

December 23, 2021

VIA EMAIL ONLY

Nancy Breems
Secretary of State, Elections Division
180 State Office Building
100 Rev Dr Martin Luther King Jr Blvd
St. Paul, Minnesota 55155-1299
official.documents@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 R4671**

Dear Ms. Breems:

Enclosed for filing is an electronic copy of the above-entitled adopted rules.

Please send the agency copy of the rules to:

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

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

Sincerely,



Denise S. Collins
Court Administrator

Enclosures

cc: Josh Skaar (via email)
Jacqueline Cavanagh (via email)

1.1 **Department of Health**

1.2 **Adopted Permanent Rules Relating to Radioactive Materials**

1.3 **4731.0100 DEFINITIONS.**

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

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

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

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

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

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

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

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

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

1.18 B. is identified as an ophthalmic physicist on a:

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

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

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

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

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

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

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

2.9 **4731.0406 GENERAL LICENSE; NRC-APPROVED PACKAGE.**

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

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

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

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

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

2.21 **4731.0419 ADVANCE NOTIFICATION OF SHIPMENT OF IRRADIATED**
2.22 **REACTOR FUEL AND NUCLEAR WASTE.**

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

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

3.2 A. The notification required under this part must:

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

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

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

3.14 *[For text of item C, see Minnesota Rules]*

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

3.16 **Subp. 6. Cancellation notice.**

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

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

3.23 **4731.0422 A₁ AND A₂ VALUES FOR RADIONUCLIDES.**

3.24 Subpart 1. [Repealed, 32 SR 831]

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

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

4.4	Element and Atomic		
4.5	Number and Symbol of		
4.6	Radionuclide		Specific Activity
4.7		(TBq/g)	(Ci/g)

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

4.9 Samarium (62)

4.10	Sm-145	9.8 x 10 ¹	2.6 x 10 ³
4.11	Sm-147	8.5 x 10 ⁻¹⁰	2.3 x 10 ⁻⁸
4.12	Sm-151	9.7 x 10 ⁻¹	2.6 x 10 ¹
4.13	Sm-153	1.6 x 10 ⁴	4.4 x 10 ⁵

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

4.15 *[For text of subpart 3, see Minnesota Rules]*

4.16 **4731.2750 ANNUAL LIMITS ON INTAKE AND DERIVED AIR**
 4.17 **CONCENTRATIONS.**

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

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

4.20		Table			Table		Table
4.21		1			2		3
4.22	Atomic Number (AN),						
4.23	Radionuclide, and Class	1	2	3	1	2	

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

4.25 **AN 56**

4.26 Barium-126²

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		Stom					
5.7		(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-133m						
5.11	D, all compounds	2E+3	9E+3	4E-6	1E-8	---	---
5.12		LLI					
5.13		(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		LLI					
5.23		(6E+2)	---	---	---	8E-6	8E-5
5.24	Barium-141 ²						

6.1	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
6.2	Barium-142 ²						
6.3	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3

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

6.5 FOOTNOTES:

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

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

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

6.27
$$SA = 3.6E-7 \text{ curies/gram U U-depleted}$$

6.28
$$SA = [0.4 + 0.38 (\text{enrichment}) + 0.0034 (\text{enrichment})^2] E-6, \text{ enrichment} > 0.72$$

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

6.30 *[For text of subpart 8, see Minnesota Rules]*

7.1 **4731.3075 TERMS AND CONDITIONS OF LICENSES.**

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

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

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

7.12 **4731.3330 SPECIFIC LICENSE; CERTAIN DEVICES CONTAINING**
7.13 **RADIOACTIVE MATERIALS; MANUFACTURE OR INITIAL TRANSFER.**

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

7.15 Subp. 4. **Transfer for use under general license; requirements.** If a device containing
7.16 radioactive material is to be transferred for use under a general license issued under part
7.17 4731.3215, a person that is licensed under this part must provide the information specified
7.18 in this subpart to each person to whom a device is to be transferred. The information must
7.19 be provided before the device may be transferred. In case of a transfer through an intermediate
7.20 person, the information must also be provided to the intended user before the initial transfer
7.21 to the intermediate person. The required information includes:

7.22 *[For text of item A, see Minnesota Rules]*

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

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

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

8.1 **4731.3395 SPECIFIC LICENSE; RADIOACTIVE DRUGS FOR MEDICAL USE;**
8.2 **MANUFACTURE, PREPARATION, OR TRANSFER.**

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

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

8.8 D. commits to the following labeling requirements:

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

8.10 Subp. 2. **Pharmacy licensees.**

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

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

8.16 (1) the individual's certification by a specialty board whose certification
8.17 process has been recognized as specified in part 4731.4413, subpart 1; or

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

8.19 *[For text of subpart 3, see Minnesota Rules]*

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

8.22 *[For text of subpart 4, see Minnesota Rules]*

9.1 **4731.4170 PERSONNEL MONITORING.**

9.2 Subpart 1. **Monitoring requirements.**

9.3 A. A licensee may not permit an individual to act as a radiographer or a
9.4 radiographer's assistant unless, at all times during radiographic operations, each individual
9.5 wears, on the trunk of the body, a combination of direct reading dosimeter, an operating
9.6 alarm ratemeter, and a personnel dosimeter.

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

9.8 E. Film badges must be replaced at periods not to exceed one month and other
9.9 personnel dosimeters that require replacement must be replaced at periods not to exceed
9.10 three months. All personnel dosimeters must be evaluated at periods not to exceed three
9.11 months or promptly after replacement, whichever is more frequent.

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

9.13 Subp. 4. **High readings.** If an individual's pocket chamber is found to be off-scale,
9.14 or if the individual's electronic personal dosimeter reads greater than 200 millirems (2 mSv),
9.15 and the possibility of radiation exposure cannot be ruled out as the cause, the individual's
9.16 personnel dosimeter that requires processing must be sent for processing and evaluation
9.17 within 24 hours. For personnel dosimeters that do not require processing, evaluation of the
9.18 dosimeter must be started within 24 hours. The individual may not resume work associated
9.19 with licensed material use until a determination of the individual's radiation exposure has
9.20 been made. The determination must be made by the radiation safety officer or the radiation
9.21 safety officer's designee. The results of the determination must be included in the records
9.22 maintained according to part 4731.4310.

9.23 *[For text of subpart 5, see Minnesota Rules]*

9.24 Subp. 6. **Report retention.** Dosimetry results must be retained according to part
9.25 4731.4310.

10.1 *[For text of subpart 7, see Minnesota Rules]*

10.2 **4731.4310 RECORDS; PERSONNEL MONITORING.**

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

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

10.5 C. personnel dosimeter results until the commissioner terminates the license; and

10.6 *[For text of item D, see Minnesota Rules]*

10.7 **4731.4403 SPECIFIC LICENSE; MEDICAL USE OF RADIOACTIVE MATERIALS.**

10.8 *[For text of subpart 1, see Minnesota Rules]*

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

10.10 *[For text of item A, see Minnesota Rules]*

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

10.14 (1) an original application for radioactive material license form prescribed
10.15 by the commissioner that includes the facility diagram, equipment, and training and
10.16 experience qualifications of the radiation safety officer, associate radiation safety officers,
10.17 authorized users, authorized medical physicists, ophthalmic physicists, and authorized
10.18 nuclear pharmacists; and

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

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

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

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

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

11.4 (1) information regarding any radiation safety aspects of the medical use of
11.5 the material that is not addressed in, or differs from, parts 4731.4400 to 4731.4427 and
11.6 4731.4500 to 4731.4528;

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

11.10 (3) any additional specific information on:

11.11 (a) radiation safety precautions and instructions;

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

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

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

11.18 *[For text of item E, see Minnesota Rules]*

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

11.21 *[For text of item A, see Minnesota Rules]*

11.22 B. before the licensee permits anyone to work as an authorized user, authorized
11.23 nuclear pharmacist, authorized medical physicist, or ophthalmic physicist under the license,

12.1 except that the licensee may permit an individual to work as an authorized user, authorized
12.2 nuclear pharmacist, authorized medical physicist, or ophthalmic physicist for 60 days before
12.3 being authorized on a license if the individual is an authorized user, authorized nuclear
12.4 pharmacist, authorized medical physicist, or ophthalmic physicist for the same type of use:

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

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

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

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

12.17 *[For text of item C, see Minnesota Rules]*

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

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

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

13.4 G. before the licensee changes an address identified in the application or on the
13.5 license;

13.6 H. before the licensee revises procedures required under parts 4731.4466 and
13.7 4731.4472 to 4731.4474, as applicable, when the revision reduces radiation safety; and

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

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

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

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

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

13.20 (4) the licensee has added to or changed the areas of use identified in the
13.21 application or license where radioactive material is used according to part 4731.4432 or
13.22 4731.4434;

13.23 (5) the licensee permits an individual qualified to be a radiation safety officer
13.24 under parts 4731.4411 and 4731.4415, to function as a temporary radiation safety officer

14.1 and to perform the functions of a radiation safety officer as described under part 4731.4405,
14.2 subpart 1, item C; or

14.3 (6) the licensee permits an individual to work under the provisions of subpart
14.4 3, item B, as an authorized user, authorized medical physicist, ophthalmic physicist, or
14.5 authorized nuclear pharmacist prior to being added to the license. The notification must
14.6 include a copy of the commissioner, NRC, or agreement state license, the permit issued by
14.7 an NRC master material licensee, the permit issued by a commissioner, NRC, or agreement
14.8 state licensee of broad scope, or the permit issued by an NRC master material license broad
14.9 scope permittee.

14.10 *[For text of item B, see Minnesota Rules]*

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

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

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

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

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

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

14.21 **4731.4405 RADIATION PROTECTION PROGRAM.**

14.22 Subpart 1. **Authority and responsibilities.**

14.23 *[For text of item A, see Minnesota Rules]*

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

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

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

15.18 *[For text of subpart 2, see Minnesota Rules]*

15.19 **4731.4408 WRITTEN DIRECTIVES.**

15.20 *[For text of subpart 1, see Minnesota Rules]*

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

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

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

16.1 F. for permanent implant brachytherapy:

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

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

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

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

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

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

16.14 **4731.4409 PROCEDURES FOR ADMINISTRATIONS REQUIRING WRITTEN**
16.15 **DIRECTIVE.**

16.16 *[For text of item A, see Minnesota Rules]*

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

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

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

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

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

17.2 and

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

17.8 *[For text of item C, see Minnesota Rules]*

17.9 **4731.4411 RADIATION SAFETY OFFICER AND ASSOCIATE RADIATION**
17.10 **SAFETY OFFICER TRAINING.**

17.11 Subpart 1. **Training and education requirements.** Except as provided under part
17.12 4731.4414, a licensee must require an individual fulfilling the responsibilities of a radiation
17.13 safety officer or an individual assigned duties and tasks as an associate radiation safety
17.14 officer as provided under part 4731.4405, subpart 1, to be an individual who:

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

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

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

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

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

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

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

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

18.23 C. (1) is a medical physicist who has been certified by a specialty board whose
18.24 certification process has been recognized by the NRC or an agreement state under part
18.25 4731.4412, has experience in radiation safety for similar types of use of radioactive material

19.1 for which the licensee is seeking approval of the individual as radiation safety officer or
19.2 associate radiation safety officer; and

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

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

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

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

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

20.3 *[For text of subpart 2, see Minnesota Rules]*

20.4 **4731.4412 AUTHORIZED MEDICAL PHYSICIST TRAINING.**

20.5 Subpart 1. **Training and education requirements.** Except as provided in part
20.6 4731.4414, a licensee must require an authorized medical physicist to be an individual who:

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

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

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

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

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

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

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

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

21.4 *[For text of item A, see Minnesota Rules]*

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

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

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

21.10 *[For text of item C, see Minnesota Rules]*

21.11 **4731.4413 AUTHORIZED NUCLEAR PHARMACIST TRAINING.**

21.12 Subpart 1. **Training and education requirements.** Except as provided in part
21.13 4731.4414, a licensee must require an authorized nuclear pharmacist to be a pharmacist
21.14 who:

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

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

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

21.22 i. radiation physics and instrumentation;

21.23 ii. radiation protection;

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

22.3 iv. chemistry of radioactive material for medical use; and

22.4 v. radiation biology; and

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

22.6 (2) has obtained written attestation signed by a preceptor authorized nuclear
22.7 pharmacist, that the individual has satisfactorily completed the requirements in this item
22.8 and is able to independently fulfill the radiation safety-related duties as an authorized nuclear
22.9 pharmacist.

22.10 *[For text of subpart 2, see Minnesota Rules]*

22.11 **4731.4414 TRAINING; EXPERIENCED RADIATION SAFETY OFFICER,**
22.12 **TELETHERAPY OR MEDICAL PHYSICIST, AUTHORIZED USER, AND**
22.13 **NUCLEAR PHARMACIST.**

22.14 A. An individual identified as a radiation safety officer, a teletherapy or medical
22.15 physicist, or a nuclear pharmacist on a license issued by the NRC or an agreement state; a
22.16 permit issued by an NRC or agreement state broad scope licensee; a master material license
22.17 permit; or a permit issued by a master material license permittee of broad scope before
22.18 January 14, 2019, need not comply with the training requirements under parts 4731.4411,
22.19 4731.4412, or 4731.4413, respectively, except a radiation safety officer or authorized medical
22.20 physicist identified in this item must meet the training requirements in part 4731.4411,
22.21 subpart 1, item A, subitem (2), or 4731.4412, subpart 1, item A, subitem (2), as appropriate,
22.22 for any material or uses for which they were not authorized prior to this date.

22.23 B. An individual certified by the American Board of Health Physics in
22.24 Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear
22.25 Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical

23.1 Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology
23.2 physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American
23.3 Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine
23.4 before October 24, 2005, need not comply with the training requirements of part 4731.4411
23.5 to be identified as a radiation safety officer or as an associate radiation safety officer on a
23.6 commission or an agreement state license or commission master material license permit for
23.7 those materials and uses that these individuals performed before October 24, 2005.

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

23.14 D. Physicians, dentists, or podiatrists identified as authorized users for the medical
23.15 use of radioactive material on a license issued by the NRC or an agreement state; a permit
23.16 issued by an NRC master material licensee; a permit issued by an NRC or agreement state
23.17 broad scope licensee; or a permit issued by an NRC master material license broad scope
23.18 permittee before January 14, 2019, who perform only those medical uses for which they
23.19 were authorized on that date, need not comply with the training requirements of parts
23.20 4731.4432 to 4731.4479.

23.21 E. Physicians, dentists, or podiatrists not identified as authorized users for the
23.22 medical use of radioactive material on a license issued by the NRC or an agreement state,
23.23 a permit issued by an NRC master material licensee, a permit issued by an NRC or agreement
23.24 state broad scope licensee, or a permit issued by an NRC master material license broad
23.25 scope permittee before October 24, 2005, need not comply with the training requirements

24.1 of parts 4731.4432 to 4731.4479 for those materials and uses that these individuals performed
24.2 before October 24, 2005, as follows:

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

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

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

24.21 (4) for uses authorized under part 4731.4460, a physician who was certified
24.22 before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or
24.23 radiation oncology by the American Board of Radiology; nuclear medicine by the American
24.24 Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic
24.25 Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons
24.26 of Canada.

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

25.4 **4731.4423 AUTHORIZATION FOR CHECK, CALIBRATION, TRANSMISSION,**
25.5 **AND REFERENCE USE.**

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

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

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

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

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

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

25.20 **4731.4433 UPTAKE, DILUTION, AND EXCRETION STUDIES; TRAINING.**

25.21 Subpart 1. **Training and education requirements.** Except as provided under part
25.22 4731.4414, a licensee must require the authorized user of unsealed radioactive material for
25.23 the uses authorized under part 4731.4432 to be a physician who:

26.1 A. is certified by a medical specialty board whose certification process has been
26.2 recognized by the NRC or an agreement state. The names of board certifications that have
26.3 been recognized by the NRC or an agreement state are posted on the NRC's Medical Use
26.4 Licensee Toolkit web page;

26.5 *[For text of item B, see Minnesota Rules]*

26.6 C. has:

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

26.8 (2) obtained written attestation that the individual has satisfactorily completed
26.9 the requirements in this item and is able to independently fulfill the radiation safety-related
26.10 duties as an authorized user for the medical uses authorized under part 4731.4432. The
26.11 attestation must be obtained from either:

26.12 (a) a preceptor authorized user who meets the requirements in part
26.13 4731.4414, 4731.4433, 4731.4436, or 4731.4443, or equivalent requirements of the NRC
26.14 or an agreement state; or

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

26.24 *[For text of subpart 2, see Minnesota Rules]*

27.1 **4731.4435 PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82, AND**
27.2 **STRONTIUM-85 CONCENTRATION.**

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

27.4 (1) more than 0.15 microcurie of molybdenum-99 per millicurie of
27.5 technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of
27.6 technetium-99m);

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

27.8 B. A licensee that uses molybdenum-99/technetium-99m generators for preparing
27.9 a technetium-99m radiopharmaceutical must measure the molybdenum-99 concentration
27.10 in each eluate from a generator to demonstrate compliance with item A.

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

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

27.14 **4731.4436 IMAGING AND LOCALIZATION STUDIES; TRAINING.**

27.15 Subpart 1. **Training and education requirements.** Except as provided under part
27.16 4731.4414, a licensee must require an authorized user of unsealed radioactive material for
27.17 the uses authorized under part 4731.4434 to be a physician who:

27.18 A. is certified by a medical specialty board whose certification process has been
27.19 recognized by the NRC or an agreement state. The names of board certification that have
27.20 been recognized by the NRC or an agreement state are posted on the NRC's Medical Use
27.21 Licensee Toolkit web page;

27.22 B. is an authorized user under part 4731.4443 and meets the requirements in item
27.23 C, subitem (1), unit (b), subunit vii, or equivalent requirements of the NRC or an agreement
27.24 state; or

28.1 C. has:

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

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

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

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

28.13 (2) obtained written attestation that the individual physician has satisfactorily
28.14 completed the requirements in this item and is able to independently fulfill the radiation
28.15 safety-related duties as an authorized user for the medical uses authorized under parts
28.16 4731.4432 and 4731.4434. The attestation must be obtained from either:

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

28.20 (b) a residency program director who affirms in writing that the attestation
28.21 represents the consensus of the residency program faculty where at least one faculty member
28.22 is an authorized user who meets the requirements in this part, part 4731.4414, or in subitem
28.23 (1), unit (b), subunit vii, and part 4731.4443, or equivalent requirements of the NRC or an
28.24 agreement state, and concurs with the attestation provided by the residency program director.
28.25 The residency training program must be approved by the Residency Review Committee of

29.1 the Accreditation Council for Graduate Medical Education or the Royal College of Physicians
29.2 and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic
29.3 Association and must include training and experience specified in this item.

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

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

29.7 **4731.4440 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE**
29.8 **REQUIRED.**

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

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

29.13 **4731.4443 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE**
29.14 **REQUIRED; TRAINING.**

29.15 Subpart 1. **Training and education requirements.** Except as provided under part
29.16 4731.4414, a licensee must require an authorized user of unsealed radioactive material for
29.17 the uses authorized under part 4731.4440 to be a physician who:

29.18 A. is certified by a medical specialty board whose certification process has been
29.19 recognized by the NRC or an agreement state, and meets the requirements in item B, subitem
29.20 (1), unit (b), subunit vi. The names of board certifications that have been recognized by the
29.21 NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web
29.22 page; or

29.23 B. has:

29.24 (1) completed 700 hours of training and experience, including a minimum
29.25 of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques

30.1 applicable to the medical use of unsealed radioactive material requiring a written directive.

30.2 The training and experience must include:

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

30.4 (b) work experience, under the supervision of an authorized user who
30.5 meets the requirements in this part, part 4731.4414, or equivalent requirements of the NRC
30.6 or an agreement state. A supervising authorized user who meets the requirements in this
30.7 item must also have experience in administering dosages in the same dosage category or
30.8 categories under subunit vi as the individual requesting authorized user status. The work
30.9 experience must involve:

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

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

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

31.1 (2) obtained written attestation that the individual has satisfactorily completed
31.2 the requirements in this item and is able to independently fulfill the radiation safety-related
31.3 duties as an authorized user for the medical uses authorized under part 4731.4440 for which
31.4 the individual is requesting authorized user status. The attestation must be obtained from
31.5 either:

31.6 (a) a preceptor authorized user who meets the requirements of this part,
31.7 part 4731.4414, or equivalent requirements of the NRC or an agreement state and has
31.8 experience in administering dosages in the same dosage category or categories as the
31.9 individual requesting authorized user status; or

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

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

31.22 A. successfully complete residency training in a radiation therapy or nuclear
31.23 medicine training program or a program in a related medical specialty. These residency
31.24 training programs must include 700 hours of training and experience as described in subpart
31.25 1, item B, subitem (1), units (a) and (b), subunits i to v. Eligible training programs must be
31.26 approved by the Residency Review Committee of the Accreditation Council for Graduate

32.1 Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council
32.2 on Postdoctoral Training of the American Osteopathic Association; and

32.3 *[For text of item B, see Minnesota Rules]*

32.4 **4731.4444 ORAL ADMINISTRATION OF SODIUM IODIDE I-131; QUANTITIES**
32.5 **LESS THAN OR EQUAL TO 33 MILLICURIES (1.22 GBq); WRITTEN DIRECTIVE**
32.6 **REQUIRED; TRAINING.**

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

32.10 A. is certified by a medical specialty board whose certification process has been
32.11 recognized by the NRC or an agreement state and includes all of the requirements of item
32.12 C, subitems (1) and (2). The names of board certifications that have been recognized by the
32.13 NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web
32.14 page;

32.15 *[For text of item B, see Minnesota Rules]*

32.16 C. has:

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

32.18 (3) obtained written attestation that the individual has satisfactorily completed
32.19 the requirements of this item and is able to independently fulfill the radiation safety-related
32.20 duties as an authorized user for oral administration of less than or equal to 33 millicuries
32.21 (1.22 GBq) of sodium iodide I-131 for medical uses authorized under part 4731.4440. The
32.22 written attestation must be obtained from either:

32.23 (a) a preceptor authorized user who meets the requirements of this part,
32.24 part 4731.4414, 4731.4443, or 4731.4445, or equivalent requirements of the NRC or an
32.25 agreement state and has experience in oral administration of less than or equal to 33

33.1 millicuries (1.22 GBq) of sodium iodide (I-131) for which a written directive is required or
33.2 oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide (I-131) as
33.3 specified in part 4731.4443; or

33.4 (b) a residency program director who affirms in writing that the attestation
33.5 represents the consensus of the residency program faculty where at least one faculty member
33.6 is an authorized user who meets the requirements of this part, part 4731.4414, 4731.4443,
33.7 or 4731.4445, or equivalent requirements of the NRC or an agreement state, has experience
33.8 in oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide
33.9 (I-131) for which a written directive is required or oral administration of greater than 33
33.10 millicuries (1.22 GBq) of sodium iodide (I-131) as specified in part 4731.4443, subpart 1,
33.11 item B, subitem (1), unit (b), subunit vi, and concurs with the attestation provided by the
33.12 residency program director. The residency training program must be approved by the
33.13 Residency Review Committee of the Accreditation Council for Graduate Medical Education
33.14 or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral
33.15 Training of the American Osteopathic Association and must include training and experience
33.16 specified in subitems (1) and (2).

33.17 **4731.4445 ORAL ADMINISTRATION OF SODIUM IODIDE; QUANTITIES**
33.18 **GREATER THAN 33 MILLICURIES (1.22 GBq); WRITTEN DIRECTIVE**
33.19 **REQUIRED; TRAINING.**

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

33.23 A. is certified by a medical specialty board whose certification process has been
33.24 recognized by the NRC or an agreement state and includes all the requirements in item C,
33.25 subitems (1) and (2). The names of board certifications that have been recognized by the
33.26 NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit web
33.27 page;

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

34.4 C. has:

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

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

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

34.13 (3) obtained written attestation that the individual has satisfactorily completed
34.14 the requirements of this item and is able to independently fulfill the radiation-related duties
34.15 as an authorized user for oral administration of greater than 33 millicuries (1.22 GBq) of
34.16 sodium iodide I-131 for medical uses authorized under part 4731.4440. The written attestation
34.17 must be obtained from either:

34.18 (a) a preceptor authorized user who meets the requirements in this part,
34.19 part 4731.4414 or 4731.4443, or equivalent requirements of the NRC or an agreement state,
34.20 and has experience in the oral administration of I-131 in quantities greater than 33 millicuries
34.21 (1.22 GBq) as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit
34.22 vi; or

34.23 (b) a residency program director who affirms in writing that the attestation
34.24 represents the consensus of the residency program faculty where at least one faculty member
34.25 is an authorized user who meets the requirements in this part, part 4731.4414 or 4731.4443,

35.1 or equivalent requirements of the NRC or an agreement state, has experience in the oral
35.2 administration of I-131 in quantities greater than 33 millicuries (1.22 GBq) as specified in
35.3 part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi, and concurs with the
35.4 attestation provided by the residency program director. The residency training program
35.5 must be approved by the Residency Review Committee of the Accreditation Council for
35.6 Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada
35.7 or the Council on Postdoctoral Training of the American Osteopathic Association and must
35.8 include training and experience specified in subitems (1) and (2).

35.9 **4731.4446 PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE**
35.10 **MATERIAL; WRITTEN DIRECTIVE REQUIRED; TRAINING.**

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

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

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

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

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

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

36.1 (2) work experience, under the supervision of an authorized user who meets
36.2 the requirements in this part, part 4731.4414 or 4731.4443, or equivalent requirements of
36.3 the NRC or agreement state, in the parenteral administration of any radioactive drug that
36.4 contains a radionuclide that is primarily used for its electron emission, beta radiation
36.5 characteristics, alpha radiation characteristics, or a photon-energy of less than 150 kilo
36.6 electron volts for which a written directive is required. A supervising authorized user who
36.7 meets the requirements in this part or part 4731.4443, or equivalent requirements of the
36.8 NRC or agreement state, must have experience in administering dosages in the same category
36.9 or categories as the individual requesting authorized user status. The work experience must
36.10 involve:

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

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

36.17 (3) obtained written attestation that the individual has satisfactorily completed
36.18 the requirements in this item and item A, subitem (2) or (3), and is able to independently
36.19 fulfill the radiation safety-related duties as an authorized user for the parenteral administration
36.20 of unsealed radioactive material requiring a written directive. The written attestation must
36.21 be obtained from either:

36.22 (a) a preceptor authorized user who meets the requirements in this part,
36.23 part 4731.4414, or 4731.4443, or equivalent requirements of the NRC or agreement state.
36.24 A preceptor authorized user who meets the requirements in this part or part 4731.4443, or
36.25 equivalent requirements of the NRC or agreement state, must have experience in

37.1 administering dosages in the same category or categories as the individual requesting
37.2 authorized user status; or

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

37.13 **4731.4450 USE OF BRACHYTHERAPY SOURCES.**

37.14 A licensee must use only brachytherapy sources:

37.15 A. as approved in the sealed source and device registry for manual brachytherapy
37.16 medical use. The manual brachytherapy sources may be used for manual brachytherapy
37.17 uses that are not explicitly listed in the sealed source and device registry, but must be used
37.18 in accordance with the radiation safety conditions and limitations described in the sealed
37.19 source and device registry; or

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

38.1 **4731.4456 DECAY OF STRONTIUM-90 SOURCES FOR OPHTHALMIC**
38.2 **TREATMENTS.**

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

38.5 (1) an authorized medical physicist; or

38.6 (2) an individual who:

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

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

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

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

38.13 or

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

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

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

38.22 (d) has documented training in:

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

38.24 ii. procedures for administrations requiring a written directive; and

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

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

39.4 (1) calculate the activity of each strontium-90 source that is used to determine
39.5 the treatment times for ophthalmic treatments. The decay must be based on the activity
39.6 determined under part 4731.4455; and

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

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

39.15 **4731.4458 MANUAL BRACHYTHERAPY TRAINING.**

39.16 Subpart 1. **Training and education requirements.** Except as provided under part
39.17 4731.4414, a licensee must require an authorized user of a manual brachytherapy source
39.18 for the uses authorized under part 4731.4450 to be a physician who:

39.19 A. is certified by a medical specialty board whose certification has been recognized
39.20 by the NRC or an agreement state. The names of board certifications that have been
39.21 recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee
39.22 Toolkit web page; or

39.23 B. has:

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

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

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

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

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

40.17 (3) obtained written attestation that the individual has satisfactorily completed
40.18 the requirements of this item and is able to independently fulfill the radiation safety-related
40.19 duties as an authorized user of manual brachytherapy sources for the medical uses authorized
40.20 under part 4731.4450. The attestation must be obtained from either:

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

40.23 (b) a residency program director who affirms in writing that the attestation
40.24 represents the consensus of the residency program faculty where at least one faculty member
40.25 is an authorized user who meets the requirements of this part, part 4731.4414, or equivalent

41.1 requirements of the NRC or an agreement state, and concurs with the attestation provided
41.2 by the residency program director. The residency training program must be approved by
41.3 the Residency Review Committee of the Accreditation Council for Graduate Medical
41.4 Education or the Royal College of Physicians and Surgeons of Canada or the Council on
41.5 Postdoctoral Training of the American Osteopathic Association and must include training
41.6 and experience specified in subitems (1) and (2).

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

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

41.14 *[For text of item B, see Minnesota Rules]*

41.15 **4731.4459 OPTHALMIC USE OF STRONTIUM-90; TRAINING.**

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

41.18 *[For text of item A, see Minnesota Rules]*

41.19 B. has:

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

41.21 (3) obtained written attestation, signed by a preceptor authorized user who
41.22 meets the requirements of this part, part 4731.4414, or 4731.4458, or equivalent requirements
41.23 of the NRC or an agreement state, that the individual has satisfactorily completed the

42.1 requirements in subitems (1) and (2) and is able to independently fulfill the radiation
42.2 safety-related duties as an authorized user of strontium-90 for ophthalmic use.

42.3 **4731.4460 USE OF SEALED SOURCES AND MEDICAL DEVICES FOR**
42.4 **DIAGNOSIS.**

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

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

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

42.21 **4731.4461 USE OF SEALED SOURCES FOR DIAGNOSIS; TRAINING.**

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

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

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

43.8 C. has completed eight hours of classroom and laboratory training in basic
43.9 radionuclide handling techniques specifically applicable to the use of the device. The training
43.10 must include:

43.11 (1) radiation physics and instrumentation;

43.12 (2) radiation protection;

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

43.14 (4) radiation biology; and

43.15 D. completed training in the use of the device for the uses requested.

43.16 **4731.4463 USE OF A SEALED SOURCE; REMOTE AFTERLOADER UNIT,**
43.17 **TELE THERAPY UNIT, OR GAMMA STEREOTACTIC RADIOSURGERY UNIT.**

43.18 A. A licensee must only use sealed sources:

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

43.22 (2) in research involving photon-emitting remote afterloader units, teletherapy
43.23 units, or gamma stereotactic radiosurgery units according to an active investigational device

44.1 exemption application accepted by the Food and Drug Administration, provided the
44.2 requirements of part 4731.4410, item A, are met.

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

44.5 (1) approved in the sealed source and device registry to deliver a therapeutic
44.6 dose for medical use. These devices may be used for therapeutic medical treatments that
44.7 are not explicitly provided for in the sealed source and device registry, but must be used in
44.8 accordance with radiation safety conditions and limitations described in the sealed source
44.9 and device registry; or

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

44.13 **4731.4466 REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND**
44.14 **GAMMA STEREOTACTIC RADIOSURGERY UNITS; SAFETY PROCEDURES**
44.15 **AND INSTRUCTIONS.**

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

44.17 E. A licensee must:

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

45.1 (2) provide operational and safety instructions, initially and at least annually,
45.2 to all individuals who operate the unit, as appropriate to the individual's assigned duties.

45.3 The instructions must include instruction in:

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

45.5 (b) the operating procedures of the unit.

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

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

45.9 **4731.4477 TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY**
45.10 **UNITS; FULL-INSPECTION SERVICING.**

45.11 Subpart 1. **Inspection and servicing required.** A licensee must have each teletherapy
45.12 unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source
45.13 replacement to assure proper functioning of the source exposure mechanism and other safety
45.14 components. The interval between each full-inspection servicing must not exceed five years
45.15 for each teletherapy unit, and must not exceed seven years for each gamma stereotactic
45.16 radiosurgery unit.

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

45.19 *[For text of subpart 3, see Minnesota Rules]*

45.20 **4731.4479 REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND**
45.21 **GAMMA STEREOTACTIC RADIOSURGERY UNITS; TRAINING.**

45.22 Subpart 1. **Training and education requirements.** Except as provided under part
45.23 4731.4414, a licensee must require an authorized user of a sealed source for a use authorized
45.24 under part 4731.4463 to be a physician who:

46.1 A. is certified by a medical specialty board whose certification process has been
46.2 recognized by the NRC or an agreement state, and meets the requirements in item B, subitem
46.3 (4). The names of board certifications that have been recognized by the NRC or an agreement
46.4 state are posted on the NRC's Medical Use Licensee Toolkit web page; or

46.5 B. has:

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

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

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

46.13 i. reviewing full calibration measurements and periodic spot checks;

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

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

46.23 (3) obtained written attestation that the individual has satisfactorily completed
46.24 the requirements in subitems (1), (2), and (4), and is able to independently fulfill the radiation
46.25 safety-related duties as an authorized user of each type of therapeutic medical unit for which

47.1 the individual is requesting authorized user status. The written attestation must be obtained
47.2 from either:

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

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

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

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

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

47.24 B. pass an examination, administered by diplomates of the specialty board, that
47.25 tests knowledge and competence in radiation safety, radionuclide handling, treatment

48.1 planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders,
48.2 and external beam therapy.

48.3 **4731.4500 RADIATION PROTECTION PROGRAM RECORDS.**

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

48.6 A. a record of actions taken by the licensee's management according to part
48.7 4731.4405, subpart 1, item A, for five years. The record must include a summary of the
48.8 actions taken and a signature of licensee management;

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

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

48.19 *[For text of subpart 2, see Minnesota Rules]*

48.20 **4731.4510 SAFETY INSTRUCTION RECORDS.**

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

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

49.1 **4731.4524 FULL-INSPECTION SERVICING RECORDS; TELETHERAPY AND**
49.2 **GAMMA STEREOTACTIC RADIOSURGERY UNITS.**

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

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

49.7 **4731.4525 MEDICAL EVENT; REPORT AND NOTIFICATION.**

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

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

49.12 (1) a dose that differs from the prescribed dose or dose that would have
49.13 resulted from the prescribed dose by more than five rems (0.05 Sv) effective dose equivalent,
49.14 50 rems (0.5 Sv) to an organ or tissue, or 50 rems (0.5 Sv) shallow dose equivalent to the
49.15 skin and:

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

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

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

49.22 (2) a dose that exceeds five rems (0.05 Sv) effective dose equivalent, 50 rems
49.23 (0.5 Sv) to an organ or tissue, or 50 rems (0.5 Sv) shallow dose equivalent to the skin from:

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

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

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

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

50.9 (e) a leaking sealed source; or

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

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

50.15 (b) 50 percent or more the expected dose to that site from the procedure
50.16 if the administration had been given in accordance with the written directive prepared or
50.17 revised before administration.

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

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

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

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

51.5 (a) the wrong radionuclide;

51.6 (b) the wrong individual or human research subject;

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

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

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

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

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

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

51.16 (2) the identification number or if no other identification number is available,
51.17 the Social Security number of the individual who is the subject of the event; and

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

51.20 **4731.4526 DOSE TO AN EMBRYO/FETUS OR CHILD; REPORT AND**
51.21 **NOTIFICATION.**

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

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

- 52.1 A. annotate a copy of the report provided to the commissioner with:
- 52.2 (1) the name of the pregnant individual or the nursing child who is the subject
- 52.3 of the event; and
- 52.4 (2) the identification number or if no other identification number is available,
- 52.5 the Social Security number of the individual who is the subject of the event; and
- 52.6 B. provide a copy of the annotated report to the referring physician, if other than
- 52.7 the licensee, no later than 15 days after the discovery of the event.

52.8 **4731.4528 REPORT AND NOTIFICATION FOR AN ELUATE EXCEEDING**

52.9 **PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82, AND STRONTIUM-85**

52.10 **CONCENTRATIONS.**

52.11 Subpart 1. **Telephone notification.** The licensee must notify, by telephone, the

52.12 commissioner and the distributor of the generator, within seven days after discovery, that

52.13 an eluate exceeded the permissible concentration listed in part 4731.4435, item A, at the

52.14 time of generator elution. The telephone report to the commissioner must include the

52.15 manufacturer, model number, and serial number (or lot number) of the generator; the results

52.16 of the measurement; the date of the measurement; whether dosages were administered to

52.17 patients or human research subjects, when the distributor was notified, and the action taken.

52.18 Subp. 2. **Written report.** The licensee must submit a written report to the commissioner

52.19 within 30 days after discovery of an eluate exceeding the permissible concentration at the

52.20 time of generator elution. The written report must include the action taken by the licensee;

52.21 the patient dose assessment; the methodology used to make this dose assessment if the eluate

52.22 was administered to patients or human research subjects; the probable cause and an

52.23 assessment of failure in the licensee's equipment, procedures, or training that contributed

52.24 to the excessive readings if an error occurred in the licensee's breakthrough determination;

52.25 and the information in the telephone report as required by subpart 1.

53.1 **4731.6180 PERSONNEL MONITORING.**

53.2 Subpart 1. **Irradiator operators.** Irradiator operators must wear a personnel dosimeter
53.3 while operating a panoramic irradiator or while in the area around the pool of an underwater
53.4 irradiator. The personnel dosimeter must be capable of detecting high energy photons in
53.5 the normal and accident dose ranges. Each personnel dosimeter must be assigned to and
53.6 worn by only one individual. Film badges must be replaced at least monthly and other
53.7 personnel dosimeters that require replacement must be replaced at least quarterly. All
53.8 personnel dosimeters must be evaluated at least quarterly or promptly after replacement,
53.9 whichever is more frequent.

53.10 *[For text of subpart 2, see Minnesota Rules]*

53.11 **4731.7220 PERSONNEL MONITORING.**

53.12 A. A licensee may not permit an individual to act as a logging supervisor or logging
53.13 assistant unless the individual wears a personnel dosimeter at all times during the handling
53.14 of licensed radioactive materials. Each personnel dosimeter must be assigned to and worn
53.15 by only one individual. Film badges must be replaced at least monthly and other personnel
53.16 dosimeters that require replacement must be replaced at least quarterly. All personnel
53.17 dosimeters must be evaluated at least quarterly or promptly after replacement, whichever
53.18 is more frequent.

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

53.20 **4731.8015 ACCESS AUTHORIZATION PROGRAM REQUIREMENTS.**

53.21 *[For text of subpart 1, see Minnesota Rules]*

53.22 Subp. 2. **Reviewing officials.**

53.23 *[For text of item A, see Minnesota Rules]*

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

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

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

54.13 **4731.8025 REQUIREMENTS FOR CRIMINAL HISTORY RECORDS CHECKS**
54.14 **OF INDIVIDUALS GRANTED UNESCORTED ACCESS TO CATEGORY 1 OR**
54.15 **CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL.**

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

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

54.18 A. For the purpose of complying with parts 4731.8010 to 4731.8040, licensees
54.19 must submit to the U.S. Nuclear Regulatory Commission, Director, Division of Physical
54.20 and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail
54.21 Stop T-8B20, Rockville, MD 20852, one completed, legible standard fingerprint card (Form
54.22 FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other
54.23 fingerprint record for each individual requiring unescorted access to category 1 or category
54.24 2 quantities of radioactive material. Copies of these forms may be obtained by emailing
54.25 MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found
54.26 at <https://www.nrc.gov/security/chp.html>.

55.1 B. Fees for the processing of fingerprint checks are due upon application. Licensees
55.2 must submit payment with the application for the processing of fingerprints through corporate
55.3 check, certified check, cashier's check, money order, or electronic payment, made payable
55.4 to "U.S. NRC." For guidance on making electronic payments, contact the, Division of
55.5 Physical and Cyber Security Policy by emailing crimhist.resource@nrc.gov. Combined
55.6 payment for multiple applications is acceptable. The NRC publishes the amount of the
55.7 fingerprint check application fee on the NRC public website. To find the current fee amount,
55.8 go to the Licensee Criminal History Records Checks & Firearms Background Check
55.9 information page at <https://www.nrc.gov/security/chp.html> and see the link for "How do I
55.10 determine how much to pay for the request?".

55.11 *[For text of item C, see Minnesota Rules]*

55.12 **4731.8055 GENERAL SECURITY PROGRAM REQUIREMENTS.**

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

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

55.15 *[For text of item A, see Minnesota Rules]*

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

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

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

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

56.2 *[For text of item D, see Minnesota Rules]*

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

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

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

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

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

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

57.1 **4731.8115 ADVANCE NOTIFICATION OF SHIPMENT OF CATEGORY 1**
57.2 **QUANTITIES OF RADIOACTIVE MATERIAL.**

57.3 *[For text of subpart 1, see Minnesota Rules]*

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

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

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

57.15 *[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

A handwritten signature in black ink, reading "Sandy Glass-Sirany", written over a horizontal line.

Sandy Glass-Sirany
Senior Assistant Revisor