131) for which a written directive is required or oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide (I-131) as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi~~. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page;

[For text of item B, see Minnesota Rules]

C. has:

[For text of subitems (1) and (2), see Minnesota Rules]

(3) obtained written attestation that the individual has satisfactorily completed the requirements of this item and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide I-131 for medical uses authorized under part 4731.4440. The written attestation must be ~~signed by~~ obtained from either:

(a) a preceptor authorized user who meets the requirements of this part, part 4731.4414, 4731.4443, or 4731.4445, or equivalent requirements of the NRC or an agreement state~~. A preceptor authorized user who meets the requirement in part 4731.4443, subpart 1, item B, must also have~~ and has experience in oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide (I-131) for which a written directive is required or oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide (I-131) as specified in part 4731.4443~~.~~; or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this part, part 4731.4414, 4731.4443, or 4731.4445, or equivalent requirements of the NRC or an agreement state, has experience in oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide (I-131) for which a written directive is required or oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide (I-131) as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral

Training of the American Osteopathic Association and must include training and experience specified in subitems (1) and (2).

4731.4445 ORAL ADMINISTRATION OF SODIUM IODIDE; QUANTITIES GREATER THAN 33 MILLICURIES (1.22 GBq); WRITTEN DIRECTIVE REQUIRED; TRAINING.

Except as provided under part 4731.4414, a licensee must require an authorized user for the oral administration of sodium iodide (I-131) requiring a written directive in quantities greater than 33 millicuries (1.22 GBq) to be a physician who:

A. is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and includes all the requirements in item C, subitems (1) and (2)~~, and who has obtained written attestation that the individual has satisfactorily completed the requirements of this item and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under part 4731.4440. The written attestation must be signed by a preceptor authorized user who meets the requirements in this part, part 4731.4414 or 4731.4443, or equivalent requirements of the NRC or an agreement state. A preceptor authorized user who meets the requirements in part 4731.4443, subpart 1, item B, must also have experience in the oral administration of I-131 in quantities greater than 33 millicuries as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi~~. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page;

B. is an authorized user ~~under part 4731.4443, subpart 1, item A; 4731.4443, subpart 1, item B,~~ for the oral administration of I-131 in quantities greater than 33 millicuries under part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi; or equivalent requirements of the NRC or an agreement state; or

C. has:

[For text of subitem (1), see Minnesota Rules]

(2) has work experience, under the supervision of an authorized user who meets the requirements of this part, part 4731.4414 or 4731.4443, ~~subpart 1, item A or B,~~ or equivalent requirements of the NRC or an agreement state. A supervising authorized user who meets the requirements in part 4731.4443, subpart 1, item B, must also have experience in the oral administration of I-131 in quantities greater than 33 millicuries under part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi. The work experience must involve:

[For text of units (a) to (f), see Minnesota Rules]

(3) obtained written attestation that the individual has satisfactorily completed the requirements of this item and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation-related duties as an authorized user for oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide I-131 for medical uses authorized under part 4731.4440. The written attestation must be ~~signed by~~ obtained from either:

(a) a preceptor authorized user who meets the requirements in this part, part 4731.4414 or 4731.4443, or equivalent requirements of the NRC or an agreement state~~.~~ ~~A preceptor authorized user who meets the requirements in part 4731.4443, subpart 1, item B, must also have~~, and has experience in the oral administration of I-131 in quantities greater than 33 millicuries ~~under~~ (1.22 GBq) as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi~~.~~; or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this part, part 4731.4414 or 4731.4443, or equivalent requirements of the NRC or an agreement state, has experience in the oral administration of I-131 in quantities greater than 33 millicuries (1.22 GBq) as specified in

part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subitems (1) and (2).

4731.4446 PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE REQUIRED; TRAINING.

A. Except as provided in part 4731.4414, the licensee must require an authorized user for the parenteral administration requiring a written directive to be a physician who is:

(1) an authorized user under part 4731.4443 for the parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or a photon-energy of less than 150 kilo electron volts for which a written directive is required, or equivalent requirements of the NRC or an agreement state;

[For text of subitems (2) and (3), see Minnesota Rules]

B. The physician under item A, subitems (2) and (3), must have:

(1) successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations~~, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide~~ of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or a photon-energy of less than 150 kilo electron volts for which a written directive is required. The training must include:

[For text of units (a) to (e), see Minnesota Rules]

(2) work experience, under the supervision of an authorized user who meets the requirements in this part, part 4731.4414 or 4731.4443, or equivalent requirements of the NRC or agreement state, in the parenteral administration~~, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide~~ of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or a photon-energy of less than 150 kilo electron volts for which a written directive is required. A supervising authorized user who meets the requirements in this part or part 4731.4443, or equivalent requirements of the NRC or agreement state, must have experience in ~~parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 kilo electron volts for which a written directive is required or parenteral administration of any other radionuclide for which a written directive is required as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi~~ administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve:

[For text of units (a) to (e), see Minnesota Rules]

(f) administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration, for which a written directive is required, of any ~~beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required~~ radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or a photon-energy of less than 150 kilo electron volts; and

(3) obtained written attestation that the individual has satisfactorily completed the requirements in this item and item A, subitem (2) or (3), and ~~has achieved a level of~~

~~competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be ~~signed by~~ obtained from either:

(a) a preceptor authorized user who meets the requirements in this part, part 4731.4414, or 4731.4443, or equivalent requirements of the NRC or agreement state. A preceptor authorized user who meets the requirements in this part or part 4731.4443, or equivalent requirements of the NRC or agreement state, must have experience in ~~parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 kilo electron volts for which a written directive is required or parenteral administration of any other radionuclide for which a written directive is required as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi.~~ administering dosages in the same category or categories as the individual requesting authorized user status; or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this part, part 4731.4414 or 4731.4443, or equivalent requirements of the NRC or agreement state, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subitems (1) and (2).

4731.4450 USE OF BRACHYTHERAPY SOURCES.

A licensee must use only brachytherapy sources ~~for therapeutic medical uses~~:

A. as approved in the sealed source and device registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy

uses that are not explicitly listed in the sealed source and device registry, but must be used in accordance with the radiation safety conditions and limitations described in the sealed source and device registry; or

B. in research to deliver therapeutic doses for medical use, according to an active investigational device exemption application accepted by the Food and Drug Administration, provided the requirements of part 4731.4410, item A, are met.

4731.4456 DECAY OF STRONTIUM-90 SOURCES FOR OPHTHALMIC TREATMENTS.

A. Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in item B are performed by either:

(1) an authorized medical physicist; or

(2) an individual who:

(a) is identified as an ophthalmic physicist on a:

i. specific medical use license issued by the commissioner, the NRC, or an agreement state;

ii. permit issued by a commissioner, NRC, or agreement state broad scope medical use licensee;

iii. medical use permit issued by an NRC master material licensee; or

iv. permit issued by an NRC master material licensee broad scope medical use permittee; and

(b) holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(c) has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(d) has documented training in:

i. the creation, modification, and completion of written directives;

ii. procedures for administrations requiring a written directive; and

iii. performing the calibration measurements of brachytherapy sources as detailed in part 4731.4455.

~~A.~~ B. The individuals who are identified in item A must:

(1) ~~Only an authorized medical physicist shall~~ calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under part 4731.4455~~.~~; and

(2) assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in item A will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

~~B.~~ C. A licensee must maintain a record of the activity of each strontium-90 source according to part 4731.4514.

4731.4458 MANUAL BRACHYTHERAPY TRAINING.

Subpart 1. **Training and education requirements.** Except as provided under part 4731.4414, a licensee must require an authorized user of a manual brachytherapy source for the uses authorized under part 4731.4450 to be a physician who:

A. is certified by a medical specialty board whose certification has been recognized by the NRC or an agreement state ~~and has obtained written attestation, signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state, that the individual has satisfactorily completed the requirements of subpart 2 and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under part 4731.4450~~. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; or

B. has:

(1) completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

[For text of unit (a), see Minnesota Rules]

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state at a medical institution authorized to use radioactive materials under part 4731.4450, involving:

[For text of subunits i to vi, see Minnesota Rules]

(2) completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the ~~Committee~~ Council on Postdoctoral Training of the American

Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required under subitem (1), unit (b); and

(3) obtained written attestation~~, signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state,~~ that the individual has satisfactorily completed the requirements of this item and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under part 4731.4450. The attestation must be obtained from either:

(a) a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state; or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subitems (1) and (2).

Subp. 2. **Certification requirements.** A specialty board under subpart 1, item A, shall require all candidates for certification to:

A. successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians

and Surgeons of Canada, or the ~~Committee on Postgraduate~~ Council on Postdoctoral Training of the American Osteopathic Association; and

[For text of item B, see Minnesota Rules]

4731.4459 OPHTHALMIC USE OF STRONTIUM-90; TRAINING.

Except as provided under part 4731.4414, a licensee must require an authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

[For text of item A, see Minnesota Rules]

B. has:

[For text of subitems (1) and (2), see Minnesota Rules]

(3) obtained written attestation, signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, or 4731.4458, or equivalent requirements of the NRC or an agreement state, that the individual has satisfactorily completed the requirements in ~~this item~~ subitems (1) and (2) and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

4731.4460 USE OF SEALED SOURCES AND MEDICAL DEVICES FOR DIAGNOSIS.

A. A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses ~~as~~ if the sealed sources are approved in the sealed source and device registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the sealed source and device registry but must be used in accordance with the radiation safety conditions and limitations described in the sealed source and device registry.

B. A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the sealed source and device registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the sealed source and device registry but must be used in accordance with the radiation safety conditions and limitations described in the sealed source and device registry.

C. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of part 4731.4410, item A, are met.

4731.4461 USE OF SEALED SOURCES FOR DIAGNOSIS; TRAINING.

Except as provided under part 4731.4414, a licensee must require an authorized user of a diagnostic sealed source ~~for use in~~ or a device authorized under part 4731.4460 to be a physician, dentist, or podiatrist who:

A. is certified by a specialty board whose certification process includes all of the requirements of ~~item B~~ items C and D and whose certification has been recognized by ~~the commissioner,~~ the NRC~~,~~ or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; ~~or~~

B. is an authorized user for uses listed in part 4731.4434 or equivalent requirements of the NRC or an agreement state;

~~B.~~ C. has~~:~~

~~(1)~~ completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

(1) ~~(a)~~ radiation physics and instrumentation;

(2) ~~(b)~~ radiation protection;

(3) ~~(c)~~ mathematics pertaining to the use and measurement of radioactivity; and

(4) ~~(d)~~ radiation biology; and

D. ~~(2)~~ completed training in the use of the device for the uses requested.

4731.4463 USE OF A SEALED SOURCE; REMOTE AFTERLOADER UNIT, TELETHERAPY UNIT, OR GAMMA STEREOTACTIC RADIOSURGERY UNIT.

A. A licensee must only use sealed sources ~~in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses~~:

~~A.~~ (1) ~~as~~ approved and as provided for in the sealed source and device registry in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

~~B.~~ (2) in research~~,~~ involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units according to an active investigational device exemption application accepted by the Food and Drug Administration, provided the requirements of part 4731.4410, item A, are met.

B. A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(1) approved in the sealed source and device registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the sealed source and device registry, but must be used in

accordance with radiation safety conditions and limitations described in the sealed source and device registry; or

(2) in research according to an active investigational device exemption application accepted by the FDA provided the requirements of part 4731.4410, item A, are met.

4731.4466 REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS; SAFETY PROCEDURES AND INSTRUCTIONS.

[For text of items A to D, see Minnesota Rules]

E. A licensee must:

(1) prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training; and

(2) provide ~~instruction~~ operational and safety instructions, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties~~;~~. The instructions must include instruction in:

~~(1)~~ (a) the procedures identified under item B, subitem (4); and

~~(2)~~ (b) the operating procedures of the unit.

[For text of items F and G, see Minnesota Rules]

H. A licensee must retain a copy of the procedures required under item B, subitem (4), and item E, subitem (2), unit (b),according to part 4731.4516.

4731.4477 TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS; ~~FIVE-YEAR INSPECTION~~ FULL-INSPECTION SERVICING.

Subpart 1. **Inspection and servicing required.** A licensee must have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement ~~or at intervals~~ to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing must not ~~to~~ exceed five years~~, whichever comes first, to ensure proper functioning of the source exposure mechanism~~ for each teletherapy unit, and must not exceed seven years for each gamma stereotactic radiosurgery unit.

Subp. 2. **Qualified inspectors.** The inspection and servicing ~~may~~ must be performed ~~only~~ by persons specifically licensed to do so by the commissioner, the NRC, or an agreement state.

[For text of subpart 3, see Minnesota Rules]

4731.4479 REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS; TRAINING.

Subpart 1. **Training and education requirements.** Except as provided under part 4731.4414, a licensee must require an authorized user of a sealed source for a use authorized under part 4731.4463 to be a physician who:

A. is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state, and meets the requirements in item B, subitem (4)~~, and has obtained written attestation that the individual has satisfactorily completed the requirements in this item and subpart 2 and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state for an authorized~~

~~user for each type of therapeutic medical unit for which the individual is requesting authorized user status~~. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; or

B. has:

(1) completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

[For text of unit (a), see Minnesota Rules]

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state, at a medical institution that is authorized to use radioactive material in part 4731.4463, involving:

i. reviewing full calibration measurements and periodic spot ~~check~~ checks;

[For text of subunits ii to vi, see Minnesota Rules]

(2) completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the ~~Committee~~ Council on Postdoctoral Training of the American Osteopathic Association. The experience may be obtained concurrently with the supervised work experience required under subitem (1), unit (b);

(3) obtained written attestation that the individual has satisfactorily completed the requirements in ~~this item~~ subitems (1), (2), and (4), and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related

duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be ~~signed by~~ obtained from either:

(a) a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state ~~for an authorized user~~ for each type of therapeutic medical unit for which the individual is requesting authorized user status; ~~and~~ or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subitems (1) and (2); and

[For text of subitem (4), see Minnesota Rules]

Subp. 2. **Certification requirements.** A specialty board under subpart 1, item A, shall require all candidates for certification to:

A. successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the ~~Committee on Postgraduate~~ Council on Postdoctoral Training of the American Osteopathic Association; and

B. pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy.

4731.4500 RADIATION PROTECTION PROGRAM RECORDS.

Subpart 1. **Records of authority and responsibilities; radiation protection programs.** A licensee must retain:

A. a record of actions taken by the licensee's management according to part 4731.4405, subpart 1, item A, for five years. The record must include a summary of the actions taken and a signature of licensee management; ~~and~~

B. a copy of the authorities, duties, and responsibilities of the radiation safety officer, as required under part 4731.4405, subpart 1, item E, and a signed copy of the radiation safety officer's agreement to be responsible for implementing the radiation safety program, as required under part 4731.4405, subpart 1, item B, for the duration of the license. The records must include the signature of the radiation safety officer and licensee management~~.~~; and

C. for each associate radiation safety officer appointed under part 4731.4405, subpart 1, item B, the licensee shall retain, for five years after the associate radiation safety officer is removed from the license, a copy of the written document appointing the associate radiation safety officer signed by the licensee's management.

[For text of subpart 2, see Minnesota Rules]

4731.4510 SAFETY INSTRUCTION RECORDS.

A licensee must maintain a record of safety instructions required under parts 4731.4441~~,~~ and 4731.4453, and the operational and safety instructions required by part 4731.4466 for three years. The record must include:

[For text of items A to D, see Minnesota Rules]

4731.4524 ~~INSPECTION~~ FULL-INSPECTION SERVICING RECORDS; TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS.

A licensee must maintain a record of the ~~five-year inspections~~ full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units required under part 4731.4477 for the duration of use of the unit. The record must contain:

[For text of items A to E, see Minnesota Rules]

4731.4525 MEDICAL EVENT; REPORT AND NOTIFICATION.

Subpart 1. **Report required.** A licensee must report any event as a medical event, except for an event that results from patient intervention, in which:

A. the administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

~~A.~~ (1) a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dose by more than five rems (0.05 Sv) effective dose equivalent, 50 rems (0.5 Sv) to an organ or tissue, or 50 rems (0.5 Sv) shallow dose equivalent to the skin and:

~~(1)~~ (a) the total dose delivered differs from the prescribed dose by 20 percent or more;

~~(2)~~ (b) the total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

~~(3)~~ (c) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more;

~~B.~~ (2) a dose that exceeds five rems (0.05 Sv) effective dose equivalent, 50 rems (0.5 Sv) to an organ or tissue, or 50 rems (0.5 Sv) shallow dose equivalent to the skin from:

~~(1)~~ (a) an administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;

~~(2)~~ (b) an administration of a radioactive drug containing radioactive material by the wrong route of administration;

~~(3)~~ (c) an administration of a dose or dosage to the wrong individual or human research subject;

~~(4)~~ (d) an administration of a dose or dosage delivered by the wrong mode of treatment; or

~~(5)~~ (e) a leaking sealed source; or

~~C.~~ (3) a dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(a) 50 rems (0.5 Sv) ~~to an organ or tissue and exceeds~~ or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(b) 50 percent or more ~~of~~ the ~~dose~~ expected dose to that site from the procedure if the administration ~~defined in~~ had been given in accordance with the written directive~~, excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site~~ prepared or revised before administration.

B. for permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material excluding sources that were implanted in the correct site but migrated outside the treatment site that results in:

(1) the total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(2) the total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(3) an administration that includes any of the following:

(a) the wrong radionuclide;

(b) the wrong individual or human research subject;

(c) sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

(d) a leaking sealed source resulting in a dose that exceeds 50 rem (0.5 Sv) to an organ or tissue.

[For text of subparts 2 to 6, see Minnesota Rules]

Subp. 7. **Individual identification.** A licensee must:

A. annotate a copy of the report provided to the commissioner with:

(1) the name of the individual who is the subject of the event; and

(2) the ~~social security number or other identification number, if one has been assigned,~~ identification number or if no other identification number is available, the Social Security number of the individual who is the subject of the event; and

B. provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the medical event.

4731.4526 DOSE TO AN EMBRYO/FETUS OR CHILD; REPORT AND NOTIFICATION.

[For text of subparts 1 to 5, see Minnesota Rules]

Subp. 6. **Individual identification.** A licensee must:

A. annotate a copy of the report provided to the commissioner with:

(1) the name of the pregnant ~~woman~~ individual or the nursing child who is the subject of the event; and

(2) the ~~Social Security number or other identification number, if one has been assigned, of the pregnant woman or the nursing child~~ identification number or if no other identification number is available, the Social Security number of the individual who is the subject of the event; and

B. provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

4731.4528 REPORT AND NOTIFICATION FOR AN ELUATE EXCEEDING PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82, AND STRONTIUM-85 CONCENTRATIONS.

Subpart 1. **Telephone notification.** The licensee must notify, by telephone, the commissioner and the distributor of the generator, within seven days after discovery, that an eluate exceeded the permissible concentration listed in part 4731.4435, item A, at the time of generator elution. The telephone report to the commissioner must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

Subp. 2. **Written report.** The licensee must submit a written report to the commissioner within 30 days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; the probable cause and an assessment of failure in the licensee's equipment, procedures, or training that contributed

to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by subpart 1

4731.6180 PERSONNEL MONITORING.

Subpart 1. **Irradiator operators.** Irradiator operators must wear a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~ while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter ~~processor must be accredited for~~ must be capable of detecting high energy photons in the normal and accident dose ranges ~~under part 4731.2200, subpart 3~~. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be ~~processed~~ replaced at least monthly and other personnel dosimeters that require replacement must be ~~processed~~ replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

[For text of subpart 2, see Minnesota Rules]

4731.7220 PERSONNEL MONITORING.

A. A licensee may not permit an individual to act as a logging supervisor or logging assistant unless the individual wears~~,~~ a personnel dosimeter at all times during the handling of licensed radioactive materials~~, a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and other personnel dosimeters that require replacement must be replaced at least quarterly. ~~After replacement, each personnel dosimeter must be promptly processed.~~ All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

[For text of items B and C, see Minnesota Rules]

4731.8015 ACCESS AUTHORIZATION PROGRAM REQUIREMENTS.

[For text of subpart 1, see Minnesota Rules]

Subp. 2. **Reviewing officials.**

[For text of item A, see Minnesota Rules]

B. Each licensee must name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee must provide, under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Provide oath or affirmation certifications to the Radioactive Materials Unit, Minnesota Department of Health, 625 Robert Street N, P.O. Box 64975, St. Paul, MN 55164-0975. The fingerprints of the named reviewing official must be taken by a law enforcement agency, federal or state agency that provides fingerprinting services to the public, or commercial fingerprinting services authorized by a state to take fingerprints. The licensee must recertify that the reviewing official is deemed trustworthy and reliable every ten years in accordance with part 4731.8020, subpart 3.

[For text of items C to E, see Minnesota Rules]

[For text of subparts 3 to 8, see Minnesota Rules]

4731.8025 REQUIREMENTS FOR CRIMINAL HISTORY RECORDS CHECKS OF INDIVIDUALS GRANTED UNESCORTED ACCESS TO CATEGORY 1 OR CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL.

[For text of subparts 1 and 2, see Minnesota Rules]

Subp. 3. **Procedures for processing of fingerprint checks.**

A. For the purpose of complying with parts 4731.8010 to 4731.8040, licensees must submit to the U.S. Nuclear Regulatory Commission, Director, Division of ~~Facilities and Security~~ Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop ~~TWB-05 B32M~~ T-8B20, Rockville, MD ~~20852-2738~~ 20852,

one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by ~~writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling (630) 829-9565, or by e-mail to FORMS.Resource@nrc.gov~~ emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at ~~http://www.nrc.gov/site-help/e-submittals.html~~ https://www.nrc.gov/security/chp.html.

B. Fees for the processing of fingerprint checks are due upon application. Licensees must submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." For guidance on making electronic payments, contact the ~~Security Branch~~, Division of ~~Facilities~~ Physical and Cyber Security ~~at (301) 492-3531~~ Policy by emailing crimhist.resource@nrc.gov. Combined payment for multiple applications is acceptable. The ~~commission~~ NRC publishes the amount of the fingerprint check application fee on the NRC public website. To find the current fee amount, go to the ~~Electronic Submittals page at http://www.nrc.gov/site-help/e-submittals.html and see the link for the Criminal History Program under Electronic Submission Systems~~ Licensee Criminal History Records Checks & Firearms Background Check information page at https://www.nrc.gov/security/chp.html and see the link for "How do I determine how much to pay for the request?".

[For text of item C, see Minnesota Rules]

4731.8055 GENERAL SECURITY PROGRAM REQUIREMENTS.

[For text of subparts 1 to 3, see Minnesota Rules]

Subp. 4. **Protection of information.**

[For text of item A, see Minnesota Rules]

B. Efforts to limit access must include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan ~~and~~, implementing procedures, and the list of individuals that have been approved for unescorted access.

C. Before granting an individual access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access, licensees must:

(1) evaluate an individual's need to know the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access; and

[For text of subitem (2), see Minnesota Rules]

[For text of item D, see Minnesota Rules]

E. The licensee must document the basis for concluding that an individual is trustworthy and reliable in order to be granted access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access.

F. Licensees must maintain a list of persons currently approved for access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access, or no longer meets the access authorization requirements for access to the information, the licensee must remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to obtain the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access.

G. When not in use, the licensee must store its security plan ~~and~~, implementing procedures, and the list of individuals that have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

H. The licensee must retain as a record for three years after the document is no longer needed:

(1) a copy of the information protection procedures; and

(2) the list of individuals approved for access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access.

4731.8115 ADVANCE NOTIFICATION OF SHIPMENT OF CATEGORY 1 QUANTITIES OF RADIOACTIVE MATERIAL.

[For text of subpart 1, see Minnesota Rules]

Subp. 2. **Procedures for submitting advance notification.**

A. The notification must be made to the commissioner and to the office of each appropriate governor or governor's designee. The contact information, including telephone numbers and mailing addresses, of governors and governors' designees, is available on the NRC website at https://scp.nrc.gov/special/designee.pdf. A list of the contact information is also available upon request from the Director, Division of ~~Material~~ Materials Safety, Security, State, and Tribal~~, and Rulemaking~~ Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC ~~20555~~ 20555-0001. Notifications to the commissioner must be to the Radioactive Materials Unit, Minnesota Department of Health, 625 Robert Street N, P.O. Box 64975, St. Paul, MN 55164-0975, or e-mail at health.ram@state.mn.us.

[For text of items B and C, see Minnesota Rules]

[For text of subparts 3 to 7, see Minnesota Rules]

Office of the Revisor of Statutes
Administrative Rules

TITLE: Proposed Permanent Rules Relating to Radioactive Materials

AGENCY: Department of Health

REVISOR ID: R-4671

MINNESOTA RULES: Chapter 4731

The attached rules are approved for
publication in the State Register

Sandy Glass-Sirany
Senior Assistant Revisor

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.

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

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 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;

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)

- 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;
- 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]

[3] govinfo.gov | U.S. Government Publishing Office

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:

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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.

(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)].

"(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 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.

4 *See* 42 U.S.C. § 2021(j)(1).

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

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

5 *See* Minn. Stat. § 144.1203

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 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

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).

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

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

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.

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 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.

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

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.

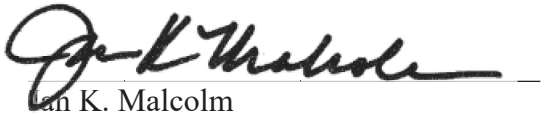
LIST OF EXHIBITS

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
Date



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

Minnesota Department of Health

Environmental Health Division

NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING

Proposed Amendment to Rules Governing Radiation Safety, Minnesota Rules, Chapter 4731; Revisor's ID Number R-4671

Introduction. The Department of Health (MDH) intends to adopt rules without a public hearing following the procedures in the rules of the Office of Administrative Hearings (OAH), Minnesota Rules, parts 1400.2300 to 1400.2310, and the Administrative Procedure Act, Minnesota Statutes, sections 14.22 to 14.28. Specific rule parts to be revised are:

- 4731.0100, subps. 19a, 157a, 174;
- 4731.0406, subp. 3;
- 4731.0419, subps. 3, 6;
- 4731.0422, subp. 2;
- 4731.2750, subp. 7;
- 4731.3075, subp. 7;
- 4731.3330, subp. 4;
- 4731.3395, subps. 1, 2, 3a;
- 4731.4170, subps. 1, 4, 6;
- 4731.4310
- 4731.4403, subps. 2–5;
- 4731.4405, subp. 1;
- 4731.4408, subp 2;
- 4731.4409;
- 4731.4411, subp. 1;
- 4731.4412, subps. 1, 2;
- 4731.4413, subp. 1;
- 4731.4414;
- 4731.4423, subps. 1–3;
- 4731.4433, subp. 1;
- 4731.4435;
- 4731.4436, subps. 1, 2;
- 4731.4440;
- 4731.4443, subps. 1, 2;
- 4731.4444;
- 4731.4445;
- 4731.4446;
- 4731.4450;
- 4731.4456;
- 4731.4458, subps. 1, 2;
- 4731.4459;
- 4731.4460;
- 4731.4461;
- 4731.4463;
- 4731.4466;
- 4731.4477, subps. 1, 2;
- 4731.4479, subps. 1, 2;
- 4731.4500, subp. 1;
- 4731.4510;
- 4731.4524;
- 4731.4525, subps. 1, 7;
- 4731.4526, subp. 6;
- 4731.4528, subps. 1, 2;
- 4731.6180, subp. 1;
- 4731.7220;
- 4731.8015, subp. 2;
- 4731.8025, subp. 3;
- 4731.8055, subp. 4; and
- 4731.8115, subp. 2.

Subject of Rules and Statutory Authority. Minnesota Statutes, sections 144.1202 and 144.1203, authorize MDH to adopt rules that allow the state to assume regulatory authority under an agreement with the U.S. Nuclear Regulatory Commission (NRC), including licensing and regulation of radioactive materials, and to ensure that individuals handling or using radioactive materials have proper training and qualifications.

Minnesota Rules, Chapter 4731, which the proposed rules are amending, is where the rules adopted pursuant to this statutory authority are contained. MDH proposes to amend this chapter, as noted above, to reflect NRC's recent regulation changes. The proposed changes conform MDH's rules to NRC-mandated regulations. The proposed changes also include revisions to clarify existing requirements and to correct editorial issues. The current rule can be accessed at https://www.revisor.mn.gov/rules/4731/. A free copy of the rule is also available upon request from the agency contact person listed below.

Proposed Rule Revision Language and Statement of Need and Reasonableness. The rule amendments and the Statement of Need and Reasonableness (SONAR) can be reviewed at

https://www.health.state.mn.us/communities/environment/radiation/monitor/rule/index.html. The SONAR contains a summary of the justification for the proposed rules, including a description of who will be affected by the proposed rules and an estimate of the probable cost of the proposed rules. It is now available from the agency contact person. You may review it or obtain copies for the cost of reproduction by contacting the agency contact person.

Agency Contact Person. You may submit questions on the rules and written requests for a public hearing to the agency contact person. The agency contact person is:

Brandon Juran
Minnesota Department of Health
P.O. Box 64975
St. Paul, MN 55164-0975
Phone: (651) 201-4526
Fax: (651) 201-4606
brandon.juran@state.mn.us.

Comments. MDH encourages comment. You have until 4:30 p.m. on November 10, 2021, to submit written comments in support of or in opposition to the proposed rules and any part or subpart of the rules. You must submit all written comments via the OAH Rulemaking e-comments website (https://minnesotaoah.granicusideas.com/discussion), where you may also review the proposed rule and SONAR. Your comments must be in writing. Your comments should identify the portion of the proposed rules addressed and the reason for the comment. You are encouraged to propose any change desired. Any comments that you have about the legality of the proposed rules must also be made during this comment period.

Request for a Hearing. In addition to submitting comments, you may also request that MDH hold a hearing on the rules. Your request must be in writing, and the agency contact person must receive it by 4:30 p.m. on November 10, 2021. Your written request for a public hearing must include your name and address. You must identify the portion or portions of the proposed rules that you object to or state that you oppose the entire set of rules. Any request that does not comply with these requirements is not valid and MDH cannot count it when determining whether it must hold a public hearing. You are also encouraged to state the reason for the request and any changes you want made to the proposed rules.

Withdrawal of Requests. If 25 or more persons submit a valid written request for a hearing, MDH will hold a public hearing unless a sufficient number withdraw their requests in writing. If enough requests for hearing are withdrawn to reduce the number below 25, the agency must give written notice of this to all persons who requested a hearing, explain the actions the agency took to effect the withdrawal, and ask for written comments on this action. If a public hearing is required, the agency will follow the procedures in Minnesota Statutes, sections 14.131 to 14.20.

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 the agency contact person at the address or telephone number listed above.

Modifications. MDH may modify the proposed rules as a result of public comment. The modifications must be supported by comments and information submitted to the agency, and the

adopted rules may not be substantially different than these proposed rules, unless the agency follows the procedure under Minnesota Rules, part 1400.2110. If the proposed rules affect you in any way, MDH encourages you to participate in the rulemaking process.

Lobbyist Registration. *Minnesota Statutes*, chapter 10A, requires each lobbyist to register with the State Campaign Finance and Public Disclosure Board. You should direct questions about this requirement to the Campaign Finance and Public Disclosure Board at: Suite 190, Centennial Building, 658 Cedar Street, St. Paul, Minnesota 55155, telephone (651) 539-1180 or 1-800-657-3889.

Adoption and Review of Rules. If no hearing is required, MDH may adopt the rules after the end of the comment period. MDH will then submit the rules and supporting documents to OAH for review for legality. You may ask to be notified of the date MDH submits the rules to OAH. If you want to be so notified, receive a copy of the adopted rules, or register with MDH to receive notice of future rule proceedings, submit your request to the agency contact person listed above.

October 11, 2021

Jan Malcolm
Commissioner
Department of Health

Proposed Rules 4

Comments on Planned Rules or Rule Amendments. An agency must first solicit Comments on Planned 4 Rules or Comments on Planned Rule Amendments from the public on the subject matter of a possible rulemaking 4 proposal under active consideration within the agency (*Minnesota Statutes* §§ 14.101). It does this by publishing a 4 notice in the *State Register* at least 60 days before publication of a notice to adopt or a notice of hearing, and within 4 60 days of the effective date of any new statutory grant of required rulemaking. 4

Rules to be Adopted After a Hearing. After receiving comments and deciding to hold a public hearing on the 4 rule, an agency drafts its rule. It then publishes its rules with a notice of hearing. All persons wishing to make a 4 statement must register at the hearing. Anyone who wishes to submit written comments may do so at the hearing, 4 or within five working days of the close of the hearing. Administrative law judges may, during the hearing, extend 4 the period for receiving comments up to 20 calendar days. For five business days after the submission period the 4 agency and interested persons may respond to any new information submitted during the written submission period 4 and the record then is closed. The administrative law judge prepares a report within 30 days, stating findings of fact, 4 conclusions and recommendations. After receiving the report, the agency decides whether to adopt, withdraw or 4 modify the proposed rule based on consideration of the comments made during the rule hearing procedure and the 4 report of the administrative law judge. The agency must wait five days after receiving the report before taking any 4 action. 4

Rules to be Adopted Without a Hearing. Pursuant to *Minnesota Statutes* § 14.22, an agency may propose to 4 adopt, amend, suspend or repeal rules without first holding a public hearing. An agency must first solicit **Comments** 4 **on Planned Rules** or **Comments on Planned Rule Amendments** from the public. The agency then publishes 4 a notice of intent to adopt rules without a public hearing, together with the proposed rules, in the *State Register*. 4 If, during the 30-day comment period, 25 or more persons submit to the agency a written request for a hearing of 4 the proposed rules, the agency must proceed under the provisions of §§ 14.1414.20, which state that if an agency 4 decides to hold a public hearing, it must publish a notice of intent in the *State Register*. 4

KEY: Proposed Rules - Underlining indicates additions to existing rule language. ~~Strikeouts~~ indicate deletions 4 from existing rule language. If a proposed rule is totally new, it is designated "all new material." **Adopted Rules** 4 - Underlining indicates additions to proposed rule language. ~~Strikeout~~ indicates deletions from proposed rule 4 language. 4

Minnesota Department of Health 4

Environmental Health Division 4

Notice of Intent to Adopt Rules without a Public Hearing; Proposed Amendment to Rules 4 Governing Radiation Safety, Minnesota Rules, Chapter 731; Revisor's ID Number R- 671 4

Introduction. The Department of Health (MDH) intends to adopt rules without a public hearing following the 4 procedures in the rules of the Office of Administrative Hearings (OAH), Minnesota Rules, parts 1400.2300 to 1400.2310, 4 and the Administrative Procedure Act, Minnesota Statutes, sections 14.22 to 14.28. Specific rule parts to be revised are: 4

- 4731.0100, subps. 19a, 157a, 174; 4
- 4731.0406, subp. 3; 4
- 4731.0419, subps. 3, 6; 4
- 4731.0422, subp. 2; 4
- 4731.2750, subp. 7; 4
- 4731.3075, subp. 7; 4
- 4731.3330, subp. 4; 4
- 4731.3395, subps. 1, 2, 3a; 4
- 4731.4170, subps. 1, 4, 6; 4
- 4731.4310 4
- 4731.4403, subps. 2–5; 4
- 4731.4405, subp. 1; 4
- 4731.4408, subp 2; 4
- 4731.4409; 4
- 4731.4411, subp. 1; 4
- 4731.4412, subps. 1, 2; 4
- 4731.4413, subp. 1; 4
- 4731.4414; 4
- 4731.4423, subps. 1–3; 4
- 4731.4433, subp. 1; 4
- 4731.4435; 4
- 4731.4436, subps. 1, 2; 4
- 4731.4440; 4
- 4731.4443, subps. 1, 2; 4
- 4731.4444; 4
- 4731.4445; 4
- 4731.4446; 4
- 4731.4450; 4
- 4731.4456; 4
- 4731.4458, subps. 1, 2; 4
- 4731.4459; 4
- 4731.4460; 4
- 4731.4461; 4
- 4731.4463; 4
- 4731.4466; 4
- 4731.4474, subps. 1, 2; 4
- 4731.4479, subps. 1, 2; 4
- 4731.4500, subp. 1; 4
- 4731.4510; 4
- 4731.4524; 4
- 4731.4525, subps. 1, 7; 4
- 4731.4526, subp. 6; 4
- 4731.4528, subps. 1, 2; 4
- 4731.6180, subp. 1; 4
- 4731.7220; 4
- 4731.8015, subp. 2; 4
- 4731.8025, subp. 3; 4
- 4731.8054, subp. 4; and 4
- 4731.8115, subp. 2. 4

Subject of Rules and Statutory Authority. Minnesota Statutes, sections 144.1202 and 144.1203, authorize MDH to adopt rules that allow the state to assume regulatory authority under an agreement with the U.S. Nuclear Regulatory Commission (NRC), including licensing and regulation of radioactive materials, and to ensure that individuals handling or using radioactive materials have proper training and qualifications.

Minnesota Rules, Chapter 4731, which the proposed rules are amending, is where the rules adopted pursuant to this statutory authority are contained. MDH proposes to amend this chapter, as noted above, to reflect NRC's recent regulation changes. The proposed changes conform MDH's rules to NRC-mandated regulations. The proposed changes also include revisions to clarify existing requirements and to correct editorial issues. The current rule can be accessed at ***https://www.revisor.mn.gov/rules/4731/***. A free copy of the rule is also available upon request from the agency contact person listed below.

Proposed Rule Revision Language and Statement of Need and Reasonableness. The rule amendments and the Statement of Need and Reasonableness (SONAR) can be reviewed at ***https://www.health.state.mn.us/communities/environment/radiation/monitor/rule/index.html***. The SONAR contains a summary of the justification for the proposed rules, including a description of who will be affected by the proposed rules and an estimate of the probable cost of the proposed rules. It is now available from the agency contact person. You may review it or obtain copies for the cost of reproduction by contacting the agency contact person.

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Brandon Juran
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Request for a Hearing. In addition to submitting comments, you may also request that MDH hold a hearing on the rules. Your request must be in writing, and the agency contact person must receive it by 4:30 p.m. on November 10, 2021. Your written request for a public hearing must include your name and address. You must identify the portion or portions of the proposed rules that you object to or state that you oppose the entire set of rules. Any request that does not comply with these requirements is not valid and MDH cannot count it when determining whether it must hold a public hearing. You are also encouraged to state the reason for the request and any changes you want made to the proposed rules.

Withdrawal of Requests. If 25 or more persons submit a valid written request for a hearing, MDH will hold a public hearing unless a sufficient number withdraw their requests in writing. If enough requests for hearing are withdrawn to reduce the number below 25, the agency must give written notice of this to all persons who requested a hearing, explain the actions the agency took to effect the withdrawal, and ask for written comments on this action. If a public hearing is required, the agency will follow the procedures in Minnesota Statutes, sections 14.131 to 14.20.

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 the agency contact person at the address or telephone number listed above.

Modifications. MDH may modify the proposed rules as a result of public comment. The modifications must be supported by comments and information submitted to the agency, and the adopted rules may not be substantially different than these proposed rules, unless the agency follows the procedure under Minnesota Rules, part 1400.2110. If the proposed rules affect you in any way, MDH encourages you to participate in the rulemaking process.

Lobbyist Registration. *Minnesota Statutes*, chapter 10A, requires each lobbyist to register with the State Campaign Finance and Public Disclosure Board. You should direct questions about this requirement to the Campaign Finance and Public Disclosure Board at: Suite 190, Centennial Building, 658 Cedar Street, St. Paul, Minnesota 55155, telephone (651) 539-1180 or 1-800-657-3889.

Adoption and Review of Rules. If no hearing is required, MDH may adopt the rules after the end of the comment period. MDH will then submit the rules and supporting documents to OAH for review for legality. You may ask to be notified of the date MDH submits the rules to OAH. If you want to be so notified, receive a copy of the adopted rules, or register with MDH to receive notice of future rule proceedings, submit your request to the agency contact person listed above.

October 11, 2021

J an Malcolm
C ommissioner
D epartment of Health

Minnesota Public Utilities Commission

Proposed Permanent Rules Relating to Power Plants or Lines; Revising the Certificate of Need and Site or Route Permit Requirements; DUAL NOTICE: Notice of Intent to Adopt Rules Without a Public Hearing Unless 25 or More Persons Request a Hearing, and Notice of Hearing if 25 or More Requests for Hearing Are Received; Revisor's ID 4151

Proposed Amendment to Rules Governing Certificates of Need and Site and Route Permits for Large Electric Power Plants and High-Voltage Transmission Lines, *Minnesota Rules* Chapters 7849 and 7850 and Governing Notice Plan Filing Requirements, *Minnesota Rules*, part 7829.2550; Request to Schedule a Rules Hearing; and Request to Review Additional Notice Plan; Including Repeal of Minn. R. 7829.2550; 7849.0230; 7849.0240; 7849.1100; 7849.1300; 7850.1000; 7850.2000; 7850.2100; 7850.2900; 7850.3000; 7850.3100; 7850.3200; 7850.3300; 7850.3400; 7850.3500; 7850.3700; 7850.4000; 7850.4200

Introduction. The Public Utilities Commission intends to adopt rules without a public hearing following the procedures in the rules of the Office of Administrative Hearings, *Minnesota Rules*, parts 1400.2300 to 1400.2310, and the Administrative Procedure Act, *Minnesota Statutes*, sections 14.22 to 14.28. If, however, 25 or more persons submit a written request for a hearing on the rules by 4:30 p.m. on November 17, 2021, the Commission will hold a public hearing remotely via WebEx using the following instructions for joining the meeting:

Meeting link: ***Webex Meeting Link***
Meeting number: 2494 669 6453
Password: Hearing7849 H ost key: 245668

Join by video system
D ial 24946696453@minnesota.webex.com
Y ou can also dial 173.243.2.68 and enter your meeting number.

Join by phone
+ 1-415-655-0003 United States Toll
1 -855-282-6330 United States Toll Free Access code: 2494 669 6453
H ost PIN: 4862

MINNESOTA
OFFICE OF
ADMINISTRATIVE
HEARINGS

PO Box 64620
Saint Paul, MN 55164-0620
mn.gov/oah

PH (651) 361-7900

August 30, 2021

VIA EMAIL ONLY
Josh Skaar
Attorney at Law
Minnesota Department of Health
625 N Robert St
Saint Paul, MN 55164
Josh.skaar@state.mn.us

Re: ***In the Matter of Minn. R. 4731, Possible Amendment to Rules Governing Radiation Safety, Revisor's ID No. R-4671***
OAH 82-9000-37774; Revisor R-4671

Dear Mr. Skaar:

Enclosed herewith and served upon you please find the **ORDER ON REVIEW OF ADDITIONAL NOTICE PLAN** and **ORDER ON REQUEST TO OMIT FROM THE NOTICE THE TEXT OF PROPOSED RULES, PURSUANT TO MINN. STAT. § 14.22, SUBD. 1(B) (2020),** in the above-entitled matter.

Prior to publishing the in the State Register, please notify the Office of Administrative Hearings (OAH) at denise.collins@state.mn.us in order to activate the agency's eComments page on the OAH's website. **Please note that if you do not notify us of the publication, the eComments site will not be available to receive public comments.**

If you have any questions regarding this matter, please contact Denise Collins at (651) 361-7875, denise.collins@state.mn.us or via facsimile at (651) 539-0310.

Sincerely,

Michelle Severson

MICHELLE SEVERSON
Legal Assistant

Enclosure

OAH 82-9000-37774
Revisor R-4671

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of Minn. R. 4731, Possible Amendment to Rules Governing Radiation Safety, Revisor's ID No. R-4671

ORDER ON REVIEW OF ADDITIONAL NOTICE PLAN

This matter came before Administrative Law Judge Barbara J. Case upon the Minnesota Department of Health's (Department) request for review of its Additional Notice Plan under Minn. R. 1400.2060 (2021). Pursuant to its Additional Notice Plan filed on August 27, 2021, the Department proposes to send the Notice of Intent to Adopt to everyone who has registered to be on the department's rulemaking mailing list under Minn. Stat. § 14.14, subd. 1a (2020). The Department will also give notice to the Legislature per Minn. Stat. § 14.116 (2020).

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 150 facilities that have an MDH-specific radioactive materials license, and the 56 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 Department's website.

Based upon a review of the written submissions by the Department,

IT IS HEREBY ORDERED THAT:

The Additional Notice Plan is **APPROVED**.

Dated: August 30, 2021

Barbara J. Case
Administrative Law Judge

[164157/1]

OAH 82-9000-37774
Revisor R-4671

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of Minn. R. 4731, Possible Amendment to Rules Governing Radiation Safety, Revisor's ID No. R-4671	**ORDER ON REQUEST TO OMIT FROM THE NOTICE THE TEXT OF PROPOSED RULES, PURSUANT TO MINN. STAT. § 14.22, SUBD. 1(B) (2020)**

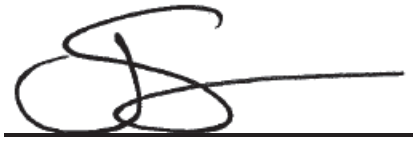
This matter came before Chief Administrative Law Judge Jenny Starr on August 27, 2021. The Minnesota Department of Health (Department) seeks an order authorizing the omission of the proposed rule text when it publishes the Notice of Intent to Adopt Rules Without a Public Hearing (Notice). The Department asserts that publication of the proposed rules in the *State Register* is cost-prohibitive.

As an alternative to publication, the Department pledges that the Notice will state that a free copy of the entire proposed rules will be available upon request to the Department and indicate how to make that request. The Notice will also identify the website link where a copy may be obtained. Finally, the Notice will state the subject matter of the omitted rules, cite the statutory authority for the proposed rules, and outline the proposed rules' purpose. In addition, the Department's Statement of Need and Reasonableness (SONAR) will be transmitted as outlined in the Notice Plan, which SONAR will be available free of charge by request and posted on the Department's website.

IT IS HEREBY ORDERED THAT:

Conditioned upon the Department's use of the procedures outlined in its petition of August 27, 2021, the petition to omit the proposed rule text is **GRANTED**.

Dated: August 30, 2021



JENNY STARR
Chief Administrative Law Judge

[164148/1]

Minnesota Department of Health

CERTIFICATE OF ACCURACY OF THE MAILING LIST

Proposed Rules Governing Radiation Safety, Minnesota Rules, Chapter 4731; Revisor's ID Number R-4671; OAH Docket No. 82-9000-37774

I certify that the list of persons and associations who have requested that their names be placed on the Department of Health rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a, is accurate, complete, and current as of October 5, 2021. A copy of the mailing list is attached to this Certificate.

Cretia Weaver
Legal Secretary

Minnesota Department of Health

CERTIFICATE OF MAILING THE NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING TO THE RULEMAKING MAILING LIST

Proposed Rules Governing Radiation Safety, Minnesota Rules, Chapter 4731; Revisor's ID Number R-4671; OAH Docket No. 82-9000-37774

I certify that on October 5, 2021, at least 33 days before the end of the comment period, at St. Paul, Ramsey County, Minnesota, I mailed the Notice of Intent to Adopt Rules (Notice) by depositing a copy in the State of Minnesota's central mail system for United States mail with postage prepaid, to the four people on the rulemaking mailing list established by Minnesota Statutes, section 14.14, subdivision 1a. Copies of the Notice and of the mailing list are attached to this Certificate.

Norma Leland

Norma Leland
Office & Administrative Specialist Intermediate

Minnesota Department of Health

CERTIFICATE OF MAILING THE NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING TO THE RULEMAKING EMAILING LIST

Proposed Rules Governing Radiation Safety, Minnesota Rules, Chapter 4731; Revisor's ID Number R-4671**;** OAH Docket No. 82-9000-37774

I certify that on October 6, 2021, at least 33 days before the end of the comment period, I sent an email with a link to a copy of the Notice of Intent to Adopt Rules and the Statement of Need and Reasonableness to the two people on the Department's rulemaking emailing list established by Minnesota Statutes, section 14.14, subdivision 1a. Attached is a copy of the email.

Brandon Juran
Radiation Protection Specialist

From: Juran, Brandon (MDH)
To: Juran, Brandon (MDH)
Bcc: [redacted]
Subject: Notice of Intent to Adopt Rules without a Hearing - Radioactive Materials
Date: Wednesday, October 6, 2021 10:43:00 AM
Attachments: image001.png
image002.gif

Protecting, Maintaining and Improving the Health of All Minnesotans

The Minnesota Department of Health (department) has opened the official public comment period for revised rules that govern radioactive materials. The department is proposing rule amendments that incorporate requirements to maintain compatibility with U.S. Nuclear Regulatory Commission regulations as required by our agreement. The department has also proposed minor editorial changes.

The proposed rule revisions, the Notice of Intent to Adopt Rules without a Hearing, and the Statement of Need and Reasonableness (SONAR) are now available to view at www.health.state.mn.us/communities/environment/radiation/monitor/rule/index.html. The official comment period begins on October 11, 2021, giving the public 30 days to comment on the proposed rules.

The department encourages comments. Persons or groups may submit comments on these rules in writing until 4:30 pm on November 10. You must submit all written comments via the Office of Administrative Hearings Rulemaking eComments website. You can find instructions on how to submit your written comments at Office of Administrative Hearings/Comment On Proposed Rules.

You are receiving this communication because you or your organization has requested to receive information about rulemakings from the Minnesota Department of Health or because you or your organization are affected by the proposed rules.

Sincerely,

Radioactive Materials Unit
Division of Environmental Health
P.O. Box 64975
St. Paul, MN 55164-0975
(651) 201-4400
health.ram@state.mn.us
www.health.state.mn.us

iconmdhmnemail

Minnesota Department of Health

CERTIFICATE OF SENDING THE NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING AND THE STATEMENT OF NEED AND REASONABLENESS TO LEGISLATORS AND THE LEGISLATIVE COORDINATING COMMISSION

Proposed Rules Governing Radiation Safety, Minnesota Rules, Chapter 4731
Revisor's ID Number R-4671; OAH Docket No. 82-9000-37774

I certify that on October 6, 2021, when the Department mailed Notice of Intent to Adopt Rules under Minnesota Statutes, section 14.22, I sent an email with a link to a copy of the Notice of Intent to Adopt Rules and the Statement of Need and Reasonableness to certain Legislators and the Legislative Coordinating Commission. I emailed these documents to comply with Minnesota Statutes, section 14.116. A copy of the email is attached to this Certificate.

Brandon Juran
Radiation Protection Specialist

From:	Juran, Brandon (MDH)
To:	Juran, Brandon (MDH)
Bcc:	Ackert, Kristen (MDH); Baily Strand; Legislative Coordinating Commission; Lisa Thimjon; Matthew Elfritz; Megan Hennen; Michelle Weber - LCC; Mike Molzahn; Patrick McQuillan; Peter Strohmeier; Rep. Jennifer Schultz; Rep. Joe Schomacker; Rep. Josh Heintzeman; Rep. Leon Lillie; Rep. Rick Hansen; Rep. Steve Green; Rep. Tina Liebling; Rep. Tony Albright; Sen Bill Ingebrigtsen; Sen. Carrie Ruud; Sen. Foung Hawj; Sen. Jim Abeler; Sen. John Hoffman; Sen. Michelle Benson; Sen. Michelle Wiklund; Sen. Patricia Torres Ray; Tom Brennan; Yingya Vang
Subject:	Notice of Intent to Adopt Rules without a Hearing - Radioactive Materials
Date:	Wednesday, October 6, 2021 10:55:00 AM
Attachments:	image001.png image002.gif

Protecting, Maintaining and Improving the Health of All Minnesotans

The Minnesota Department of Health (department) has opened the official public comment period for revised rules that govern radioactive materials. The department is proposing rule amendments that incorporate requirements to maintain compatibility with U.S. Nuclear Regulatory Commission regulations as required by our agreement. The department has also proposed minor editorial changes.

The proposed rule revisions, the Notice of Intent to Adopt Rules without a Hearing, and the Statement of Need and Reasonableness (SONAR) are now available to view at www.health.state.mn.us/communities/environment/radiation/monitor/rule/index.html. The official comment period begins on October 11, 2021, giving the public 30 days to comment on the proposed rules.

The department encourages comments. Persons or groups may submit comments on these rules in writing until 4:30 pm on November 10. You must submit all written comments via the Office of Administrative Hearings Rulemaking eComments website. You can find instructions on how to submit your written comments at Office of Administrative Hearings/Comment On Proposed Rules.

You are receiving this communication because you or your organization has requested to receive information about rulemakings from the Minnesota Department of Health or because you or your organization are affected by the proposed rules.

Sincerely,

Radioactive Materials Unit
Division of Environmental Health
P.O. Box 64975
St. Paul, MN 55164-0975
(651) 201-4400
health.ram@state.mn.us
www.health.state.mn.us


iconmdhmnemail

From: Juran, Brandon (MDH)
To: Juran, Brandon (MDH)
Bcc: foungh@senate.mn
Subject: Notice of Intent to Adopt Rules without a Hearing - Radioactive Materials
Date: Wednesday, October 6, 2021 2:38:00 PM
Attachments: image001.png
image002.gif

Protecting, Maintaining and Improving the Health of All Minnesotans

The Minnesota Department of Health (department) has opened the official public comment period for revised rules that govern radioactive materials. The department is proposing rule amendments that incorporate requirements to maintain compatibility with U.S. Nuclear Regulatory Commission regulations as required by our agreement. The department has also proposed minor editorial changes.

The proposed rule revisions, the Notice of Intent to Adopt Rules without a Hearing, and the Statement of Need and Reasonableness (SONAR) are now available to view at www.health.state.mn.us/communities/environment/radiation/monitor/rule/index.html. The official comment period begins on October 11, 2021, giving the public 30 days to comment on the proposed rules.

The department encourages comments. Persons or groups may submit comments on these rules in writing until 4:30 pm on November 10. You must submit all written comments via the Office of Administrative Hearings Rulemaking eComments website. You can find instructions on how to submit your written comments at Office of Administrative Hearings/Comment On Proposed Rules.

You are receiving this communication because you or your organization has requested to receive information about rulemakings from the Minnesota Department of Health or because you or your organization are affected by the proposed rules.

Sincerely,

Radioactive Materials Unit
Division of Environmental Health
P.O. Box 64975
St. Paul, MN 55164-0975
(651) 201-4400
health.ram@state.mn.us
www.health.state.mn.us

iconmdhmnemail

Minnesota Department of Health

CERTIFICATE OF GIVING ADDITIONAL NOTICE UNDER THE ADDITIONAL NOTICE PLAN

Proposed Rules Governing Radiation Safety, Minnesota Rules, Chapter 4731; Revisor's ID Number R-4671; OAH Docket No. 82-9000-37774

I certify that on October 6, 2021, I gave notice according to the additional notice plan approved by the Office of Administrative Hearings on August 30, 2021. Specifically:

- I sent an email with a link to a copy of the Notice and the Statement of Need and Reasonableness to 167 specific licensee contacts for the 148 specific licensees. Attached is a copy of the email.
- I sent an email with a link to a copy of the Notice and the Statement of Need and Reasonableness to 49 registered general licensee contacts for the 50 registered general licensees (two of the people are contacts for more than one licensee). Attached is a copy of the email.

Brandon Juran
Radiation Protection Specialist

From: Juran, Brandon (MDH)
To: Juran, Brandon (MDH)
Bcc: [redacted]
Subject: Notice of Intent to Adopt Rules without a Hearing - Radioactive Materials
Date: Wednesday, October 6, 2021 10:51:00 AM
Attachments: image001.png
image002.gif

Protecting, Maintaining and Improving the Health of All Minnesotans

The Minnesota Department of Health (department) has opened the official public comment period for revised rules that govern radioactive materials. The department is proposing rule amendments that incorporate requirements to maintain compatibility with U.S. Nuclear Regulatory Commission regulations as required by our agreement. The department has also proposed minor editorial changes.

The proposed rule revisions, the Notice of Intent to Adopt Rules without a Hearing, and the Statement of Need and Reasonableness (SONAR) are now available to view at www.health.state.mn.us/communities/environment/radiation/monitor/rule/index.html. The official comment period begins on October 11, 2021, giving the public 30 days to comment on the proposed rules.

The department encourages comments. Persons or groups may submit comments on these rules in writing until 4:30 pm on November 10. You must submit all written comments via the Office of Administrative Hearings Rulemaking eComments website. You can find instructions on how to submit your written comments at Office of Administrative Hearings/Comment On Proposed Rules.

You are receiving this communication because you or your organization has requested to receive information about rulemakings from the Minnesota Department of Health or because you or your organization are affected by the proposed rules.

Sincerely,

Radioactive Materials Unit
Division of Environmental Health
P.O. Box 64975
St. Paul, MN 55164-0975
(651) 201-4400
health.ram@state.mn.us
www.health.state.mn.us

iconmdhmnemail

From: Juran, Brandon (MDH)
To: Juran, Brandon (MDH)
Bcc: [redacted]
Subject: Notice of Intent to Adopt Rules without a Hearing - Radioactive Materials
Date: Wednesday, October 6, 2021 10:49:00 AM
Attachments: image001.png
image002.gif

Protecting, Maintaining and Improving the Health of All Minnesotans

The Minnesota Department of Health (department) has opened the official public comment period for revised rules that govern radioactive materials. The department is proposing rule amendments that incorporate requirements to maintain compatibility with U.S. Nuclear Regulatory Commission regulations as required by our agreement. The department has also proposed minor editorial changes.

The proposed rule revisions, the Notice of Intent to Adopt Rules without a Hearing, and the Statement of Need and Reasonableness (SONAR) are now available to view at www.health.state.mn.us/communities/environment/radiation/monitor/rule/index.html. The official comment period begins on October 11, 2021, giving the public 30 days to comment on the proposed rules.

The department encourages comments. Persons or groups may submit comments on these rules in writing until 4:30 pm on November 10. You must submit all written comments via the Office of Administrative Hearings Rulemaking eComments website. You can find instructions on how to submit your written comments at Office of Administrative Hearings/Comment On Proposed Rules.

You are receiving this communication because you or your organization has requested to receive information about rulemakings from the Minnesota Department of Health or because you or your organization are affected by the proposed rules.

Sincerely,

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Division of Environmental Health
P.O. Box 64975
St. Paul, MN 55164-0975
(651) 201-4400
health.ram@state.mn.us
www.health.state.mn.us


iconmdhmnemail

Minnesota Department of Health

CERTIFICATE OF GIVING ADDITIONAL NOTICE TO CORRECT AN INCORRECT LINK TO THE OFFICE OF ADMINISTRATIVE HEARINGS PUBLIC COMMENT WEBSITE IN THE NOTICE OF INTENT TO ADOPT RULES.

Proposed Rules Governing Radiation Safety, Minnesota Rules, Chapter 4731; Revisor's ID Number R-4671; OAH Docket No. 82-9000-37774

It was discovered on October 14, 2021, that the Notice of Intent to Adopt Rules Without a Public Hearing (Notice) had an incorrect link to the eComment page of the Office of Administrative Hearings. On October 15, 2021, I corrected this error as follows:

- I mailed a revised Notice of Intent to Adopt Rules (Revised Notice) by depositing a copy in the State of Minnesota's central mail system for United States mail with postage prepaid, to the four people on the rulemaking mailing list established by Minnesota Statutes, section 14.14, subdivision 1a. A copy of the Revised Notice is attached to this Certificate.
- I sent an email describing the error with a correct link to the OAH e-Comments page and attaching the Revised Notice to the two people on the Department's rulemaking emailing list established by Minnesota Statutes, section 14.14, subdivision 1a. Attached is a copy of the email.
- I sent an email describing the error with a correct link to the OAH e-Comments page and attaching the Revised Notice to the to 167 specific licensee contacts for the 148 specific licensees. Attached is a copy of the email.
- I sent an email describing the error with a correct link to the OAH e-Comments page and attaching the Revised Notice to 49 registered general licensee contacts for the 50 registered general licensees (two of the people are contacts for more than one licensee). Attached is a copy of the email.
- I sent an email describing the error with a correct link to the OAH e-Comments page and attaching the Revised Notice to certain Legislators and the Legislative Coordinating Commission. Attached is a copy of the email.

MDH is not aware of any person who actually attempted to follow the Notice's broken link or who otherwise encountered any issues when seeking to make comments during the formal comment period. Accordingly, MDH took immediate corrective action, and no person was deprived of an opportunity to meaningfully participate in this rulemaking process.

Brandon Juran
Radiation Protection Specialist

DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

October 15, 2021

The Notice of Intent to Adopt Rules without a Public Hearing, published in the State Register on October 11, 2021, regarding the Minnesota Department of Health's (department) proposed amendments to rules governing radiation safety, Minn. R. ch. 4731, contained an incorrect link to the OAH e-Comments page for submitting formal comments on the proposed rule amendment. The correct link to the OAH e-Comments page is as follows: https://minnesotaoah.granicusideas.com/discussions. Enclosed is a corrected copy of the original Notice.

We apologize for any inconvenience this may have caused.

Sincerely,

Radioactive Materials Unit
Division of Environmental Health
P.O. Box 64975
St. Paul, MN 55164-0975
(651) 201-4400
health.ram@state.mn.us
www.health.state.mn.us

From: Juran, Brandon (MDH)
To: Juran, Brandon (MDH)
Bcc: [redacted]
Subject: Correction - Notice of Intent to Adopt Rules without a Hearing - Radioactive Materials
Date: Friday, October 15, 2021 9:31:00 AM
Attachments: image001.png
20211015 FIXED Notice.pdf

Protecting, Maintaining and Improving the Health of All Minnesotans

The Notice of Intent to Adopt Rules without a Public Hearing, published in the State Register on October 11, 2021, regarding the Minnesota Department of Health's (department) proposed amendments to rules governing radiation safety, Minn. R. ch. 4731, contained an incorrect link to the OAH e-Comments page for submitting formal comments on the proposed rule amendment. The correct link to the OAH e-Comments page is as follows: https://minnesotaoah.granicusideas.com/discussions. Attached is a corrected copy of the original Notice.

We apologize for any inconvenience this may have caused.

Sincerely,

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St. Paul, MN 55164-0975
(651) 201-4400
health.ram@state.mn.us
www.health.state.mn.us

From: Juran, Brandon (MDH)
To: Juran, Brandon (MDH)
Bcc: [redacted]
Subject: Correction - Notice of Intent to Adopt Rules without a Hearing - Radioactive Materials
Date: Friday, October 15, 2021 9:43:00 AM
Attachments: 20211015 FIXED Notice.pdf
image001.png

Protecting, Maintaining and Improving the Health of All Minnesotans

The Notice of Intent to Adopt Rules without a Public Hearing, published in the State Register on October 11, 2021, regarding the Minnesota Department of Health's (department) proposed amendments to rules governing radiation safety, Minn. R. ch. 4731, contained an incorrect link to the OAH e-Comments page for submitting formal comments on the proposed rule amendment. The correct link to the OAH e-Comments page is as follows: https://minnesotaoah.granicusideas.com/discussions. Attached is a corrected copy of the original Notice.

We apologize for any inconvenience this may have caused.

Sincerely,

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P.O. Box 64975
St. Paul, MN 55164-0975
(651) 201-4400
health.ram@state.mn.us

www.health.state.mn.us

From: Juran, Brandon (MDH)
To: Juran, Brandon (MDH)
Bcc: [redacted]
Subject: Correction - Notice of Intent to Adopt Rules without a Hearing - Radioactive Materials
Date: Friday, October 15, 2021 9:40:00 AM
Attachments: image001.png
20211015 FIXED Notice.pdf

Protecting, Maintaining and Improving the Health of All Minnesotans

The Notice of Intent to Adopt Rules without a Public Hearing, published in the State Register on October 11, 2021, regarding the Minnesota Department of Health's (department) proposed amendments to rules governing radiation safety, Minn. R. ch. 4731, contained an incorrect link to the OAH e-Comments page for submitting formal comments on the proposed rule amendment. The correct link to the OAH e-Comments page is as follows: https://minnesotaoah.granicusideas.com/discussions. Attached is a corrected copy of the original Notice.

We apologize for any inconvenience this may have caused.

Sincerely,

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Division of Environmental Health
P.O. Box 64975
St. Paul, MN 55164-0975
(651) 201-4400
health.ram@state.mn.us
www.health.state.mn.us

From:	Juran, Brandon (MDH)
To:	Juran, Brandon (MDH)
Bcc:	Ackert, Kristen (MDH); Baily Strand; Legislative Coordinating Commission; Lisa Thimjon; Matthew Elfritz; Megan Hennen; Michelle Weber - LCC; Mike Molzahn; Patrick McQuillan; Peter Strohmeier; Rep. Jennifer Schultz; Rep. Joe Schomacker; Rep. Josh Heintzeman; Rep. Leon Lillie; Rep. Rick Hansen; Rep. Steve Green; Rep. Tina Liebling; Rep. Tony Albright; Sen Bill Ingebrigtsen; Sen. Carrie Ruud; Sen. Foung Hawj; Sen. Jim Abeler; Sen. John Hoffman; Sen. Michelle Benson; Sen. Michelle Wiklund; Sen. Patricia Torres Ray; Tom Brennan; Yingya Vang
Subject:	Correction - Notice of Intent to Adopt Rules without a Hearing - Radioactive Materials
Date:	Friday, October 15, 2021 9:47:00 AM
Attachments:	20211015 FIXED Notice.pdf image001.png

Protecting, Maintaining and Improving the Health of All Minnesotans

The Notice of Intent to Adopt Rules without a Public Hearing, published in the State Register on October 11, 2021, regarding the Minnesota Department of Health's (department) proposed amendments to rules governing radiation safety, Minn. R. ch. 4731, contained an incorrect link to the OAH e-Comments page for submitting formal comments on the proposed rule amendment. The correct link to the OAH e-Comments page is as follows: https://minnesotaoah.granicusideas.com/discussions. Attached is a corrected copy of the original Notice.

We apologize for any inconvenience this may have caused.

Sincerely,

Radioactive Materials Unit
Division of Environmental Health
P.O. Box 64975
St. Paul, MN 55164-0975
(651) 201-4400
health.ram@state.mn.us
www.health.state.mn.us

Minnesota Department of Health

Environmental Health Division

NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING

Proposed Amendment to Rules Governing Radiation Safety, Minnesota Rules, Chapter 4731; Revisor's ID Number R-4671

Introduction. The Department of Health (MDH) intends to adopt rules without a public hearing following the procedures in the rules of the Office of Administrative Hearings (OAH), Minnesota Rules, parts 1400.2300 to 1400.2310, and the Administrative Procedure Act, Minnesota Statutes, sections 14.22 to 14.28. Specific rule parts to be revised are:

- 4731.0100, subps. 19a, 157a, 174;
- 4731.0406, subp. 3;
- 4731.0419, subps. 3, 6;
- 4731.0422, subp. 2;
- 4731.2750, subp. 7;
- 4731.3075, subp. 7;
- 4731.3330, subp. 4;
- 4731.3395, subps. 1, 2, 3a;
- 4731.4170, subps. 1, 4, 6;
- 4731.4310
- 4731.4403, subps. 2–5;
- 4731.4405, subp. 1;
- 4731.4408, subp 2;
- 4731.4409;
- 4731.4411, subp. 1;
- 4731.4412, subps. 1, 2;
- 4731.4413, subp. 1;
- 4731.4414;
- 4731.4423, subps. 1–3;
- 4731.4433, subp. 1;
- 4731.4435;
- 4731.4436, subps. 1, 2;
- 4731.4440;
- 4731.4443, subps. 1, 2;
- 4731.4444;
- 4731.4445;
- 4731.4446;
- 4731.4450;
- 4731.4456;
- 4731.4458, subps. 1, 2;
- 4731.4459;
- 4731.4460;
- 4731.4461;
- 4731.4463;
- 4731.4466;
- 4731.4477, subps. 1, 2;
- 4731.4479, subps. 1, 2;
- 4731.4500, subp. 1;
- 4731.4510;
- 4731.4524;
- 4731.4525, subps. 1, 7;
- 4731.4526, subp. 6;
- 4731.4528, subps. 1, 2;
- 4731.6180, subp. 1;
- 4731.7220;
- 4731.8015, subp. 2;
- 4731.8025, subp. 3;
- 4731.8055, subp. 4; and
- 4731.8115, subp. 2.

Subject of Rules and Statutory Authority. Minnesota Statutes, sections 144.1202 and 144.1203, authorize MDH to adopt rules that allow the state to assume regulatory authority under an agreement with the U.S. Nuclear Regulatory Commission (NRC), including licensing and regulation of radioactive materials, and to ensure that individuals handling or using radioactive materials have proper training and qualifications.

Minnesota Rules, Chapter 4731, which the proposed rules are amending, is where the rules adopted pursuant to this statutory authority are contained. MDH proposes to amend this chapter, as noted above, to reflect NRC's recent regulation changes. The proposed changes conform MDH's rules to NRC-mandated regulations. The proposed changes also include revisions to clarify existing requirements and to correct editorial issues. The current rule can be accessed at https://www.revisor.mn.gov/rules/4731/. A free copy of the rule is also available upon request from the agency contact person listed below.

Proposed Rule Revision Language and Statement of Need and Reasonableness. The rule amendments and the Statement of Need and Reasonableness (SONAR) can be reviewed at

https://www.health.state.mn.us/communities/environment/radiation/monitor/rule/index.html. The SONAR contains a summary of the justification for the proposed rules, including a description of who will be affected by the proposed rules and an estimate of the probable cost of the proposed rules. It is now available from the agency contact person. You may review it or obtain copies for the cost of reproduction by contacting the agency contact person.

Agency Contact Person. You may submit questions on the rules and written requests for a public hearing to the agency contact person. The agency contact person is:

Brandon Juran
Minnesota Department of Health
P.O. Box 64975
St. Paul, MN 55164-0975
Phone: (651) 201-4526
Fax: (651) 201-4606
brandon.juran@state.mn.us.

Comments. MDH encourages comment. You have until 4:30 p.m. on November 10, 2021, to submit written comments in support of or in opposition to the proposed rules and any part or subpart of the rules. You must submit all written comments via the OAH Rulemaking e-comments website (https://minnesotaoah.granicusideas.com/discussions), where you may also review the proposed rule and SONAR. Your comments must be in writing. Your comments should identify the portion of the proposed rules addressed and the reason for the comment. You are encouraged to propose any change desired. Any comments that you have about the legality of the proposed rules must also be made during this comment period.

Request for a Hearing. In addition to submitting comments, you may also request that MDH hold a hearing on the rules. Your request must be in writing, and the agency contact person must receive it by 4:30 p.m. on November 10, 2021. Your written request for a public hearing must include your name and address. You must identify the portion or portions of the proposed rules that you object to or state that you oppose the entire set of rules. Any request that does not comply with these requirements is not valid and MDH cannot count it when determining whether it must hold a public hearing. You are also encouraged to state the reason for the request and any changes you want made to the proposed rules.

Withdrawal of Requests. If 25 or more persons submit a valid written request for a hearing, MDH will hold a public hearing unless a sufficient number withdraw their requests in writing. If enough requests for hearing are withdrawn to reduce the number below 25, the agency must give written notice of this to all persons who requested a hearing, explain the actions the agency took to effect the withdrawal, and ask for written comments on this action. If a public hearing is required, the agency will follow the procedures in Minnesota Statutes, sections 14.131 to 14.20.

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 the agency contact person at the address or telephone number listed above.

Modifications. MDH may modify the proposed rules as a result of public comment. The modifications must be supported by comments and information submitted to the agency, and the

adopted rules may not be substantially different than these proposed rules, unless the agency follows the procedure under Minnesota Rules, part 1400.2110. If the proposed rules affect you in any way, MDH encourages you to participate in the rulemaking process.

Lobbyist Registration. *Minnesota Statutes*, chapter 10A, requires each lobbyist to register with the State Campaign Finance and Public Disclosure Board. You should direct questions about this requirement to the Campaign Finance and Public Disclosure Board at: Suite 190, Centennial Building, 658 Cedar Street, St. Paul, Minnesota 55155, telephone (651) 539-1180 or 1-800-657-3889.

Adoption and Review of Rules. If no hearing is required, MDH may adopt the rules after the end of the comment period. MDH will then submit the rules and supporting documents to OAH for review for legality. You may ask to be notified of the date MDH submits the rules to OAH. If you want to be so notified, receive a copy of the adopted rules, or register with MDH to receive notice of future rule proceedings, submit your request to the agency contact person listed above.

October 11, 2021

Jan Malcolm
Commissioner
Department of Health

Minnesota Department of Health

CERTIFICATE OF MAILING THE STATEMENT OF NEED AND REASONABLENESS TO THE LEGISLATIVE REFERENCE LIBRARY

Proposed Rules Governing Radiation Safety, Minnesota Rules, Chapter 4731; Revisor's ID Number R-4671; OAH Docket No. 82-9000-37774

I certify that on October 6, 2021, when the Notice of Intent to Adopt Rule Without a Hearing was mailed, I submitted an electronic copy of the Statement of Need and Reasonableness to the Legislative Reference Library via email to sonars@lrl.leg.mn. I emailed this copy to comply with Minnesota Statutes, sections 14.131 and 14.23. A copy of the email is attached to this Certificate.

Brandon Juran
Radiation Protection Specialist

From: Juran, Brandon (MDH)
To: sonars@lrl.mn.gov
Subject: SONAR - Radioactive Materials Rules (R-4671)
Date: Wednesday, October 6, 2021 12:57:00 PM
Attachments: 2021.10.06_Ltr_Legislative Reference Library_R-4671.pdf
2021.10.04_MDH_NRC SONAR_R-4671.pdf
image001.gif

Good afternoon,

Please see attached cover letter and Statement of Need and Reasonableness for Department of Health rulemaking governing radioactive materials (R-4671).

Sincerely,

Brandon Juran

Brandon Juran
Radiation Protection Specialist | Radioactive Materials Unit

Minnesota Department of Health
Office: 651-201-4526

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

From: [redacted]
To: Juran, Brandon (MDH)
Subject: RE: Notice of Intent to Adopt Rules without a Hearing - Radioactive Materials
Date: Wednesday, October 6, 2021 4:10:14 PM

Brandon,
I am still and always have held the I131 cats for 9 to 14 days depending on the dose they received and their clearance... I never did an early release. Is there anything in the proposed changes that you think might apply to me as someone who receives materials that I should look for or focus on specifically?
Ralph Weichselbaum
Veterinary Radiation Therapy Clinic, Inc.
[redacted]

They are long and odds are I might miss the important bits.

Sent from my Sprint Samsung Galaxy S9.

-------- Original message --------
From: "Juran, Brandon (MDH)" <brandon.juran@state.mn.us>
Date: 10/6/21 10:52 AM (GMT-06:00)
To: "Juran, Brandon (MDH)" <brandon.juran@state.mn.us>
Subject: Notice of Intent to Adopt Rules without a Hearing - Radioactive Materials

Protecting, Maintaining and Improving the Health of All Minnesotans

The Minnesota Department of Health (department) has opened the official public comment period for revised rules that govern radioactive materials. The department is proposing rule amendments that incorporate requirements to maintain compatibility with U.S. Nuclear Regulatory Commission regulations as required by our agreement. The department has also proposed minor editorial changes.

The proposed rule revisions, the Notice of Intent to Adopt Rules without a Hearing, and the Statement of Need and Reasonableness (SONAR) are now available to view at www.health.state.mn.us/communities/environment/radiation/monitor/rule/index.html. The official comment period begins on October 11, 2021, giving the public 30 days to comment on the proposed rules.

The department encourages comments. Persons or groups may submit comments on these rules in writing until 4:30 pm on November 10. You must submit all written comments via the Office of Administrative Hearings Rulemaking eComments website. You can find instructions on how to submit your written comments at Office of Administrative Hearings/Comment On Proposed Rules.

You are receiving this communication because you or your organization has requested to receive information about rulemakings from the Minnesota Department of Health or because you or your organization are affected by the proposed rules.

Sincerely,

Radioactive Materials Unit
Division of Environmental Health
P.O. Box 64975
St. Paul, MN 55164-0975

(651) 201-4400

health.ram@state.mn.us

www.health.state.mn.us

iconmdhmnemail

From: [redacted]
To: Juran, Brandon (MDH)
Subject: Radiation Safety Rules Amendment
Date: Tuesday, October 12, 2021 11:44:15 AM
Attachments: image003.png

Good afternoon, Brandon.

We were reviewing the latest Register and saw the section saying there will be proposed amendments to a swath of rules (4731) relating to radiation safety.

Is there a way to see what those may be as there? There are certain sections that could impact our organization and just trying gauge if they are material changes.

Thanks again for the help and any insights!

CDI IS NOW RAYUS RADIOLOGY

ZACHARY BRUNNERT | DIRECTOR, STATE LEGISLATIVE POLICY
[redacted]
www.RAYUSradiology.com

Minnesota Department of Health

ORDER ADOPTING RULES

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

BACKGROUND

1. The Minnesota Department of Health has complied with all notice and procedural requirements in Minnesota Statutes, chapter 14, Minnesota Rules, chapter 1400, and other applicable law. The department discovered an error in the Notice of Intent to Adopt Rules that was published in the October 11, 2021, State Register and corrected the error as described in the Certificate of Giving Additional Notice to Correct an Incorrect Link that is included in this rulemaking record. The department is aware of no person or entity that was deprived of an opportunity to participate in this rulemaking process as a result of this error and took immediate efforts to correct it. Accordingly, the Office of Administrative Hearings should find it to be harmless under Minnesota Statutes, section 14.26, subdivision 3, paragraph (d).

2. The agency received written comments and submissions on the rules. No persons requested a public hearing. The agency received no requests for notice of submission to the Office of Administrative Hearings.

3. No changes were made between the proposed rules and the adopted rules.

4. The rules are needed and reasonable.

ORDER

The above-named rules, in the form published in the State Register on October 11, 2021, are adopted.

Date

Jan Malcolm, Commissioner
Department of Health

Minnesota Department of Health

Proposed Rules Governing Radiation Safety, Minnesota Rules, Chapter 4731; Revisor's ID Number R-4671; OAH Docket No. 82-9000-37774

A notice of submission of the rule to the Office of Administrative Hearings was not requested by anyone.

Minnesota Department of Health

CERTIFICATE OF NO IMPACT ON FARMING OPERATIONS PURSUANT TO MINNESOTA STATUES, SECTION 14.111

In the Matter of the Proposed Rules of the Department of Health Governing Radioactive Materials; OAH Docket No. 82-9000-37774; Revisor's ID Number 4671

I certify that these rule revisions will have no impact on farming operations.

Brandon Juran
Radiation Protection Specialist

OAH 82-9000-37774
Revisor R-4671

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of Minn. R. 4731, Possible Amendment to Rules Governing Radiation Safety, Revisor's ID No. R-4671

ORDER ON REVIEW OF ADDITIONAL NOTICE PLAN

This matter came before Administrative Law Judge Barbara J. Case upon the Minnesota Department of Health's (Department) request for review of its Additional Notice Plan under Minn. R. 1400.2060 (2021). Pursuant to its Additional Notice Plan filed on August 27, 2021, the Department proposes to send the Notice of Intent to Adopt to everyone who has registered to be on the department's rulemaking mailing list under Minn. Stat. § 14.14, subd. 1a (2020). The Department will also give notice to the Legislature per Minn. Stat. § 14.116 (2020).

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 150 facilities that have an MDH-specific radioactive materials license, and the 56 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 Department's website.

Based upon a review of the written submissions by the Department,

IT IS HEREBY ORDERED THAT:

The Additional Notice Plan is **APPROVED**.

Dated: August 30, 2021

Barbara J. Case
Administrative Law Judge

[164157/1]

OAH 82-9000-37774
Revisor R-4671

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of Minn. R. 4731, Possible Amendment to Rules Governing Radiation Safety, Revisor's ID No. R-4671

ORDER ON REQUEST TO OMIT FROM THE NOTICE THE TEXT OF PROPOSED RULES, PURSUANT TO MINN. STAT. § 14.22, SUBD. 1(B) (2020)

This matter came before Chief Administrative Law Judge Jenny Starr on August 27, 2021. The Minnesota Department of Health (Department) seeks an order authorizing the omission of the proposed rule text when it publishes the Notice of Intent to Adopt Rules Without a Public Hearing (Notice). The Department asserts that publication of the proposed rules in the *State Register* is cost-prohibitive.

As an alternative to publication, the Department pledges that the Notice will state that a free copy of the entire proposed rules will be available upon request to the Department and indicate how to make that request. The Notice will also identify the website link where a copy may be obtained. Finally, the Notice will state the subject matter of the omitted rules, cite the statutory authority for the proposed rules, and outline the proposed rules' purpose. In addition, the Department's Statement of Need and Reasonableness (SONAR) will be transmitted as outlined in the Notice Plan, which SONAR will be available free of charge by request and posted on the Department's website.

IT IS HEREBY ORDERED THAT:

Conditioned upon the Department's use of the procedures outlined in its petition of August 27, 2021, the petition to omit the proposed rule text is **GRANTED**.

Dated: August 30, 2021

JENNY STARR
Chief Administrative Law Judge

[164148/1]

MINNESOTA
OFFICE OF
ADMINISTRATIVE
HEARINGS

PO Box 64620
Saint Paul, MN 55164-0620
mn.gov/oah

PH (651) 361-7900

August 30, 2021

VIA EMAIL ONLY
Josh Skaar
Attorney at Law
Minnesota Department of Health
625 N Robert St
Saint Paul, MN 55164
Josh.skaar@state.mn.us

Re: ***In the Matter of Minn. R. 4731, Possible Amendment to Rules Governing Radiation Safety, Revisor's ID No. R-4671***
OAH 82-9000-37774; Revisor R-4671

Dear Mr. Skaar:

Enclosed herewith and served upon you please find the **ORDER ON REVIEW OF ADDITIONAL NOTICE PLAN** and **ORDER ON REQUEST TO OMIT FROM THE NOTICE THE TEXT OF PROPOSED RULES, PURSUANT TO MINN. STAT. § 14.22, SUBD. 1(B) (2020),** in the above-entitled matter.

Prior to publishing the in the State Register, please notify the Office of Administrative Hearings (OAH) at denise.collins@state.mn.us in order to activate the agency's eComments page on the OAH's website. **Please note that if you do not notify us of the publication, the eComments site will not be available to receive public comments.**

If you have any questions regarding this matter, please contact Denise Collins at (651) 361-7875, denise.collins@state.mn.us or via facsimile at (651) 539-0310.

Sincerely,

Michelle Severson

MICHELLE SEVERSON
Legal Assistant

Enclosure

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS
ADMINISTRATIVE LAW SECTION
PO BOX 64620
600 NORTH ROBERT STREET
ST. PAUL, MINNESOTA 55164

CERTIFICATE OF SERVICE

In the Matter of Minn. R. 4731, Possible Amendment to Rules Governing Radiation Safety, Revisor's ID No. R-4671	OAH Docket No. 82-9000-37774 R-4671

Michelle Severson certifies that on August 30, 2021, she served a true and correct copy of the attached **ORDER ON REVIEW OF ADDITIONAL NOTICE PLAN** and **ORDER ON REQUEST TO OMIT FROM THE NOTICE THE TEXT OF PROPOSED RULES, PURSUANT TO MINN. STAT. § 14.22, SUBD. 1(B) (2020)**; by placing it in the United States mail or by courier service with postage prepaid, addressed to the following individuals:

VIA EMAIL ONLY Josh Skaar Attorney at Law Minnesota Department of Health 625 N Robert St Saint Paul, MN 55164 Josh.skaar@state.mn.us	

RECEIVED
By: OAH on 8/27/2021 @ 2:19 pm

DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

August 27, 2021

The Honorable Jenny Starr
Chief Administrative Law Judge
Office of Administrative Hearings
600 North Robert Street P.O. Box 64620
Saint Paul, Minnesota 55164-0620

Re: In the Matter of the Proposed Rules of Minnesota Department of Health Governing Assisted Living Facilities; Minnesota Rules 4731, Revisor's ID Number 4671; OAH Docket No. 82-9000-37774.

Request for Review and Approval of the Additional Notice Plan under Minnesota Rules, 1400.2060; and

Request for authorization to omit the text of the proposed rules from the Department Notice of Intent to Adopt Rules without a Public Hearing under Minnesota Statutes, section 14.22, subdivision 1(b).

Dear Chief Judge Starr:

The Minnesota Department of Health (MDH) requests that you review and approve our Additional Notice Plan. The proposed revisions that are the subject of this rulemaking pertain to the Nuclear Regulatory Commission's (NRC) updated requirements for radiation safety.

The documents for the Administrative Law Judge's review, as required by Minnesota Rules, 1400.2060, subpart 2, item B, have been e-filed. They are:

(1) a copy of the proposed rules;
(2) a draft of the Statement of Need and Reasonableness (SONAR), containing a description of our Additional Notice Plan on page 8; and
(3) a draft Notice of Intent to Adopt Rules without a Public Hearing.

Part 1400.2060 also requires an explanation of why we believe our Additional Notice Plan complies with Minnesota Statutes, section 14.22 (i.e., why our Additional Notice Plan constitutes reasonable efforts to notify persons or classes of persons who might be significantly affected by the rules). We believe our Additional Notice Plan complies with the statute as described further at page 8 of the SONAR. Moreover, this plan is substantially similar to previous additional notice plans regarding changes to these rules that have received Office of Administrative Hearings (OAH) approval. *See, e.g.*, SONAR dated April 18, 2019, at 5 (available at https://www.lrl.mn.gov/archive/sonar/SONAR-04477.pdf).

We also respectfully request your authorization to omit the text of the proposed rule amendments from our publication of the Notice Intent under Minnesota Statutes, section

14.22, subdivision 1(b), for the following reasons. First, the department believes publishing the rule would be cumbersome, expensive, and inexpedient. The Environmental Health Division of MDH, in consultation with the State Register, estimates that publishing the rules text would be more than $8,700.00 and a similar amount when the rules need to be published again with the Notice of Adoption and Order. Second, knowledge of the rule is likely to be important to only a small class of persons including program licensees, many of whom will already receive copies of the rule revisions under the Additional Notice Plan. Other persons interested in this rule will be more likely to find the Notice on the MDH website than in the State Register. Third, the Notice of Intent states that a free copy of the rule is available upon request. In addition, we will post the draft rules and the Statement of Need and Reasonableness on the department's dedicated RAM Licensure website. We will make any additional arrangements you deem appropriate to supplement access to the proposed rule in lieu of publication. Finally, the Notice of Intent to Adopt Rules without a Public Hearing includes the rule-related information required under section 14.22, subdivision 1(b)(3).

Thank you for your consideration. If you have any questions or need more information, please contact me at josh.skaar@state.mn.us or 651-201-5923.

Sincerely,

/s/ *Josh Skaar*

Josh Skaar, MDH Rulemaking Coordinator
Minnesota Department of Health
625 Robert Street North
P.O. Box 64975
Saint Paul, MN 55164-0975

Enclosures:

Minnesota Department of Health

Environmental Health Division

NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING

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

Introduction. The Department of Health (MDH) intends to adopt rules without a public hearing following the procedures in the rules of the Office of Administrative Hearings (OAH), Minnesota Rules, parts 1400.2300 to 1400.2310, and the Administrative Procedure Act, Minnesota Statutes, sections 14.22 to 14.28. Specific rule parts to be revised are:

- 4731.0100, subps. 19a, 157a, 174;
- 4731.0406, subp. 3;
- 4731.0419, subps. 3, 6;
- 4731.0422, subp. 2;
- 4731.2750, subp. 7;
- 4731.3075, subp. 7;
- 4731.3330, subp. 4;
- 4731.3395, subps. 1, 2, 3a;
- 4731.4170, subps. 1, 4, 6;
- 4731.4310
- 4731.4403, subps. 2–5;
- 4731.4405, subp. 1;
- 4731.4408, subp 2;
- 4731.4409;
- 4731.4411, subp. 1;
- 4731.4412, subps. 1, 2;
- 4731.4413, subp. 1;
- 4731.4414;
- 4731.4423, subps. 1–3;
- 4731.4433, subp. 1;
- 4731.4435;
- 4731.4436, subps. 1, 2;
- 4731.4440;
- 4731.4443, subps. 1, 2;
- 4731.4444;
- 4731.4445;
- 4731.4446;
- 4731.4450;
- 4731.4456;
- 4731.4458, subps. 1, 2;
- 4731.4459;
- 4731.4460;
- 4731.4461;
- 4731.4463;
- 4731.4466;
- 4731.4477, subps. 1, 2;
- 4731.4479, subps. 1, 2;
- 4731.4500, subp. 1;
- 4731.4510;
- 4731.4524;
- 4731.4525, subps. 1, 7;
- 4731.4526, subp. 6;
- 4731.4528, subps. 1, 2;
- 4731.6180, subp. 1;
- 4731.7220;
- 4731.8015, subp. 2;
- 4731.8025, subp. 3;
- 4731.8055, subp. 4; and
- 4731.8115, subp. 2.

Subject of Rules and Statutory Authority. Minnesota Statutes, sections 144.1202 and 144.1203, authorize MDH to adopt rules that allow the state to assume regulatory authority under an agreement with the U.S. Nuclear Regulatory Commission (NRC), including licensing and regulation of radioactive materials, and to ensure that individuals handling or using radioactive materials have proper training and qualifications.

Minnesota Rules, Chapter 4731, which the proposed rules are amending, is where the rules adopted pursuant to this statutory authority are contained. MDH proposes to amend this chapter, as noted above, to reflect NRC's recent regulation changes. The proposed changes conform MDH's rules to NRC-mandated regulations. The proposed changes also include revisions to clarify existing requirements and to correct editorial issues. The current rule can be accessed at https://www.revisor.mn.gov/rules/4731/. A free copy of the rule is also available upon request from the agency contact person listed below.

Proposed Rule Revision Language and Statement of Need and Reasonableness. The rule amendments and the Statement of Need and Reasonableness (SONAR) can be reviewed at https://www.health.state.mn.us/communities/environment/radiation/monitor/rule/index.html. The SONAR contains a summary of the justification for the proposed rules, including a description of who will be affected by the proposed rules and an estimate of the probable cost of the proposed rules. It is now available from the agency contact person. You may review it or obtain copies for the cost of reproduction by contacting the agency contact person.

Agency Contact Person. You may submit questions on the rules and written requests for a public hearing to the agency contact person. The agency contact person is:

Brandon Juran
Minnesota Department of Health
P.O. Box 64975
St. Paul, MN 55164-0975
Phone: (651) 201-4526
Fax: (651) 201-4606
brandon.juran@state.mn.us.

Comments. MDH encourages comment. You have until 4:30 p.m. on [month], [date], [year], to submit written comments in support of or in opposition to the proposed rules and any part or subpart of the rules. You must submit all written comments via the OAH Rulemaking e-comments website (https://minnesotaoah.granicusideas.com/discussion), where you may also review the proposed rule and SONAR. Your comments must be in writing. Your comments should identify the portion of the proposed rules addressed and the reason for the comment. You are encouraged to propose any change desired. Any comments that you have about the legality of the proposed rules must also be made during this comment period.

Request for a Hearing. In addition to submitting comments, you may also request that MDH hold a hearing on the rules. Your request must be in writing, and the agency contact person must receive it by 4:30 p.m. on [month] [date], [year]. Your written request for a public hearing must include your name and address. You must identify the portion or portions of the proposed rules that you object to or state that you oppose the entire set of rules. Any request that does not comply with these requirements is not valid and MDH cannot count it when determining whether it must hold a public hearing. You are also encouraged to state the reason for the request and any changes you want made to the proposed rules.

Withdrawal of Requests. If 25 or more persons submit a valid written request for a hearing, MDH will hold a public hearing unless a sufficient number withdraw their requests in writing. If enough requests for hearing are withdrawn to reduce the number below 25, the agency must give written notice of this to all persons who requested a hearing, explain the actions the agency took to effect the withdrawal, and ask for written comments on this action. If a public hearing is required, the agency will follow the procedures in Minnesota Statutes, sections 14.131 to 14.20.

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 the agency contact person at the address or telephone number listed above.

Modifications. MDH may modify the proposed rules as a result of public comment. The modifications must be supported by comments and information submitted to the agency, and the adopted rules may not be substantially different than these proposed rules, unless the agency follows the procedure under Minnesota Rules, part 1400.2110. If the proposed rules affect you in any way, MDH encourages you to participate in the rulemaking process.

Lobbyist Registration. *Minnesota Statutes*, chapter 10A, requires each lobbyist to register with the State Campaign Finance and Public Disclosure Board. You should direct questions about this requirement to the Campaign Finance and Public Disclosure Board at: Suite 190, Centennial Building, 658 Cedar Street, St. Paul, Minnesota 55155, telephone (651) 539-1180 or 1-800-657-3889.

Adoption and Review of Rules. If no hearing is required, MDH may adopt the rules after the end of the comment period. MDH will then submit the rules and supporting documents to OAH for review for legality. You may ask to be notified of the date MDH submits the rules to OAH. If you want to be so notified, receive a copy of the adopted rules, or register with MDH to receive notice of future rule proceedings, submit your request to the agency contact person listed above.

_____ _____

Date [Name]
[Title]

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

The 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 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.

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 the rule. 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;

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 definitions, duties, and qualification requirements for the new positions of associate radiation safety officer and ophthalmic physicist;
- 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.

A detailed summary and discussion of NRC changes are found in the Federal Register using the citations in paragraphs 1 through 6.[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.

[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)].

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
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 agency 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 federal 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 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.

4 *See* 42 U.S.C. § 2021(j)(1).

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 150 facilities that have an MDH-specific radioactive materials license, and the 56 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 will consult with Minnesota Management and Budget (MMB). We will do this by sending MMB copies of the proposed rules and the SONAR. We will do this before the Department's publishing the Notice of Intent to Adopt. The Department will submit a copy of the cover correspondence and any response received from Minnesota Management and Budget to OAH with the documents it submits for ALJ review. [Put in date sent]

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 on page 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 handing handling or utilizing radioactive materials "must be at least as stringent as" NRC regulations of these areas.5 The need and reasonableness of these NCR C and D 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

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

5 *See* Minn. Stat. § 144.1203

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, the 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. In 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 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.

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).

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 and amendment or renewal. This is needed and reasonable so licensees know what to submit with their amendment or renewal request.

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.

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

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 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.

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

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

CONCLUSION

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

_____	_____
Date	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 [(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
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		

MN Rule Part	Title	10 CFR	Compatibility
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**
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

MN Rule Part	Title	10 CFR	Compatibility
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)**
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**

MN Rule Part	Title	10 CFR	Compatibility
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.

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Department of Health

Proposed Permanent Rules Relating to Radioactive Materials

4731.0100 DEFINITIONS.

[For text of subparts 1 to 19, see Minnesota Rules]

Subp. 19a. **Associate radiation safety officer.** "Associate radiation safety officer" means an individual who:

A. meets the requirements in parts 4731.4411 and 4731.4415; and

B. is currently identified as an associate radiation safety officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the radiation safety officer on:

(1) a specific medical use license issued by the commissioner, NRC, or an agreement state; or

(2) a medical use permit issued by an NRC master material licensee.

[For text of subparts 20 to 157, see Minnesota Rules]

Subp. 157a. **Ophthalmic physicist.** "Ophthalmic physicist" means an individual who:

A. meets the requirements in parts 4731.4456, item A, subitem (2), and 4731.4415; and

B. is identified as an ophthalmic physicist on a:

(1) specific medical use license issued by the commissioner, NRC, or an agreement state;

(2) permit issued by a commissioner, NRC, or agreement state broad scope medical use licensee;

(3) medical use permit issued by an NRC master material licensee; or

(4) permit issued by an NRC master material licensee broad scope medical use permittee.

[For text of subparts 158 to 173, see Minnesota Rules]

Subp. 174. **Preceptor.** "Preceptor" means an individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, ~~an~~ authorized medical physicist, ~~an~~ authorized nuclear pharmacist, ~~or~~ a radiation safety officer, or an associate radiation safety officer.

[For text of subparts 175 to 269, see Minnesota Rules]

4731.0406 GENERAL LICENSE; NRC-APPROVED PACKAGE.

[For text of subparts 1 and 2, see Minnesota Rules]

Subp. 3. **Compliance with conditions.** Each licensee issued a general license under subpart 1 must:

[For text of items A and B, see Minnesota Rules]

C. submit in writing to the NRC, before the licensee's first use of the package, the licensee's name and license number and the package identification number specified in the package approval. For the submittal to the NRC, the licensee must use an approved method listed in the Code of Federal Regulations, title 10, section 71.1(a), addressed to: ATTN: Document Control Desk, Director, Division of ~~Spent~~ Fuel ~~Storage and Transportation~~ Management, Office of Nuclear Material Safety and Safeguards.

[For text of subparts 4 and 5, see Minnesota Rules]

4731.0419 ADVANCE NOTIFICATION OF SHIPMENT OF IRRADIATED REACTOR FUEL AND NUCLEAR WASTE.

[For text of subparts 1 and 2, see Minnesota Rules]

Subp. 3. **Procedures for submitting notification.**

A. The notification required under this part must:

(1) be made in writing to the commissioner, the office of each appropriate state governor or governor's designee, the office of each appropriate Tribal official or Tribal official's designee, and to the director ~~of the Division of Security Policy~~, Office of Nuclear Security and Incident Response, NRC;

[For text of subitems (2) and (3), see Minnesota Rules]

B. Contact information, including telephone and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on the NRC website at: https://scp.nrc.gov/special/designee.pdf. The information is also available on request from the Director, Division of ~~Material~~ Materials Safety, Security, State, and Tribal~~, and Rulemaking~~ Programs, Office of Nuclear Material Safety and Safeguards, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

[For text of item C, see Minnesota Rules]

[For text of subparts 4 to 5a, see Minnesota Rules]

Subp. 6. **Cancellation notice.**

A. A licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent must send a cancellation notice to the commissioner, the governor of each state or the governor's designee previously notified, each Tribal official or the Tribal official's designee previously notified, and the director ~~of the Division of Security Policy~~, Office of Nuclear Security and Incident Response, NRC.

[For text of items B and C, see Minnesota Rules]

4731.0422 A_1 AND A_2 VALUES FOR RADIONUCLIDES.

Subpart 1. [Repealed, 32 SR 831]

[For text of subpart 1a, see Minnesota Rules]

Subp. 2. **Specific activity.** This subpart specifies specific activity for individual radionuclides.

Element and Atomic Number and Symbol of Radionuclide	Specific Activity (TBq/g)	Specific Activity (Ci/g)

[For text of Actinium (89) to Silicon (14), see Minnesota Rules]

Samarium (62)		
Sm-145	9.8×10^{1}	2.6×10^{3}
	~~8.5×10^{-1}~~	
Sm-147	8.5×10^{-10}	2.3×10^{-8}
Sm-151	9.7×10^{-1}	2.6×10^{1}
Sm-153	1.6×10^{4}	4.4×10^{5}

[For text of Tin (50) to Zirconium (40), see Minnesota Rules]

[For text of subpart 3, see Minnesota Rules]

4731.2750 ANNUAL LIMITS ON INTAKE AND DERIVED AIR CONCENTRATIONS.

[For text of subparts 1 to 6, see Minnesota Rules]

Subp. 7. **Table of ALIs and DACs.**

	Table 1			Table 2		Table 3
Atomic Number (AN), Radionuclide, and Class	1	2	3	1	2	

[For text of Atomic Numbers 1 to 55 (AN 1 to AN 55), see Minnesota Rules]

AN 56

Barium-126[2]

77.23	D, all compounds	6E+3	2E+4	6E-6	2E-8	8E-5	8E-4
78.1	Barium-128						
78.2	D, all compounds	5E+2	2E+3	7E-7	2E-9	7E-6	7E-5
78.3	Barium-131m[2]						
78.4	D, all compounds	4E+5	1E+6	6E-4	2E-6	---	---
78.5 78.6		Stom (5E+5)	---	---	---	7E-3	7E-2
78.7	Barium-131						
78.8	D, all compounds	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
78.9	~~Barium-133~~ Barium-133m						
78.10	D, all compounds	2E+3	9E+3	4E-6	1E-8	---	---
78.11 78.12		LLI (3E+3)	---	---	---	4E-5	4E-4
78.13	Barium-133						
78.14	D, all compounds	2E+3	7E+2	3E-7	9E-10	2E-5	2E-4
78.15	Barium-135m						
78.16	D, all compounds	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
78.17	Barium-139[2]						
78.18	D, all compounds	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
78.19	Barium-140						
78.20	D, all compounds	5E+2	1E+3	6E-7	2E-9	---	---
78.21 78.22		LLI (6E+2)	---	---	---	8E-6	8E-5
78.23	Barium-141[2]						

D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
Barium-142[2]						
D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3

[For text of Atomic Numbers 57 to 101 (AN 57 to AN 101), see Minnesota Rules]

FOOTNOTES:

[1] "Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

[2] These radionuclides have radiological half-lives of less than two hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do not include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 µCi/ml for the listed DAC to account for the submersion dose prospectively, but must use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits according to part 4731.2040.

[3] For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor according to part 4731.2020, subpart 5. If the percent by weight (enrichment) of U-235 is not greater than five, the concentration value for a 40-hour work week is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour work week must not exceed 8E-3 (SA) µCi-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, is:

SA = 3.6E-7 curies/gram U U-depleted

SA = [0.4 + 0.38 (enrichment) + 0.0034 (enrichment) ^{2}] E-6, enrichment > 0.72

where enrichment is the percentage by weight of U-235, expressed as percent.

.[For text of subpart 8, see Minnesota Rules]

4731.3075 TERMS AND CONDITIONS OF LICENSES.

[For text of subparts 1 to 6, see Minnesota Rules]

Subp. 7. ~~**Molybdenum-99 requirement**~~ **Generator testing.** A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99 ~~or~~ / technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators must test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, according to part 4731.4435. The licensee must record the results of each test and retain each record for three years after the record is made. The licensee must report the results of any test that exceeds the permissible concentration listed in part 4731.4435, item A, at the time of generator elution, in accordance with part 4731.4528.

[For text of subparts 8 and 9, see Minnesota Rules]

4731.3330 SPECIFIC LICENSE; CERTAIN DEVICES CONTAINING RADIOACTIVE MATERIALS; MANUFACTURE OR INITIAL TRANSFER.

[For text of subparts 1 to 3, see Minnesota Rules]

Subp. 4. **Transfer for use under general license; requirements.** If a device containing radioactive material is to be transferred for use under a general license issued under part 4731.3215, a person that is licensed under this part must provide the information specified in this subpart to each person to whom a device is to be transferred. The information must be provided before the device may be transferred. In case of a transfer through an intermediate person, the information must also be provided to the intended user before the initial transfer to the intermediate person. The required information includes:

[For text of item A, see Minnesota Rules]

B. a copy of parts 4731.2600, 4731.2610, 4731.3115, and ~~4731.3205~~ 4731.3200, item B;

[For text of items C to E, see Minnesota Rules]

[For text of subparts 5 to 11, see Minnesota Rules]

4731.3395 SPECIFIC LICENSE; RADIOACTIVE DRUGS FOR MEDICAL USE; MANUFACTURE, PREPARATION, OR TRANSFER.

Subpart 1. **Approval criteria.** An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized according to parts 4731.4400 to 4731.4527 shall be approved if the applicant:

[For text of items A to C, see Minnesota Rules]

D. ~~satisfies~~ commits to the following labeling requirements:

[For text of subitems (1) and (2), see Minnesota Rules]

Subp. 2. **Pharmacy licensees.**

[For text of items A to C, see Minnesota Rules]

D. No later than 30 days after the date that a licensee described in subpart 1, item B, subitem (3) or (4), allows an individual to work as an authorized nuclear pharmacist under item A, subitem (2), unit (a) or (c), the licensee must provide to the commissioner a copy of:

(1) the individual's certification by a specialty board whose certification process has been recognized as specified in part 4731.4413, subpart 1~~, with the written attestation signed by a preceptor as required by part 4731.4413, subpart 1~~; or

[For text of subitems (2) to (4), see Minnesota Rules]

[For text of subpart 3, see Minnesota Rules]

Subp. 3a. **Labeling requirements.** A licensee must satisfy the labeling requirements of subpart 1, item D.

[For text of subpart 4, see Minnesota Rules]

4731.4170 PERSONNEL MONITORING.

Subpart 1. **Monitoring requirements.**

A. A licensee may not permit an individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of direct reading dosimeter, an operating alarm ratemeter, and a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~.

[For text of items B to D, see Minnesota Rules]

E. Film badges must be replaced at periods not to exceed one month and other personnel dosimeters ~~processed and evaluated by an accredited NVLAP processor~~ that require replacement must be replaced at periods not to exceed three months. All personnel dosimeters must be evaluated at periods not to exceed three months or promptly after replacement, whichever is more frequent.

~~F. After replacement, each personnel dosimeter must be processed as soon as possible.~~

[For text of subparts 2 and 3, see Minnesota Rules]

Subp. 4. **High readings.** If an individual's pocket chamber is found to be off-scale, or if the individual's electronic personal dosimeter reads greater than 200 millirems (2 mSv), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter that requires processing must be sent for processing and evaluation within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within 24 hours. The individual may not resume work associated with licensed material use until a determination of the individual's radiation exposure has been made. The determination must be made by the radiation safety officer or the radiation

safety officer's designee. The results of the determination must be included in the records maintained according to part 4731.4310.

[For text of subpart 5, see Minnesota Rules]

Subp. 6. **Report retention.** Dosimetry ~~reports received from the accredited NVLAP personnel dosimeter processor~~ results must be retained according to part 4731.4310.

[For text of subpart 7, see Minnesota Rules]

4731.4310 RECORDS; PERSONNEL MONITORING.

According to part 4731.4170, a licensee must maintain records of:

[For text of items A and B, see Minnesota Rules]

C. personnel dosimeter results ~~received from the accredited NVLAP processor~~ until the commissioner terminates the license; and

[For text of item D, see Minnesota Rules]

4731.4403 SPECIFIC LICENSE; MEDICAL USE OF RADIOACTIVE MATERIALS.

[For text of subpart 1, see Minnesota Rules]

Subp. 2. **Application for license, amendment, or renewal.**

[For text of item A, see Minnesota Rules]

B. An application for a license for medical use of radioactive materials as described in parts 4731.4404, 4731.4432, 4731.4434, 4731.4440, 4731.4450, 4731.4460, and 4731.4463 must include:

(1) an original ~~and one copy of an~~ application for radioactive material license form prescribed by the commissioner that includes the facility diagram, equipment, and training and experience qualifications of the radiation safety officer, associate radiation

safety officers, authorized users, authorized medical physicists, ophthalmic physicists, and authorized nuclear pharmacists; and

[For text of subitem (2), see Minnesota Rules]

C. A request for a license amendment or renewal must include:

(1) an original ~~and one copy~~ of the form prescribed by the commissioner under item B or ~~of~~ a letter requesting the amendment or renewal containing all the information in the form prescribed by the commissioner under item B; and

[For text of subitem (2), see Minnesota Rules]

D. In addition to the requirements under items B and C, an application for a license or amendment for medical use of radioactive material under part 4731.4404 must include:

(1) information regarding any radiation safety aspects of the medical use of the material that is not addressed in, or differs from, parts 4731.4400 to 4731.4427~~. The applicant must provide~~ and 4731.4500 to 4731.4528;

(2) identification of and commitment to follow the applicable radiation safety program requirements in parts 4731.4432 to 4731.4479 that are appropriate for the specific medical use;

(3) any additional specific information on:

~~(1)~~ (a) radiation safety precautions and instructions;

~~(2)~~ (b) methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

~~(3)~~ (c) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(4) any other information requested by the commissioner for review of the application.

[For text of item E, see Minnesota Rules]

Subp. 3. **License amendments.** A licensee must apply for and receive a license amendment:

[For text of item A, see Minnesota Rules]

B. before the licensee permits anyone to work as an authorized user, authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or ophthalmic physicist under the license, except that the licensee may permit an individual to work as an authorized user, ~~an~~ authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or ophthalmic physicist for 60 days before being authorized on a license if the individual is an authorized user, authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or ophthalmic physicist for the same type of use:

(1) on a license issued by the commissioner, the NRC, or an agreement state or on an equivalent permit or license recognized by the commissioner, the NRC, or an agreement state that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(2) on a permit issued by ~~an~~ a commissioner, NRC, or agreement state specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; ~~or~~

(3) on a permit issued by an NRC master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

(4) by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists;

[For text of item C, see Minnesota Rules]

D. before the licensee permits anyone to work as an associate radiation safety officer, or before the radiation safety officer assigns duties and tasks to an associate radiation safety officer that differ from those for which this individual is authorized on the license;

~~D.~~ E. before the licensee receives radioactive material in excess of the amount or in a form different than authorized in the license or before the licensee receives a radionuclide that is different than the radionuclide authorized in the license;

~~E.~~ F. before the licensee adds or changes the areas of use identified in the application or in the license, except for areas of use where radioactive material is used only according to part 4731.4432 or 4731.4434;

~~F.~~ G. before the licensee changes an address identified in the application or on the license; ~~and~~

~~G.~~ H. before the licensee revises procedures required under parts 4731.4466 and 4731.4472 to 4731.4474, as applicable, when the revision reduces radiation safety~~.~~; and

I. before the licensee receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license. If a licensee obtains a sealed source in accordance with this item, the licensee must submit an amendment request to add the sealed source to their radioactive materials license within 30 days after receiving the source.

Subp. 4. **Notifications of changes.**

A. A licensee must notify the commissioner by letter no later than 30 days after:

(1) an authorized user, ~~an~~ authorized nuclear pharmacist, ~~a~~ radiation safety officer, ~~or an~~ associate radiation officer, authorized medical physicist, or ophthalmic physicist has a name change;

[For text of subitems (2) and (3), see Minnesota Rules]

(4) the licensee has added to or changed the areas of use identified in the application or license where radioactive material is used according to part 4731.4432 or 4731.4434; ~~or~~

(5) the licensee permits ~~an authorized user or~~ an individual qualified to be a radiation safety officer under parts 4731.4411 and 4731.4415, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer as described under part 4731.4405, subpart 1, item C~~.~~; or

(6) the licensee permits an individual to work under the provisions of subpart 3, item B, as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist prior to being added to the license. The notification must include a copy of the commissioner, NRC, or agreement state license, the permit issued by an NRC master material licensee, the permit issued by a commissioner, NRC, or agreement state licensee of broad scope, or the permit issued by an NRC master material license broad scope permittee.

[For text of item B, see Minnesota Rules]

Subp. 5. **Exemptions; broad scope license.** A licensee possessing a Type A specific license of broad scope for medical use, issued under parts 4731.3500 to 4731.3580, is exempt from:

[For text of items A and B, see Minnesota Rules]

C. subpart 3, item ~~E~~ F, regarding additions to or changes in the areas of use at the addresses identified in the application or license;

D. subpart 4, item A, subitem (1), for an authorized user, ~~an~~ authorized nuclear pharmacist, ~~or an~~ authorized medical physicist, or ophthalmic physicist;

[For text of items E and F, see Minnesota Rules]

[For text of subparts 6 and 7, see Minnesota Rules]

4731.4405 RADIATION PROTECTION PROGRAM.

Subpart 1. **Authority and responsibilities.**

[For text of item A, see Minnesota Rules]

B. A licensee's management must appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety officer, must ensure that radiation safety activities are being performed according to licensee-approved procedures and this chapter. A licensee's management may appoint, in writing, one or more associate radiation safety officers to support the radiation safety officer. The radiation safety officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each associate radiation safety officer. These duties and tasks are restricted to the types of use for which the associate radiation safety officer is listed on a license. The radiation safety officer may delegate duties and tasks to the associate radiation safety officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

C. For up to 60 days each year, a licensee may permit ~~an authorized user or~~ an individual qualified to be a radiation safety officer under parts 4731.4411 and 4731.4415 to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer, as provided in item G, if the licensee takes the actions required by items B, E, G, and H, and notifies the commissioner according to part 4731.4403, subpart 4, item ~~B~~ A.

[For text of items D to H, see Minnesota Rules]

[For text of subpart 2, see Minnesota Rules]

4731.4408 WRITTEN DIRECTIVES.

[For text of subpart 1, see Minnesota Rules]

Subp. 2. **Content requirements.** The written directive under subpart 1 must contain the patient or human research subject's name and:

[For text of items A to D, see Minnesota Rules]

E. for high dose-rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; ~~or~~

F. for permanent implant brachytherapy:

(1) before implantation: the treatment site, radionuclide, and total source strength; and

(2) after implantation but before the patient leaves the post-treatment recovery area: the treatment site, number of sources implanted, total source strength implanted, and date; or

~~F.~~ G. for all other brachytherapy, including low, medium, and pulsed dose-rate remote afterloaders:

(1) before implantation~~,~~: the treatment site, radionuclide, and dose; and

(2) after implantation but before completion of the procedure~~,~~: the radionuclide, treatment site, number of sources, ~~and~~ total source strength and exposure time or the total dose, and date.

[For text of subparts 3 and 4, see Minnesota Rules]

4731.4409 PROCEDURES FOR ADMINISTRATIONS REQUIRING WRITTEN DIRECTIVE.

[For text of item A, see Minnesota Rules]

B. At a minimum, the procedures required by item A must address the following that are applicable to the licensee's use of radioactive material:

[For text of subitems (1) and (2), see Minnesota Rules]

(3) checking both manual and computer-generated dose calculations; ~~and~~

(4) verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized under part 4731.4404 or 4731.4463~~.~~;

(5) determining if a medical event, as defined in part 4731.4525, has occurred; and

(6) determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

[For text of item C, see Minnesota Rules]

4731.4411 RADIATION SAFETY OFFICER AND ASSOCIATE RADIATION SAFETY OFFICER TRAINING.

Subpart 1. **Training and education requirements.** Except as provided under part 4731.4414, a licensee must require an individual fulfilling the responsibilities of a radiation safety officer or an individual assigned duties and tasks as an associate radiation safety officer as provided under part 4731.4405, subpart 1, to be an individual who:

A. (1) is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; and~~:~~

~~(1) has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in this item and subpart 2 and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and~~

(2) has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, associate radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval;

B. (1) has completed a structured educational program consisting of both:

[For text of unit (a), see Minnesota Rules]

(b) one year of full-time radiation safety experience under the supervision of an individual identified as the radiation safety officer on an NRC or agreement state license or permit issued by an NRC master material licensee that authorizes similar types of uses of radioactive material ~~involving~~. An associate radiation safety officer may provide supervision for those areas for which the associate radiation safety officer is authorized on an NRC or agreement state license or permit issued by an NRC master material licensee. The full-time radiation safety experience must involve:

[For text of subunits i to vii, see Minnesota Rules]

(2) has obtained written attestation, signed by a preceptor radiation safety officer~~,~~ or associate radiation safety officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a radiation safety officer or an associate radiation safety officer. The written attestation must state that the individual has satisfactorily completed the requirements in this item and ~~has achieved a level of radiation safety knowledge sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as a radiation safety officer or as an associate radiation safety officer for a medical use licensee; and

(3) has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, associate radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval;

C. (1) is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC or an agreement state under part 4731.4412 ~~and~~, has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking approval of the individual as radiation safety officer or associate radiation safety officer; and~~:~~

~~(1) has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in this item and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and~~

(2) has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer,

associate radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval; ~~or~~

D. (1) is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on ~~the licensee's license and~~ an NRC or agreement state license, a permit issued by an NRC master material licensee, a permit issued by an NRC or agreement state licensee of broad scope, or a permit issued by an NRC master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities; and~~:~~

~~(1) has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in this item and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and~~

(2) has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, associate radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval~~.~~; or

E. has experience with the radiation safety aspects of the types of use for which the individual is seeking simultaneous approval both as the radiation safety officer and the authorized user on the same new medical use license, and has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, associate radiation safety officer, authorized medical physicist,

authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval.

[For text of subpart 2, see Minnesota Rules]

4731.4412 AUTHORIZED MEDICAL PHYSICIST TRAINING.

Subpart 1. **Training and education requirements.** Except as provided in part 4731.4414, a licensee must require an authorized medical physicist to be an individual who:

A. (1) is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; and~~:~~

~~(1) has obtained written attestation that the individual has satisfactorily completed the requirements in this item and subpart 2 and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in this part, part 4731.4414, or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and~~

[For text of subitem (2), see Minnesota Rules]

B. (1) holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university, and:

(a) has completed one year of full-time training in medical physics; and

[For text of unit (b), see Minnesota Rules]

(2) has obtained written attestation that the individual has satisfactorily completed the requirements in this item and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in this part, part 4731.4414, or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

[For text of subitem (3), see Minnesota Rules]

Subp. 2. **Certification requirements.** A specialty board under subpart 1, item A, shall require all candidates for certification to:

[For text of item A, see Minnesota Rules]

B. have two years of full-time practical training or supervised experience in medical physics:

(1) under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by ~~the commissioner,~~ the NRC~~,~~ or an agreement state; or

[For text of subitem (2), see Minnesota Rules]

[For text of item C, see Minnesota Rules]

4731.4413 AUTHORIZED NUCLEAR PHARMACIST TRAINING.

Subpart 1. **Training and education requirements.** Except as provided in part 4731.4414, a licensee must require an authorized nuclear pharmacist to be a pharmacist who:

A. is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state ~~and has obtained written attestation signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subpart 2 and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist~~. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; or

B. (1) has completed 700 hours in a structured educational program consisting of both:

(a) 200 hours of classroom and laboratory training in the following areas:

i. radiation physics and instrumentation;

ii. radiation protection;

iii. mathematics pertaining to the use and measurement of radioactivity;

iv. chemistry of radioactive material for medical use; and

v. radiation biology; and

[For text of unit (b), see Minnesota Rules]

(2) has obtained written attestation signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in this item and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

[For text of subpart 2, see Minnesota Rules]

4731.4414 TRAINING; EXPERIENCED RADIATION SAFETY OFFICER, TELETHERAPY OR MEDICAL PHYSICIST, AUTHORIZED USER, AND NUCLEAR PHARMACIST.

A. An individual identified as a radiation safety officer, a teletherapy or medical physicist, or a nuclear pharmacist on a license issued by the NRC or an agreement state; a permit issued by an NRC or agreement state broad scope licensee; a master material license permit; or a permit issued by a master material license permittee of broad scope before ~~October 24, 2002~~ January 14, 2019, need not comply with the training requirements under parts 4731.4411, 4731.4412, or 4731.4413, respectively, except a radiation safety officer or authorized medical physicist identified in this item must meet the training requirements in part 4731.4411, subpart 1, item A, subitem (2), or 4731.4412, subpart 1, item A, subitem (2), as appropriate, for any material or uses for which they were not authorized prior to this date.

~~B. An individual identified as a radiation safety officer, an authorized medical physicist, or an authorized nuclear pharmacist on an NRC or agreement state license; a permit issued by an NRC or agreement state broad scope licensee; an NRC or agreement state master material license permit; or a permit issued by a master material license permittee of broad scope between October 24, 2002, and April 29, 2005, need not comply with the training requirements of part 4731.4411, 4731.4412, or 4731.4413.~~

B. An individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine before October 24, 2005, need not comply with the training requirements of part 4731.4411 to be identified as a radiation safety officer or as an associate radiation safety officer on a

commission or an agreement state license or commission master material license permit for those materials and uses that these individuals performed before October 24, 2005.

C. An individual certified by the American Board of Radiology in therapeutic radiological physics, roentgen ray and gamma ray physics, x-ray and radium physics or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics before October 24, 2005, need not comply with the training requirements for an authorized medical physicist in part 4731.4412 for those materials and uses that these individuals performed before October 24, 2005.

~~C.~~ D. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or an agreement state; a permit issued by an NRC master material licensee; a permit issued by an NRC or agreement state broad scope licensee; or a permit issued by an NRC master material license broad scope permittee before ~~October 24, 2002~~ January 14, 2019, who perform only those medical uses for which they were authorized on that date, need not comply with the training requirements of parts 4731.4432 to 4731.4479.

~~D. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the commissioner, the NRC, or an agreement state; a permit issued by an NRC master material licensee; a permit issued by an NRC or agreement state broad scope licensee; or a permit issued by an NRC master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002, and April 29, 2005, need not comply with the training requirements of parts 4731.4432 to 4731.4479.~~

E. Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the NRC or an agreement state, a permit issued by an NRC master material licensee, a permit issued by an NRC or agreement state broad scope licensee, or a permit issued by an NRC master material license broad

scope permittee before October 24, 2005, need not comply with the training requirements of parts 4731.4432 to 4731.4479 for those materials and uses that these individuals performed before October 24, 2005, as follows:

(1) for uses authorized under part 4731.4432 or 4731.4434, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine, diagnostic radiology by the American Board of Radiology, diagnostic radiology or radiology by the American Osteopathic Board of Radiology, nuclear medicine by the Royal College of Physicians and Surgeons of Canada, or the American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(2) for uses authorized under part 4731.4440, a physician who was certified before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(3) for uses authorized under part 4731.4450 or 4731.4463, a physician who was certified before October 24, 2005, in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(4) for uses authorized under part 4731.4460, a physician who was certified before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic

Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

~~E.~~ F. Individuals who need not comply with training requirements described in this part may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses issued under this chapter for the same uses for which these individuals are authorized.

4731.4423 AUTHORIZATION FOR CHECK, CALIBRATION, TRANSMISSION, AND REFERENCE USE.

Subpart 1. **Check, calibration, transmission, and reference use.** A person authorized under part 4731.4403, subpart 1, for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, transmission, and reference use:

[For text of items A to E, see Minnesota Rules]

Subp. 2. **Restriction of use.** Radioactive material in sealed sources authorized by this part must not be:

A. used for medical use as defined in part 4731.0100 except in accordance with the requirements in part 4731.4460; or

B. combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this part.

Subp. 3. **Listing on license.** A licensee using calibration, transmission, and reference sources in accordance with subpart 1 or 2 need not list these sources on a specific medical use license.

4731.4433 UPTAKE, DILUTION, AND EXCRETION STUDIES; TRAINING.

Subpart 1. **Training and education requirements.** Except as provided under part 4731.4414, a licensee must require the authorized user of unsealed radioactive material for the uses authorized under part 4731.4432 to be a physician who:

A. is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state ~~and has obtained written attestation, signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, 4731.4436, or 4731.4443, or equivalent requirements of the NRC or an agreement state, that the individual has satisfactorily completed the requirements in subpart 2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under part 4731.4432~~. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page;

[For text of item B, see Minnesota Rules]

C. has:

[For text of subitem (1), see Minnesota Rules]

(2) obtained written attestation~~, signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, 4731.4436, or 4731.4443, or equivalent requirements of the NRC or an agreement state,~~ that the individual has satisfactorily completed the requirements in this item and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under part 4731.4432. The attestation must be obtained from either:

(a) a preceptor authorized user who meets the requirements in part 4731.4414, 4731.4433, 4731.4436, or 4731.4443, or equivalent requirements of the NRC or an agreement state; or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in part 4731.4414, 4731.4433, 4731.4436, or 4731.4443, or equivalent requirements of the NRC or an agreement state, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in this item.

[For text of subpart 2, see Minnesota Rules]

4731.4435 PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82, AND STRONTIUM-85 CONCENTRATION.

A. A licensee may not administer to humans a radiopharmaceutical that contains:

(1) more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m); ~~or~~

[For text of subitems (2) and (3), see Minnesota Rules]

B. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical must measure the molybdenum-99 concentration ~~of the first eluate after receipt of~~ in each eluate from a generator to demonstrate compliance with item A.

[For text of items C and D, see Minnesota Rules]

E. The licensee must report any measurement that exceeds the limits in item A at the time of generator elution, in accordance with part 4731.4528.

4731.4436 IMAGING AND LOCALIZATION STUDIES; TRAINING.

Subpart 1. **Training and education requirements.** Except as provided under part 4731.4414, a licensee must require an authorized user of unsealed radioactive material for the uses authorized under part 4731.4434 to be a physician who ~~is qualified as follows under item A, B, or C~~:

A. ~~The physician must:~~

~~(1)~~ ~~be~~ is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certification that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; ~~and~~

~~(2) must also have obtained written attestation that the individual physician has satisfactorily completed the requirements in subpart 2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under parts 4731.4432 and 4731.4434. The attestation must be signed by a preceptor authorized user who meets:~~

~~(a) the requirements in this part;~~

~~(b) the requirements in item C, subitem (1), unit (b), subunit vii, and part 4731.4443;~~

~~(c) the requirements in part 4731.4414; or~~

~~(d) equivalent requirements of the NRC or an agreement state.~~

B. ~~The physician must be~~ is an authorized user under part 4731.4443 and ~~meet~~ meets the requirements in item C, subitem (1), unit (b), subunit vii, or equivalent requirements of the NRC or an agreement state; or

C. ~~The physician must have~~ has:

(1) completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

[For text of unit (a), see Minnesota Rules]

(b) work experience, under the supervision of an authorized user who meets the requirements in this part, part 4731.4414, or in subunit vii and part 4731.4443, or equivalent requirements of the NRC or an agreement state~~, involving~~. An authorized nuclear pharmacist who meets the requirements in part 4731.4413 or 4731.4414 may provide the supervised work experience for subunit vii. Work experience must involve:

[For text of subunits i to vii, see Minnesota Rules]

(2) obtained written attestation that the individual physician has satisfactorily completed the requirements in this item and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under parts 4731.4432 and 4731.4434. The attestation must be ~~signed by a preceptor authorized user who meets~~ obtained from either:

(a) ~~the requirements in this part~~ a preceptor authorized user who meets the requirements in this part, part 4731.4414, or in subitem (1), unit (b), subunit vii, and part 4731.4443, or equivalent requirements of the NRC or an agreement state; or

(b) ~~the requirements in subitem (1), unit (b), subunit vii, and part 4731.4443;~~ a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this part, part 4731.4414, or in subitem (1), unit (b), subunit vii, and part 4731.4443, or equivalent requirements of the NRC or an agreement state, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in this item.

~~(c) the requirements in part 4731.4414; or~~

~~(d) equivalent requirements of the NRC or an agreement state.~~

Subp. 2. **Certification requirements.** A specialty board under subpart 1, item A, shall require all candidates for certification to:

[For text of items A and B, see Minnesota Rules]

4731.4440 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE REQUIRED.

A licensee may use any unsealed radioactive material identified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi, prepared for medical use and for which a written directive is required that is:

[For text of items A to D, see Minnesota Rules]

4731.4443 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE REQUIRED; TRAINING.

Subpart 1. **Training and education requirements.** Except as provided under part 4731.4414, a licensee must require an authorized user of unsealed radioactive material for the uses authorized under part 4731.4440 to be a physician who:

A. is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state, and meets the requirements in item B, subitem (1), unit (b), subunit vi~~, and has obtained written attestation that the individual has satisfactorily completed the requirements in this item and subpart 2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under part 4731.4440. The written attestation must be signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state. A preceptor authorized user who meets the requirements in item B must also have experience in administering dosages in the same dosage category or categories under item B, subitem (1), unit (b), subunit vi, as the individual requesting authorized user status~~. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; or

B. has:

(1) completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

[For text of unit (a), see Minnesota Rules]

(b) work experience, under the supervision of an authorized user who meets the requirements in this part, part 4731.4414, or equivalent requirements of the NRC

or an agreement state. A supervising authorized user who meets the requirements in this item must also have experience in administering dosages in the same dosage category or categories under subunit vi as the individual requesting authorized user status. The work experience must involve:

i. ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

[For text of subunits ii to v, see Minnesota Rules]

vi. administering dosages of radioactive drugs to patients or human research subjects ~~involving~~ from the three categories in this subunit. Radioactive drugs containing radionuclides in categories not included in this subunit are regulated under part 4731.4404. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status: oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide (I-131) for which a written directive is required; oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide (I-131) (experience with at least three cases also satisfies the requirement of oral administration of less than or equal to 33 millicuries of I-131); parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta ~~emitter~~ radiation characteristics, alpha radiation characteristics, or a ~~photon-emitting radionuclide with a~~ photon energy of less than 150 kilo electron volts for which a written directive is required; ~~or parenteral administration of any other radionuclide for which a written directive is required~~; and

(2) obtained written attestation that the individual has satisfactorily completed the requirements in this item and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under part 4731.4440~~. The written attestation~~

~~must be signed by~~ for which the individual is requesting authorized user status. The attestation must be obtained from either:

(a) a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state~~. A preceptor authorized user who meets the requirements in this item must also have~~ and has experience in administering dosages in the same dosage category or categories ~~under subitem (1), unit (b), subunit vi,~~ as the individual requesting authorized user status~~.~~; or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state; has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subitem (1).

Subp. 2. **Certification requirements.** A specialty board under subpart 1, item A, shall require all candidates for certification to:

A. successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in subpart 1, item B, subitem (1), units (a) and (b), subunits i to v. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the

~~Committee on Postgraduate Training~~ Council on Postdoctoral Training of the American Osteopathic Association; and

[For text of item B, see Minnesota Rules]

4731.4444 ORAL ADMINISTRATION OF SODIUM IODIDE I-131; QUANTITIES LESS THAN OR EQUAL TO 33 MILLICURIES (1.22 GBq); WRITTEN DIRECTIVE REQUIRED; TRAINING.

Except as provided under part 4731.4414, a licensee must require an authorized user for the oral administration of sodium iodide (I-131) requiring a written directive in quantities less than or equal to 33 millicuries (1.22 GBq) to be a physician who:

A. is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and includes all of the requirements of item C, subitems (1) and (2)~~, and who has obtained written attestation that the individual has satisfactorily completed the requirements of item C, subitems (1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under part 4731.4440. The written attestation must be signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, 4731.4443, or 4731.4445, or equivalent requirements of the NRC or an agreement state. A preceptor authorized user who meets the requirement in part 4731.4443, subpart 1, item B, must also have experience in oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide (I-131) for which a written directive is required or oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide (I-131) as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi~~. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page;

[For text of item B, see Minnesota Rules]

C. has:

[For text of subitems (1) and (2), see Minnesota Rules]

(3) obtained written attestation that the individual has satisfactorily completed the requirements of this item and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide I-131 for medical uses authorized under part 4731.4440. The written attestation must be ~~signed by~~ obtained from either:

(a) a preceptor authorized user who meets the requirements of this part, part 4731.4414, 4731.4443, or 4731.4445, or equivalent requirements of the NRC or an agreement state~~. A preceptor authorized user who meets the requirement in part 4731.4443, subpart 1, item B, must also have~~ and has experience in oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide (I-131) for which a written directive is required or oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide (I-131) as specified in part 4731.4443~~.~~; or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this part, part 4731.4414, 4731.4443, or 4731.4445, or equivalent requirements of the NRC or an agreement state, has experience in oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide (I-131) for which a written directive is required or oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide (I-131) as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral

Training of the American Osteopathic Association and must include training and experience specified in subitems (1) and (2).

4731.4445 ORAL ADMINISTRATION OF SODIUM IODIDE; QUANTITIES GREATER THAN 33 MILLICURIES (1.22 GBq); WRITTEN DIRECTIVE REQUIRED; TRAINING.

Except as provided under part 4731.4414, a licensee must require an authorized user for the oral administration of sodium iodide (I-131) requiring a written directive in quantities greater than 33 millicuries (1.22 GBq) to be a physician who:

A. is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and includes all the requirements in item C, subitems (1) and (2)~~, and who has obtained written attestation that the individual has satisfactorily completed the requirements of this item and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under part 4731.4440. The written attestation must be signed by a preceptor authorized user who meets the requirements in this part, part 4731.4414 or 4731.4443, or equivalent requirements of the NRC or an agreement state. A preceptor authorized user who meets the requirements in part 4731.4443, subpart 1, item B, must also have experience in the oral administration of I-131 in quantities greater than 33 millicuries as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi~~. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page;

B. is an authorized user ~~under part 4731.4443, subpart 1, item A; 4731.4443, subpart 1, item B,~~ for the oral administration of I-131 in quantities greater than 33 millicuries under part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi; or equivalent requirements of the NRC or an agreement state; or

C. has:

[For text of subitem (1), see Minnesota Rules]

(2) has work experience, under the supervision of an authorized user who meets the requirements of this part, part 4731.4414 or 4731.4443, ~~subpart 1, item A or B,~~ or equivalent requirements of the NRC or an agreement state. A supervising authorized user who meets the requirements in part 4731.4443, subpart 1, item B, must also have experience in the oral administration of I-131 in quantities greater than 33 millicuries under part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi. The work experience must involve:

[For text of units (a) to (f), see Minnesota Rules]

(3) obtained written attestation that the individual has satisfactorily completed the requirements of this item and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation-related duties as an authorized user for oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide I-131 for medical uses authorized under part 4731.4440. The written attestation must be ~~signed by~~ obtained from either:

(a) a preceptor authorized user who meets the requirements in this part, part 4731.4414 or 4731.4443, or equivalent requirements of the NRC or an agreement state~~.~~ ~~A preceptor authorized user who meets the requirements in part 4731.4443, subpart 1, item B, must also have~~, and has experience in the oral administration of I-131 in quantities greater than 33 millicuries ~~under~~ (1.22 GBq) as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi~~.~~; or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this part, part 4731.4414 or 4731.4443, or equivalent requirements of the NRC or an agreement state, has experience in the oral administration of I-131 in quantities greater than 33 millicuries (1.22 GBq) as specified in

part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subitems (1) and (2).

4731.4446 PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE REQUIRED; TRAINING.

A. Except as provided in part 4731.4414, the licensee must require an authorized user for the parenteral administration requiring a written directive to be a physician who is:

(1) an authorized user under part 4731.4443 for the parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or a photon-energy of less than 150 kilo electron volts for which a written directive is required, or equivalent requirements of the NRC or an agreement state;

[For text of subitems (2) and (3), see Minnesota Rules]

B. The physician under item A, subitems (2) and (3), must have:

(1) successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations~~, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide~~ of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or a photon-energy of less than 150 kilo electron volts for which a written directive is required. The training must include:

[For text of units (a) to (e), see Minnesota Rules]

(2) work experience, under the supervision of an authorized user who meets the requirements in this part, part 4731.4414 or 4731.4443, or equivalent requirements of the NRC or agreement state, in the parenteral administration~~, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide~~ of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or a photon-energy of less than 150 kilo electron volts for which a written directive is required. A supervising authorized user who meets the requirements in this part or part 4731.4443, or equivalent requirements of the NRC or agreement state, must have experience in ~~parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 kilo electron volts for which a written directive is required or parenteral administration of any other radionuclide for which a written directive is required as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi~~ administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve:

[For text of units (a) to (e), see Minnesota Rules]

(f) administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration, for which a written directive is required, of any ~~beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required~~ radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or a photon-energy of less than 150 kilo electron volts; and

(3) obtained written attestation that the individual has satisfactorily completed the requirements in this item and item A, subitem (2) or (3), and ~~has achieved a level of~~

~~competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be ~~signed by~~ obtained from either:

(a) a preceptor authorized user who meets the requirements in this part, part 4731.4414, or 4731.4443, or equivalent requirements of the NRC or agreement state. A preceptor authorized user who meets the requirements in this part or part 4731.4443, or equivalent requirements of the NRC or agreement state, must have experience in ~~parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 kilo electron volts for which a written directive is required or parenteral administration of any other radionuclide for which a written directive is required as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi.~~ administering dosages in the same category or categories as the individual requesting authorized user status; or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this part, part 4731.4414 or 4731.4443, or equivalent requirements of the NRC or agreement state, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subitems (1) and (2).

4731.4450 USE OF BRACHYTHERAPY SOURCES.

A licensee must use only brachytherapy sources ~~for therapeutic medical uses~~:

A. as approved in the sealed source and device registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy

uses that are not explicitly listed in the sealed source and device registry, but must be used in accordance with the radiation safety conditions and limitations described in the sealed source and device registry; or

B. in research to deliver therapeutic doses for medical use, according to an active investigational device exemption application accepted by the Food and Drug Administration, provided the requirements of part 4731.4410, item A, are met.

4731.4456 DECAY OF STRONTIUM-90 SOURCES FOR OPHTHALMIC TREATMENTS.

A. Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in item B are performed by either:

(1) an authorized medical physicist; or

(2) an individual who:

(a) is identified as an ophthalmic physicist on a:

i. specific medical use license issued by the commissioner, the NRC, or an agreement state;

ii. permit issued by a commissioner, NRC, or agreement state broad scope medical use licensee;

iii. medical use permit issued by an NRC master material licensee; or

iv. permit issued by an NRC master material licensee broad scope medical use permittee; and

(b) holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(c) has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(d) has documented training in:

i. the creation, modification, and completion of written directives;

ii. procedures for administrations requiring a written directive; and

iii. performing the calibration measurements of brachytherapy sources as detailed in part 4731.4455.

~~A.~~ B. The individuals who are identified in item A must:

(1) ~~Only an authorized medical physicist shall~~ calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under part 4731.4455~~.~~; and

(2) assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in item A will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

~~B.~~ C. A licensee must maintain a record of the activity of each strontium-90 source according to part 4731.4514.

4731.4458 MANUAL BRACHYTHERAPY TRAINING.

Subpart 1. **Training and education requirements.** Except as provided under part 4731.4414, a licensee must require an authorized user of a manual brachytherapy source for the uses authorized under part 4731.4450 to be a physician who:

A. is certified by a medical specialty board whose certification has been recognized by the NRC or an agreement state ~~and has obtained written attestation, signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state, that the individual has satisfactorily completed the requirements of subpart 2 and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under part 4731.4450~~. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; or

B. has:

(1) completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

[For text of unit (a), see Minnesota Rules]

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state at a medical institution authorized to use radioactive materials under part 4731.4450, involving:

[For text of subunits i to vi, see Minnesota Rules]

(2) completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the ~~Committee~~ Council on Postdoctoral Training of the American

Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required under subitem (1), unit (b); and

(3) obtained written attestation~~, signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state,~~ that the individual has satisfactorily completed the requirements of this item and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under part 4731.4450. The attestation must be obtained from either:

(a) a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state; or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subitems (1) and (2).

Subp. 2. **Certification requirements.** A specialty board under subpart 1, item A, shall require all candidates for certification to:

A. successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians

and Surgeons of Canada, or the ~~Committee on Postgraduate~~ Council on Postdoctoral Training of the American Osteopathic Association; and

[For text of item B, see Minnesota Rules]

4731.4459 OPHTHALMIC USE OF STRONTIUM-90; TRAINING.

Except as provided under part 4731.4414, a licensee must require an authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

[For text of item A, see Minnesota Rules]

B. has:

[For text of subitems (1) and (2), see Minnesota Rules]

(3) obtained written attestation, signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, or 4731.4458, or equivalent requirements of the NRC or an agreement state, that the individual has satisfactorily completed the requirements in ~~this item~~ subitems (1) and (2) and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

4731.4460 USE OF SEALED SOURCES AND MEDICAL DEVICES FOR DIAGNOSIS.

A. A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses ~~as~~ if the sealed sources are approved in the sealed source and device registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the sealed source and device registry but must be used in accordance with the radiation safety conditions and limitations described in the sealed source and device registry.

B. A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the sealed source and device registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the sealed source and device registry but must be used in accordance with the radiation safety conditions and limitations described in the sealed source and device registry.

C. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of part 4731.4410, item A, are met.

4731.4461 USE OF SEALED SOURCES FOR DIAGNOSIS; TRAINING.

Except as provided under part 4731.4414, a licensee must require an authorized user of a diagnostic sealed source ~~for use in~~ or a device authorized under part 4731.4460 to be a physician, dentist, or podiatrist who:

A. is certified by a specialty board whose certification process includes all of the requirements of ~~item B~~ items C and D and whose certification has been recognized by ~~the commissioner,~~ the NRC~~,~~ or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; ~~or~~

B. is an authorized user for uses listed in part 4731.4434 or equivalent requirements of the NRC or an agreement state;

~~B.~~ C. has~~:~~

~~(1)~~ completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

(1) ~~(a)~~ radiation physics and instrumentation;

(2) ~~(b)~~ radiation protection;

(3) ~~(c)~~ mathematics pertaining to the use and measurement of radioactivity; and

(4) ~~(d)~~ radiation biology; and

D. ~~(2)~~ completed training in the use of the device for the uses requested.

4731.4463 USE OF A SEALED SOURCE; REMOTE AFTERLOADER UNIT, TELETHERAPY UNIT, OR GAMMA STEREOTACTIC RADIOSURGERY UNIT.

A. A licensee must only use sealed sources ~~in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses~~:

~~A.~~ (1) ~~as~~ approved and as provided for in the sealed source and device registry in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

~~B.~~ (2) in research~~,~~ involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units according to an active investigational device exemption application accepted by the Food and Drug Administration, provided the requirements of part 4731.4410, item A, are met.

B. A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(1) approved in the sealed source and device registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the sealed source and device registry, but must be used in

accordance with radiation safety conditions and limitations described in the sealed source and device registry; or

(2) in research according to an active investigational device exemption application accepted by the FDA provided the requirements of part 4731.4410, item A, are met.

4731.4466 REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS; SAFETY PROCEDURES AND INSTRUCTIONS.

[For text of items A to D, see Minnesota Rules]

E. A licensee must:

(1) prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training; and

(2) provide ~~instruction~~ operational and safety instructions, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties~~;~~. The instructions must include instruction in:

~~(1)~~ (a) the procedures identified under item B, subitem (4); and

~~(2)~~ (b) the operating procedures of the unit.

[For text of items F and G, see Minnesota Rules]

H. A licensee must retain a copy of the procedures required under item B, subitem (4), and item E, subitem (2), unit (b),according to part 4731.4516.

4731.4477 TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS; ~~FIVE-YEAR INSPECTION~~ FULL-INSPECTION SERVICING.

Subpart 1. **Inspection and servicing required.** A licensee must have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement ~~or at intervals~~ to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing must not ~~to~~ exceed five years~~, whichever comes first, to ensure proper functioning of the source exposure mechanism~~ for each teletherapy unit, and must not exceed seven years for each gamma stereotactic radiosurgery unit.

Subp. 2. **Qualified inspectors.** The inspection and servicing ~~may~~ must be performed ~~only~~ by persons specifically licensed to do so by the commissioner, the NRC, or an agreement state.

[For text of subpart 3, see Minnesota Rules]

4731.4479 REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS; TRAINING.

Subpart 1. **Training and education requirements.** Except as provided under part 4731.4414, a licensee must require an authorized user of a sealed source for a use authorized under part 4731.4463 to be a physician who:

A. is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state, and meets the requirements in item B, subitem (4)~~, and has obtained written attestation that the individual has satisfactorily completed the requirements in this item and subpart 2 and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state for an authorized~~

~~user for each type of therapeutic medical unit for which the individual is requesting authorized user status~~. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web page; or

B. has:

(1) completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

[For text of unit (a), see Minnesota Rules]

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state, at a medical institution that is authorized to use radioactive material in part 4731.4463, involving:

i. reviewing full calibration measurements and periodic spot ~~check~~ checks;

[For text of subunits ii to vi, see Minnesota Rules]

(2) completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the ~~Committee~~ Council on Postdoctoral Training of the American Osteopathic Association. The experience may be obtained concurrently with the supervised work experience required under subitem (1), unit (b);

(3) obtained written attestation that the individual has satisfactorily completed the requirements in ~~this item~~ subitems (1), (2), and (4), and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related

duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be ~~signed by~~ obtained from either:

(a) a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state ~~for an authorized user~~ for each type of therapeutic medical unit for which the individual is requesting authorized user status; ~~and~~ or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subitems (1) and (2); and

[For text of subitem (4), see Minnesota Rules]

Subp. 2. **Certification requirements.** A specialty board under subpart 1, item A, shall require all candidates for certification to:

A. successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the ~~Committee on Postgraduate~~ Council on Postdoctoral Training of the American Osteopathic Association; and

B. pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy.

4731.4500 RADIATION PROTECTION PROGRAM RECORDS.

Subpart 1. **Records of authority and responsibilities; radiation protection programs.** A licensee must retain:

A. a record of actions taken by the licensee's management according to part 4731.4405, subpart 1, item A, for five years. The record must include a summary of the actions taken and a signature of licensee management; ~~and~~

B. a copy of the authorities, duties, and responsibilities of the radiation safety officer, as required under part 4731.4405, subpart 1, item E, and a signed copy of the radiation safety officer's agreement to be responsible for implementing the radiation safety program, as required under part 4731.4405, subpart 1, item B, for the duration of the license. The records must include the signature of the radiation safety officer and licensee management~~.~~; and

C. for each associate radiation safety officer appointed under part 4731.4405, subpart 1, item B, the licensee shall retain, for five years after the associate radiation safety officer is removed from the license, a copy of the written document appointing the associate radiation safety officer signed by the licensee's management.

[For text of subpart 2, see Minnesota Rules]

4731.4510 SAFETY INSTRUCTION RECORDS.

A licensee must maintain a record of safety instructions required under parts 4731.4441~~,~~ and 4731.4453, and the operational and safety instructions required by part 4731.4466 for three years. The record must include:

[For text of items A to D, see Minnesota Rules]

4731.4524 ~~INSPECTION~~ FULL-INSPECTION SERVICING RECORDS; TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS.

A licensee must maintain a record of the ~~five-year inspections~~ full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units required under part 4731.4477 for the duration of use of the unit. The record must contain:

[For text of items A to E, see Minnesota Rules]

4731.4525 MEDICAL EVENT; REPORT AND NOTIFICATION.

Subpart 1. **Report required.** A licensee must report any event as a medical event, except for an event that results from patient intervention, in which:

A. the administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

~~A.~~ (1) a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dose by more than five rems (0.05 Sv) effective dose equivalent, 50 rems (0.5 Sv) to an organ or tissue, or 50 rems (0.5 Sv) shallow dose equivalent to the skin and:

~~(1)~~ (a) the total dose delivered differs from the prescribed dose by 20 percent or more;

~~(2)~~ (b) the total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

~~(3)~~ (c) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more;

~~B.~~ (2) a dose that exceeds five rems (0.05 Sv) effective dose equivalent, 50 rems (0.5 Sv) to an organ or tissue, or 50 rems (0.5 Sv) shallow dose equivalent to the skin from:

~~(1)~~ (a) an administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;

~~(2)~~ (b) an administration of a radioactive drug containing radioactive material by the wrong route of administration;

~~(3)~~ (c) an administration of a dose or dosage to the wrong individual or human research subject;

~~(4)~~ (d) an administration of a dose or dosage delivered by the wrong mode of treatment; or

~~(5)~~ (e) a leaking sealed source; or

~~C.~~ (3) a dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(a) 50 rems (0.5 Sv) ~~to an organ or tissue and exceeds~~ or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(b) 50 percent or more ~~of~~ the ~~dose~~ expected dose to that site from the procedure if the administration ~~defined in~~ had been given in accordance with the written directive~~, excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site~~ prepared or revised before administration.

B. for permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material excluding sources that were implanted in the correct site but migrated outside the treatment site that results in:

(1) the total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(2) the total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(3) an administration that includes any of the following:

(a) the wrong radionuclide;

(b) the wrong individual or human research subject;

(c) sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

(d) a leaking sealed source resulting in a dose that exceeds 50 rem (0.5 Sv) to an organ or tissue.

[For text of subparts 2 to 6, see Minnesota Rules]

Subp. 7. **Individual identification.** A licensee must:

A. annotate a copy of the report provided to the commissioner with:

(1) the name of the individual who is the subject of the event; and

(2) the ~~social security number or other identification number, if one has been assigned,~~ identification number or if no other identification number is available, the Social Security number of the individual who is the subject of the event; and

B. provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the medical event.

4731.4526 DOSE TO AN EMBRYO/FETUS OR CHILD; REPORT AND NOTIFICATION.

[For text of subparts 1 to 5, see Minnesota Rules]

Subp. 6. **Individual identification.** A licensee must:

A. annotate a copy of the report provided to the commissioner with:

(1) the name of the pregnant ~~woman~~ individual or the nursing child who is the subject of the event; and

(2) the ~~Social Security number or other identification number, if one has been assigned, of the pregnant woman or the nursing child~~ identification number or if no other identification number is available, the Social Security number of the individual who is the subject of the event; and

B. provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

4731.4528 REPORT AND NOTIFICATION FOR AN ELUATE EXCEEDING PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82, AND STRONTIUM-85 CONCENTRATIONS.

Subpart 1. **Telephone notification.** The licensee must notify, by telephone, the commissioner and the distributor of the generator, within seven days after discovery, that an eluate exceeded the permissible concentration listed in part 4731.4435, item A, at the time of generator elution. The telephone report to the commissioner must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

Subp. 2. **Written report.** The licensee must submit a written report to the commissioner within 30 days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; the probable cause and an assessment of failure in the licensee's equipment, procedures, or training that contributed

to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by subpart 1

4731.6180 PERSONNEL MONITORING.

Subpart 1. **Irradiator operators.** Irradiator operators must wear a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~ while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter ~~processor must be accredited for~~ must be capable of detecting high energy photons in the normal and accident dose ranges ~~under part 4731.2200, subpart 3~~. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be ~~processed~~ replaced at least monthly and other personnel dosimeters that require replacement must be ~~processed~~ replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

[For text of subpart 2, see Minnesota Rules]

4731.7220 PERSONNEL MONITORING.

A. A licensee may not permit an individual to act as a logging supervisor or logging assistant unless the individual wears~~,~~ a personnel dosimeter at all times during the handling of licensed radioactive materials~~, a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and other personnel dosimeters that require replacement must be replaced at least quarterly. ~~After replacement, each personnel dosimeter must be promptly processed.~~ All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

[For text of items B and C, see Minnesota Rules]

4731.8015 ACCESS AUTHORIZATION PROGRAM REQUIREMENTS.

[For text of subpart 1, see Minnesota Rules]

Subp. 2. **Reviewing officials.**

[For text of item A, see Minnesota Rules]

B. Each licensee must name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee must provide, under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Provide oath or affirmation certifications to the Radioactive Materials Unit, Minnesota Department of Health, 625 Robert Street N, P.O. Box 64975, St. Paul, MN 55164-0975. The fingerprints of the named reviewing official must be taken by a law enforcement agency, federal or state agency that provides fingerprinting services to the public, or commercial fingerprinting services authorized by a state to take fingerprints. The licensee must recertify that the reviewing official is deemed trustworthy and reliable every ten years in accordance with part 4731.8020, subpart 3.

[For text of items C to E, see Minnesota Rules]

[For text of subparts 3 to 8, see Minnesota Rules]

4731.8025 REQUIREMENTS FOR CRIMINAL HISTORY RECORDS CHECKS OF INDIVIDUALS GRANTED UNESCORTED ACCESS TO CATEGORY 1 OR CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL.

[For text of subparts 1 and 2, see Minnesota Rules]

Subp. 3. **Procedures for processing of fingerprint checks.**

A. For the purpose of complying with parts 4731.8010 to 4731.8040, licensees must submit to the U.S. Nuclear Regulatory Commission, Director, Division of ~~Facilities and Security~~ Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop ~~TWB-05 B32M~~ T-8B20, Rockville, MD ~~20852-2738~~ 20852,

one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by ~~writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling (630) 829-9565, or by e-mail to FORMS.Resource@nrc.gov~~ emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at ~~http://www.nrc.gov/site-help/e-submittals.html~~ https://www.nrc.gov/security/chp.html.

B. Fees for the processing of fingerprint checks are due upon application. Licensees must submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." For guidance on making electronic payments, contact the ~~Security Branch~~, Division of ~~Facilities~~ Physical and Cyber Security ~~at (301) 492-3531~~ Policy by emailing crimhist.resource@nrc.gov. Combined payment for multiple applications is acceptable. The ~~commission~~ NRC publishes the amount of the fingerprint check application fee on the NRC public website. To find the current fee amount, go to the ~~Electronic Submittals page at http://www.nrc.gov/site-help/e-submittals.html and see the link for the Criminal History Program under Electronic Submission Systems~~ Licensee Criminal History Records Checks & Firearms Background Check information page at https://www.nrc.gov/security/chp.html and see the link for "How do I determine how much to pay for the request?".

[For text of item C, see Minnesota Rules]

4731.8055 GENERAL SECURITY PROGRAM REQUIREMENTS.

[For text of subparts 1 to 3, see Minnesota Rules]

Subp. 4. **Protection of information.**

[For text of item A, see Minnesota Rules]

B. Efforts to limit access must include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan ~~and~~, implementing procedures, and the list of individuals that have been approved for unescorted access.

C. Before granting an individual access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access, licensees must:

(1) evaluate an individual's need to know the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access; and

[For text of subitem (2), see Minnesota Rules]

[For text of item D, see Minnesota Rules]

E. The licensee must document the basis for concluding that an individual is trustworthy and reliable in order to be granted access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access.

F. Licensees must maintain a list of persons currently approved for access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access, or no longer meets the access authorization requirements for access to the information, the licensee must remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to obtain the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access.

G. When not in use, the licensee must store its security plan ~~and~~, implementing procedures, and the list of individuals that have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

H. The licensee must retain as a record for three years after the document is no longer needed:

(1) a copy of the information protection procedures; and

(2) the list of individuals approved for access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access.

4731.8115 ADVANCE NOTIFICATION OF SHIPMENT OF CATEGORY 1 QUANTITIES OF RADIOACTIVE MATERIAL.

[For text of subpart 1, see Minnesota Rules]

Subp. 2. **Procedures for submitting advance notification.**

A. The notification must be made to the commissioner and to the office of each appropriate governor or governor's designee. The contact information, including telephone numbers and mailing addresses, of governors and governors' designees, is available on the NRC website at https://scp.nrc.gov/special/designee.pdf. A list of the contact information is also available upon request from the Director, Division of ~~Material~~ Materials Safety, Security, State, and Tribal~~, and Rulemaking~~ Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC ~~20555~~ 20555-0001. Notifications to the commissioner must be to the Radioactive Materials Unit, Minnesota Department of Health, 625 Robert Street N, P.O. Box 64975, St. Paul, MN 55164-0975, or e-mail at health.ram@state.mn.us.

[For text of items B and C, see Minnesota Rules]

[For text of subparts 3 to 7, see Minnesota Rules]

MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

RECEIVED
By: OAH on 8/27/2021 9:16 AM

OAH Docket Number: _____

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

Minn. R. 4731, Possible Amendment to Rules Governing Radiation Safety, Revisor's ID No. R-4671

NOTICE OF APPEARANCE

PLEASE TAKE NOTICE that:

1. The party/agency named below will appear at the prehearing conference and all subsequent proceedings in the above-entitled matter.

2. By providing its email address below, the Party/Agency chooses to opt into receiving electronic notice from the Office of Administrative Hearings in this matter. **Note: Provision of an email address DOES NOT constitute consent to electronic service from any opposing party or agency in this proceeding.**[1]

3. The Party/Agency agrees to use best efforts to provide the Office of Administrative Hearings with the email address(es) for opposing parties and their legal counsel.

Party's/Agency's Name: Minnesota Department of Health

Email: josh.skaar@state.mn.us Telephone: (651) 201-5923

Mailing Address: 625 Robert Street North, Saint Paul, MN 55101

Party's/Agency's Attorney: Josh Skaar

Firm Name: Minnesota Department of Health

Email: josh.skaar@state.mn.us Telephone: (651) 201-5923

Mailing Address: 625 Robert Street North, Saint Paul, MN 55101

Respondent's/Opposing Party's Name: N/A

Email: _____ Telephone: _____

Mailing Address: _____

Dated: August 27, 2021 */s/ Josh Skaar*

Signature of Party/Agency or Attorney

[1] In order to opt in to electronic notice, this form must be emailed to OAH.efiling.support@state.mn.us. If the party does not wish to opt in to electronic notice, this form may be filed with the Office of Administrative Hearings via facsimile, U.S. Mail, or personal service. *See* 2015 Minn. Laws Ch. 63, Minn. R. 1400.5550, subps. 2-5 (2017).

Note: This form must be served upon the opposing party/agency. Counsel may not withdraw from representation without written notice.