

1.1 **Department of Health**

1.2 **Proposed Permanent Rules Relating to Radiation Safety**

1.3 **4731.2320 EXCEPTIONS TO POSTING REQUIREMENTS.**

1.4 [For text of subps 1 to 3, see M.R.]

1.5 Subp. 4. **Hospital; teletherapy, remote afterloader, or gamma stereotactic**
1.6 **radiosurgery units.** A room in a hospital or clinic that is used for teletherapy, remote
1.7 afterloader, or gamma stereotactic radiosurgery units is exempt from the requirement
1.8 to post a caution sign if:

1.9 [For text of items A and B, see M.R.]

1.10 **4731.2360 LEAK TEST REQUIREMENTS.**

1.11 [For text of subps 1 to 4, see M.R.]

1.12 Subp. 5. **Level of detection.** The leak test must be capable of detecting the presence
1.13 of 0.005 microcurie (185 becquerel) of radioactive material on the test sample.

1.14 A. If the test reveals the presence of 0.005 microcurie (185 becquerel) or
1.15 more of removable contamination, ~~a report must be filed with the Department of~~
1.16 ~~Health according to part 4731.3110 and~~ the source must be removed immediately from
1.17 service and decontaminated, repaired, or disposed of according to ~~Department of Health~~
1.18 ~~regulations~~ this chapter.

1.19 B. A report must be filed with the commissioner within five days and must
1.20 include:

1.21 (1) the model number and serial number, if assigned, of the leaking source;

1.22 (2) the identity of the radionuclide and its estimated activity;

1.23 (3) the results of the test;

1.24 (4) the date of the test; and

2.1 (5) the action taken.

2.2 [For text of subps 6 to 8, see M.R.]

2.3 **4731.2520 DETERMINATION OF PRIOR OCCUPATIONAL DOSE.**

2.4 [For text of subps 1 to 3, see M.R.]

2.5 Subp. 4. **Record keeping.**

2.6 ~~A.~~ A licensee must record the exposure history of each individual, as required
2.7 by subpart 1 or 2, on a cumulative occupational exposure record form prescribed by the
2.8 commissioner, or other clear and legible record including all of the information required
2.9 by the commissioner's form. The form or record must show each period in which the
2.10 individual received occupational exposure to radiation or radioactive material and must
2.11 be signed by the individual who received the exposure. For each period for which the
2.12 licensee obtains reports, the licensee must use the dose shown in the report in preparing
2.13 the exposure record. For any period in which the licensee does not obtain a report, the
2.14 licensee must place a notation on the record indicating the periods and time for which
2.15 data are not available.

2.16 ~~B.~~ ~~A licensee is not required to partition historical dose between external dose~~
2.17 ~~equivalents and internal committed dose equivalents. Occupational exposure histories~~
2.18 ~~obtained and recorded on the cumulative occupational exposure record form, or its~~
2.19 ~~equivalent, before January 1, 1994, might not have included effective dose equivalents,~~
2.20 ~~but may be used in the absence of specific information on the intake of radionuclides by~~
2.21 ~~the individual.~~

2.22 ~~C.~~ ~~The form or record must:~~

2.23 ~~(1) show each period in which the individual received occupational~~
2.24 ~~exposure to radiation or radioactive material; and~~

2.25 ~~(2) be signed by the individual who received the exposure.~~

3.1 ~~D. For each period for which a licensee obtains reports, the licensee must use~~
3.2 ~~the dose shown in the report in preparing the form or its equivalent.~~

3.3 ~~E. For any period in which a licensee does not obtain a report, the licensee must~~
3.4 ~~place a notation on the form or its equivalent, indicating the periods of time for which~~
3.5 ~~data are not available.~~

3.6 [For text of subps 5 and 6, see M.R.]

3.7 **4731.4070 LEAK TESTING, REPLACEMENT, AND OTHER MODIFICATIONS**
3.8 **OF SEALED SOURCES.**

3.9 [For text of subps 1 and 2, see M.R.]

3.10 **Subp. 3. Leaking source.**

3.11 [For text of items A and B, see M.R.]

3.12 C. A report must be filed with the commissioner, within five days, ~~of any test~~
3.13 ~~with results that exceed the threshold in item A, describing the equipment involved, the~~
3.14 ~~test results, and corrective action taken.~~ and must include:

3.15 (1) the model number and serial number, if assigned, of the leaking source;

3.16 (2) the identity of the radionuclide and its estimated activity;

3.17 (3) the results of the test;

3.18 (4) the date of the test; and

3.19 (5) the action taken.

3.20 [For text of subp 4, see M.R.]

3.21 **4731.4350 NOTIFICATIONS.**

3.22 Subpart 1. ~~Reports~~ **Immediate notification required.** ~~In addition to the reporting~~
3.23 ~~required under part 4731.3110 and under other parts of this chapter, a licensee must~~

4.1 ~~provide a written report to the commissioner within 30 days of the occurrence of any of~~
4.2 ~~the following incidents involving radiographic equipment:~~

4.3 ~~A. unintentional disconnection of the source assembly from the control cable;~~

4.4 ~~B. inability to retract the source assembly to its fully shielded position and~~
4.5 ~~secure it in the fully shielded position; or~~

4.6 ~~C. failure of any component, critical to safe operation of the device, to properly~~
4.7 ~~perform its intended function.~~

4.8 A licensee must notify the commissioner as soon as possible but not later than four
4.9 hours after the discovery of any event that prevents immediate protective actions necessary
4.10 to avoid exposures to radiation or radioactive materials that could exceed regulatory limits
4.11 or releases of licensed material that could exceed regulatory limits. Reportable events
4.12 under this subpart include fires, explosions, toxic gas release, or similar hazards.

4.13 Subp. 2. **24-hour notification required information.** ~~A licensee must include the~~
4.14 ~~following information in each report submitted under subpart 1 and in each report of~~
4.15 ~~overexposure submitted under part 4731.2620 that involves failure of safety components~~
4.16 ~~of radiography equipment:~~

4.17 ~~A. a description of the equipment problem;~~

4.18 ~~B. the cause of each incident, if known;~~

4.19 ~~C. the name of the manufacturer and model number of equipment involved~~
4.20 ~~in the incident;~~

4.21 ~~D. the place, date, and time of the incident;~~

4.22 ~~E. the actions taken to establish normal operations;~~

4.23 ~~F. the corrective actions taken or planned to prevent recurrence; and~~

4.24 ~~G. the qualifications of personnel involved in the incident.~~

5.1 A licensee must notify the commissioner within 24 hours after discovery of any of the
5.2 following events involving licensed material:

5.3 A. the occurrence of any of the following incidents involving radiographic
5.4 equipment:

5.5 (1) unintentional disconnection of the source assembly from the control
5.6 cable;

5.7 (2) inability to retract the source assembly to its fully shielded position and
5.8 secure it in the fully shielded position; or

5.9 (3) failure of any component, critical to safe operation of the device, to
5.10 properly perform its intended function;

5.11 B. an event in which equipment is disabled or fails to function as designed when:

5.12 (1) the equipment is required by rule or license condition to prevent
5.13 releases exceeding regulatory limits, to prevent exposure to radiation and radioactive
5.14 materials exceeding regulatory limits, or to mitigate the consequences of an accident;

5.15 (2) the equipment is required to be available and operable when it is
5.16 disabled or fails to function; and

5.17 (3) no redundant equipment is available and operable to perform the
5.18 required safety function;

5.19 C. an unplanned contamination event that:

5.20 (1) requires access to the contaminated area, by workers or the public, to
5.21 be restricted for more than 24 hours by imposing additional radiological controls or by
5.22 prohibiting entry into the areas;

5.23 (2) involves a quantity of material greater than five times the lowest annual
5.24 limit on intake specified in part 4731.2750 for the material; and

6.1 (3) restricts access to the area for a reason other than to allow isotopes with
6.2 a half-life of less than 24 hours to decay prior to decontamination;

6.3 D. an event that requires unplanned medical treatment at a medical facility of
6.4 an individual with spreadable radioactive contamination on the individual's clothing or
6.5 body; or

6.6 E. an unplanned fire or explosion that damages any licensed material or any
6.7 device, container, or equipment containing licensed materials when:

6.8 (1) the quantity of material involved is five times the lowest annual limit
6.9 on intake specified in part 4731.2750; and

6.10 (2) the damage affects the integrity of the licensed material or its container.

6.11 Subp. 3. ~~Reporting unlisted use~~ Preparation and submission of notifications. A
6.12 licensee ~~conducting radiographic operations or storing radioactive material at any location~~
6.13 ~~not listed on the license for a period in excess of 180 days in a calendar year must notify~~
6.14 ~~the commissioner prior to exceeding the 180 days.~~ must make notifications required
6.15 under subparts 1 and 2 by telephone to the commissioner. To the extent the information is
6.16 available at the time of notification, the information provided must include:

6.17 A. the caller's name and call-back telephone number;

6.18 B. a description of the event, including date and time;

6.19 C. the exact location of the event;

6.20 D. the isotopes, quantities, and chemical and physical form of the licensed
6.21 material involved; and

6.22 E. any personnel radiation exposure data available.

6.23 Subp. 4. Reports required. A licensee who makes a notification required under
6.24 subpart 1 or 2 must submit a written follow-up report within 30 days of the notification.

7.1 Written reports prepared as required by other rules may be submitted to fulfill this
7.2 requirement if the reports contain all of the necessary information and the appropriate
7.3 distribution is made. The reports must be sent to the commissioner and include:

7.4 A. a description of the incident;

7.5 B. the cause of each incident, if known;

7.6 C. the name of the manufacturer and model number of equipment involved
7.7 in the incident;

7.8 D. the place, date, and time of the incident;

7.9 E. the actions taken to establish normal operations;

7.10 F. the corrective actions taken or planned to prevent recurrence;

7.11 G. the qualifications of personnel involved in the incident;

7.12 H. the isotopes, quantities, and chemical and physical form of the licensed
7.13 material involved;

7.14 I. the results of any evaluations or assessments; and

7.15 J. the extent of exposure of individuals to radiation or to radioactive materials,
7.16 without identification of the individuals by name.

7.17 Subp. 5. **Reporting unlisted use.** A licensee conducting radiographic operations or
7.18 storing radioactive material at any location not listed on the license for a period in excess of
7.19 180 days in a calendar year must notify the commissioner prior to exceeding the 180 days.

7.20 **4731.4430 CONTROL OF AEROSOLS AND GASES.**

7.21 Subpart 1. **Collection system.** A licensee who administers radioactive aerosols or
7.22 gases must do so with a system that will keep airborne concentrations within the limits
7.23 prescribed by parts 4731.2020 and 4731.2090.

8.1 Subp. 2. **System vented or system collection.** The system must either be directly
8.2 vented to the atmosphere through an air exhaust or provide for collection and decay or
8.3 disposal of the aerosol or gas in a shielded container.

8.4 Subp. 3. **Negative pressure required.** A licensee must only administer radioactive
8.5 gases in rooms that are at negative pressure compared to surrounding rooms.

8.6 Subp. 4. **Calculation of time needed after a release.** Before receiving, using, or
8.7 storing a radioactive gas, the licensee must calculate the amount of time needed after a
8.8 release to reduce the concentration in the area of use to the occupational limit listed in
8.9 part 4731.2750. The calculation must be based on the highest activity of gas handled in a
8.10 single container and the measured available air exhaust rate.

8.11 Subp. 5. **Posting time needed after a release.** A licensee must post the time needed
8.12 after a release to reduce the concentration to the occupational limit calculated for the area
8.13 of use and require that, in case of a gas spill, individuals evacuate the room until the
8.14 posted time has elapsed.

8.15 Subp. 6. **Monthly check on collection system.** A licensee must check the operation
8.16 of collection systems monthly and measure the ventilation rates in areas of use at intervals
8.17 not to exceed six months.

8.18 Subp. 7. **Records retention.** Records of these checks and measurements must be
8.19 maintained for three years.

8.20 **4731.4443 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE**
8.21 **REQUIRED; TRAINING.**

8.22 Subpart 1. **Training and education requirements.** Except as provided under part
8.23 4731.4414, a licensee must require an authorized user of unsealed radioactive material for
8.24 the uses authorized under part 4731.4440 to be a physician who:

9.1 A. is certified by a medical specialty board whose certification process has
 9.2 been recognized by the NRC or an agreement state, meets the requirements in item B,
 9.3 subitem (1), unit (b), subunit vi, and has obtained written attestation that the individual
 9.4 has satisfactorily completed the requirements in this item and subpart 2 and has achieved
 9.5 a level of competency sufficient to function independently as an authorized user for the
 9.6 medical uses authorized under part 4731.4440. The written attestation must be signed
 9.7 by a preceptor authorized user who meets the requirements of this part or equivalent
 9.8 requirements of the NRC or an agreement state. A preceptor authorized user who meets
 9.9 the requirements in item B must also have experience in administering dosages in the
 9.10 same dosage category or categories under item B, subitem (1), unit (b), subunit vi, as the
 9.11 individual requesting authorized user status; or

9.12 [For text of item B, see M.R.]

9.13 [For text of subp 2, see M.R.]

9.14 **4731.4525 MEDICAL EVENT; REPORT AND NOTIFICATION.**

9.15 [For text of subps 1 and 2, see M.R.]

9.16 Subp. 3. ~~Telephone~~ **24-hour notification required.** A licensee must notify the
 9.17 commissioner ~~by telephone no later than the next calendar day~~ within 24 hours after
 9.18 discovery of a medical event.

9.19 Subp. 4. **Written report.** A licensee must submit a written report to the
 9.20 commissioner within ~~15~~ 30 days after discovery of a medical event. The report must not
 9.21 contain an individual's name or any other information that could lead to identification of
 9.22 an individual. The report must include:

9.23 [For text of items A to G, see M.R.]

9.24 [For text of subps 5 and 6, see M.R.]

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

10.1 [For text of item A, see M.R.]

10.2 B. provide a copy of the annotated report to the referring physician, if other
10.3 than the licensee, no later than ~~15~~ 30 days after the discovery of the medical event.

10.4 **4731.4526 DOSE TO AN EMBRYO/FETUS OR CHILD; REPORT AND**
10.5 **NOTIFICATION.**

10.6 [For text of subps 1 and 2, see M.R.]

10.7 Subp. 3. ~~Telephone~~ **24-hour notification required.** A licensee must notify the
10.8 commissioner ~~by telephone no later than the next calendar day~~ within 24 hours after
10.9 discovery of a dose to an embryo/fetus or nursing child that requires a report under
10.10 subpart 1 or 2.

10.11 Subp. 4. **Written report.** A licensee must submit a written report to the
10.12 commissioner within ~~15~~ 30 days after discovery of a dose to an embryo/fetus or nursing
10.13 child that requires a report under subpart 1 or 2. The report must not contain the
10.14 individual's or child's name or any other information that could lead to identification of the
10.15 individual or child. The report must include:

10.16 [For text of items A to G, see M.R.]

10.17 [For text of subp 5, see M.R.]

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

10.19 [For text of item A, see M.R.]

10.20 B. provide a copy of the annotated report to the referring physician, if other
10.21 than the licensee, no later than ~~15~~ 30 days after the discovery of the event.

10.22 **4731.4600 DEFINITIONS.**

10.23 Subpart 1. **Scope.** The following definitions apply to parts 4731.4605 to 4731.4620.

11.1 Subp. 2. **Nuclear medicine technologist.** "Nuclear medicine technologist"
11.2 means a person other than a licensed practitioner of the healing arts who administers
11.3 radiopharmaceuticals and related drugs to human beings for diagnostic purposes,
11.4 performs in vivo and in vitro detection and measurement of radioactivity, and administers
11.5 radiopharmaceuticals to human beings for therapeutic purposes. A nuclear medicine
11.6 technologist may perform such procedures only while under the general supervision of
11.7 a licensed practitioner of the healing arts who is licensed to possess and use radioactive
11.8 materials.

11.9 Subp. 3. **Accredited.** "Accredited" means an individual who has satisfactorily
11.10 completed a nationally recognized examination in nuclear medicine and who maintains
11.11 the registration or certification of the examining organization. Nationally recognized
11.12 examinations are provided by the following organizations:

- 11.13 A. the American Registry of Radiologic Technologists (N) (ARRT);
11.14 B. the Nuclear Medicine Technology Certification Board (NMTCB); or
11.15 C. the American Society of Clinical Pathologists (NM) (ASCP).

11.16 **4731.4605 MINIMUM STANDARDS FOR NUCLEAR MEDICINE**
11.17 **TECHNOLOGISTS.**

11.18 Subpart 1. **General requirements.** Except as specified in part 4731.4610, any
11.19 individual functioning as a nuclear medicine technologist in Minnesota must meet the
11.20 following minimum eligibility requirements:

- 11.21 A. graduation from high school or its equivalent;
11.22 B. attainment of 18 years of age; and
11.23 C. ability to adequately perform necessary duties without constituting a hazard
11.24 to the health or safety of patients, other employees, or members of the public.

12.1 Subp. 2. Accreditation required. Except as specified in part 4731.4610, any
12.2 individual functioning as a nuclear medicine technologist in Minnesota after January 1,
12.3 2011, must be accredited.

12.4 **4731.4610 EXCEPTIONS.**

12.5 The individuals in items A to E are exempt from the examination requirement in
12.6 part 4731.4600, subpart 3:

12.7 A. a licensed practitioner of the healing arts who appears as an authorized
12.8 user on an agreement state or United States Nuclear Regulatory Commission radioactive
12.9 materials license;

12.10 B. individuals who function under the direct supervision of an individual who is
12.11 accredited in nuclear medicine or by a physician who appears as an authorized user on an
12.12 agreement state or United States Nuclear Regulatory Commission radioactive materials
12.13 license;

12.14 C. students enrolled in and participating in an accredited program for nuclear
12.15 medicine technology or a school of medicine, osteopathy, podiatry, or chiropractic who, as
12.16 a part of the students' course of study, administers radioactive material during supervised
12.17 clinical experience; or

12.18 D. an individual functioning as a nuclear medicine technologist prior to January
12.19 1, 2011, who is not accredited, provided the individual has completed a training program
12.20 designed to prepare students to demonstrate competency in the following areas:

12.21 (1) patient and personnel protection including:

12.22 (a) biological effects of radiation;

12.23 (b) basic concepts of radiation protection; and

12.24 (c) Minnesota Department of Health rules for radiation exposure;

12.25 (2) radiopharmaceutical characteristics including:

- 13.1 (a) half-life;
- 13.2 (b) method of localization; and
- 13.3 (c) biodistribution;
- 13.4 (3) proper handling of radioactive materials including:
- 13.5 (a) inspection and survey of packages;
- 13.6 (b) storage of radioactive material;
- 13.7 (c) disposal of radioactive waste; and
- 13.8 (d) Department of Transportation training requirements for shippers;
- 13.9 (4) factors effecting image quality including:
- 13.10 (a) equipment;
- 13.11 (b) patient and detector orientation;
- 13.12 (c) patient anatomical factors;
- 13.13 (d) anatomical landmarks;
- 13.14 (e) immobilization techniques; and
- 13.15 (f) radiopharmaceutical;
- 13.16 (5) facility monitoring including:
- 13.17 (a) survey equipment operation and uses; and
- 13.18 (b) radioactive spill responses; and
- 13.19 (6) administration of radiopharmaceuticals as determined during supervised
- 13.20 clinical experience.

14.1 E. Clinical experience must be supervised by an individual who is accredited in
14.2 nuclear medicine or by a physician who appears as an authorized user on an agreement
14.3 state or United States Nuclear Regulatory Commission radioactive materials license.

14.4 **4731.4615 DOCUMENTATION OF COMPETENCY.**

14.5 Subpart 1. Nuclear medicine technologist; January 1, 2011. An individual
14.6 functioning as a nuclear medicine technologist prior to January 1, 2011, and who is
14.7 not accredited must obtain documentation that the individual is competent to applying
14.8 ionizing radiation to human beings.

14.9 Subp. 2. Who can document competency. The documentation of competency must
14.10 be provided by a licensed practitioner of the healing arts under whose general supervision
14.11 the individual is employed or has been employed.

14.12 Subp. 3. Procedures and equipment. The documentation of competency must
14.13 specify the nature of procedures and the equipment the individual is competent to utilize
14.14 and must be limited to work performed before January 1, 2011.

14.15 Subp. 4. Record retention. The documentation of competency must be retained by
14.16 the individual for inspection by the department.

14.17 **4732.4620 REQUIREMENTS FOR OPERATORS OF DUAL IMAGING DEVICES.**

14.18 Subpart 1. Accreditation required. When a unit is operated as a stand-alone nuclear
14.19 medicine imaging device or in a dual mode as a SPECT/CT or PET/CT device, the
14.20 operator must be accredited.

14.21 Subp. 2. CT imaging device. When the unit is operated as a stand-alone CT imaging
14.22 device, the operator must meet the requirements in chapter 4732.