



Protecting, maintaining and improving the health of all Minnesotans

October 23, 2009

Mr. Terrence Reis, Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission T8-E24
Washington, D.C. 20555-0001

Dear Mr. Reis:

Subject: Submittal of Minnesota Department of Health's Proposed Rule for NRC Review

Thank you for the prompt review of the initial rulemaking package. MDH has removed the inappropriate changes that were identified in your letter dated September 8, 2009.

Thanks to your staff, the rule changes pertaining to Authorized User Clarification, Part 35 (RATS ID 2009-1) have been added. These changes were particularly difficult because when the rule parts were initially generated, the format was not consistent with the NRC's regulations.

MDH requests that the following rule parts pertaining to RATS ID 2009-1 be reviewed:

4731.4411	4731.4436	4731.4446
4731.4412	4731.4443	4731.4458
4731.4414	4731.4444	4731.4459
4731.4433	4731.4445	4731.4479

If you have any questions concerning the final rule, please contact me at (651) 201-4530.

Sincerely,

George F. Johns, Jr., Supervisor
Radioactive Materials Unit
PO Box 64975
St. Paul, Minnesota 55164-0975

Attachment: Draft rule

cc: Kathleen Schneider

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 **4731.4411 RADIATION SAFETY OFFICER TRAINING.**

7.21 [For text of subp 1, see M.R.]

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

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

8.2 B. (1) hold a master's or doctor's degree in physics, medical physics, other
8.3 physical science, engineering, or applied mathematics from an accredited college or
8.4 university;

8.5 (2) have two years of full-time practical training or supervised experience
8.6 in medical physics:

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

8.9 (b) in clinical nuclear medicine facilities providing diagnostic or
8.10 therapeutic services under the direction of physicians who meet the requirements for
8.11 authorized users in part 4731.4414, 4731.4436, or 4731.4443; and

8.12 (3) pass an examination, administered by diplomates of the specialty board,
8.13 that assesses knowledge and competence in clinical diagnostic radiological or nuclear
8.14 medicine physics and in radiation safety.

8.15 **4731.4412 AUTHORIZED MEDICAL PHYSICIST TRAINING.**

8.16 Subpart 1. **Training and education requirements.** Except as provided in part
8.17 4731.4414, a licensee must require an authorized medical physicist to be an individual
8.18 who:

8.19 A. is certified by a specialty board whose certification process has been
8.20 recognized by the NRC or an agreement state and:

8.21 (1) has obtained written attestation that the individual has satisfactorily
8.22 completed the requirements in this item and subpart 2 and has achieved a level of
8.23 competency sufficient to function independently as an authorized medical physicist for
8.24 each type of therapeutic medical unit for which the individual is requesting authorized
8.25 medical physicist status. The written attestation must be signed by a preceptor authorized

9.1 medical physicist who meets the requirements in this part, part 4731.4414, or equivalent
9.2 requirements of the NRC or agreement state requirements for an authorized medical
9.3 physicist for each type of therapeutic medical unit for which the individual is requesting
9.4 authorized medical physicist status; and

9.5 [For text of subitem (2), see M.R.]

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

9.9 [For text of units (a) and (b), see M.R.]

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

9.18 [For text of subitem (3), see M.R.]

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

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

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

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

10.4 (2) in clinical radiation facilities providing high-energy, external beam
10.5 therapy (photons and electrons with energies greater than or equal to 1,000,000 electron
10.6 volts) and brachytherapy services under the direction of physicians who meet the
10.7 requirements ~~for authorized users~~ in part 4731.4414, 4731.4458, or 4731.4479; and

10.8 [For text of item C, see M.R.]

10.9 **4731.4414 TRAINING; EXPERIENCED RADIATION SAFETY OFFICER,**
10.10 **TELE THERAPY OR MEDICAL PHYSICIST, AUTHORIZED USER, AND**
10.11 **NUCLEAR PHARMACIST.**

10.12 [For text of items A to D, see M.R.]

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

10.17 **4731.4430 CONTROL OF AEROSOLS AND GASES.**

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

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

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

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

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

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

11.13 Subp. 7. Records retention. Records of these checks and measurements must be
11.14 maintained for three years.

11.15 **4731.4433 UPTAKE, DILUTION, AND EXCRETION STUDIES; TRAINING.**

11.16 Subpart 1. **Training and education requirements.** Except as provided under part
11.17 4731.4414, a licensee must require the authorized user of unsealed radioactive material for
11.18 the uses authorized under part 4731.4432 to be a physician who:

11.19 A. is certified by a medical specialty board whose certification process has been
11.20 recognized by the NRC or an agreement state and has obtained written attestation, signed
11.21 by a preceptor authorized user who meets the requirements of this part, part 4731.4414,
11.22 4731.4436, or 4731.4443, or equivalent requirements of the NRC or an agreement state,
11.23 that the individual has satisfactorily completed the requirements in subpart 2 and has
11.24 achieved a level of competency sufficient to function independently as an authorized user
11.25 for the medical uses authorized under part 4731.4432;

12.1 B. is an authorized user under part 4731.4436 or 4731.4443 or under equivalent
12.2 requirements of the NRC or an agreement state; or

12.3 C. has:

12.4 (1) completed 60 hours of training and experience, including a minimum of
12.5 eight hours of classroom and laboratory training, in basic radionuclide handling techniques
12.6 applicable to the medical use of unsealed radioactive material for uptake, dilution, and
12.7 excretion studies. The training and experience must include:

12.8 [For text of unit (a), see M.R.]

12.9 (b) work experience, under the supervision of an authorized user who
12.10 meets the requirements under this part, part 4731.4414, 4731.4436₂ or 4731.4443, or
12.11 equivalent requirements of the NRC or an agreement state, involving:

12.12 [For text of subunits i to vi, see M.R.]

12.13 (2) obtained written attestation, signed by a preceptor authorized user
12.14 who meets the requirements of this part, part 4731.4414, 4731.4436₂ or 4731.4443,
12.15 or equivalent requirements of the NRC or an agreement state, that the individual has
12.16 satisfactorily completed the requirements in this item and has achieved a level of
12.17 competency sufficient to function independently as an authorized user for the medical uses
12.18 authorized under part 4731.4432.

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

12.20 **4731.4436 IMAGING AND LOCALIZATION STUDIES; TRAINING.**

12.21 Subpart 1. **Training and education requirements.** Except as provided under part
12.22 4731.4414, a licensee must require an authorized user of unsealed radioactive material for
12.23 the uses authorized under part 4731.4434 to be a physician who:

12.24 A. is certified by a medical specialty board whose certification process has been
12.25 recognized by the NRC or an agreement state and has obtained written attestation, signed

13.1 by a preceptor authorized user who meets the requirements in this part~~;~~ part 4731.4414,
13.2 or in item C, subitem (1), unit (b), subunit vii, and part 4731.4443; or equivalent
13.3 requirements of the NRC or an agreement state, that the individual has satisfactorily
13.4 completed the requirements in subpart 2 and has achieved a level of competency sufficient
13.5 to function independently as an authorized user for the medical uses authorized under
13.6 parts 4731.4432 and 4731.4434;

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

13.10 C. has:

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

13.15 [For text of unit (a), see M.R.]

13.16 (b) work experience, under the supervision of an authorized user who
13.17 meets the requirements ~~under in~~ in this part~~;~~ part 4731.4414, or in subunit vii and part
13.18 4731.4443; or equivalent requirements of the NRC or an agreement state, involving:

13.19 [For text of subunits i to vii, see M.R.]

13.20 (2) obtained written attestation, signed by a preceptor authorized user who
13.21 meets the requirements in this part~~;~~ or in subitem (1), unit (b), subunit vii, and part parts
13.22 4731.4414 and 4731.4443~~;~~ or equivalent requirements of the NRC or an agreement state,
13.23 that the individual has satisfactorily completed the requirements in this item and has
13.24 achieved a level of competency sufficient to function independently as an authorized user
13.25 for the medical uses authorized ~~under in~~ in parts 4731.4432 and 4731.4434.

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

14.2 **4731.4443 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE**
14.3 **REQUIRED; TRAINING.**

14.4 Subpart 1. **Training and education requirements.** Except as provided under part
14.5 4731.4414, a licensee must require an authorized user of unsealed radioactive material for
14.6 the uses authorized under part 4731.4440 to be a physician who:

14.7 A. is certified by a medical specialty board whose certification process has
14.8 been recognized by the NRC or an agreement state, meets the requirements in item B,
14.9 subitem (1), unit (b), subunit vi, and has obtained written attestation that the individual
14.10 has satisfactorily completed the requirements in this item and subpart 2 and has achieved
14.11 a level of competency sufficient to function independently as an authorized user for the
14.12 medical uses authorized under part 4731.4440. The written attestation must be signed by
14.13 a preceptor authorized user who meets the requirements of this part, part 4731.4414, or
14.14 equivalent requirements of the NRC or an agreement state. A preceptor authorized user
14.15 who meets the requirements in item B must also have experience in administering dosages
14.16 in the same dosage category or categories under item B, subitem (1), unit (b), subunit vi,
14.17 as the individual requesting authorized user status; or

14.18 B. has:

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

14.23 [For text of unit (a), see M.R.]

14.24 (b) work experience, under the supervision of an authorized user who
14.25 meets the requirements in this part, part 4731.4414, or equivalent requirements of the
14.26 NRC or an agreement state. A supervising authorized user who meets the requirements in

15.1 this item must also have experience in administering dosages in the same dosage category
15.2 or categories under subunit vi as the individual requesting authorized user status. The
15.3 work experience must involve:

15.4 [For text of subunits i to vi, see M.R.]

15.5 (2) obtained written attestation that the individual has satisfactorily
15.6 completed the requirements in this item and has achieved a level of competency sufficient
15.7 to function independently as an authorized user for the medical uses authorized under part
15.8 4731.4440. The written attestation must be signed by a preceptor authorized user who
15.9 meets the requirements of this part, part 4731.4414, or equivalent requirements of the
15.10 NRC or an agreement state. A preceptor authorized user who meets the requirements
15.11 in this item must also have experience in administering dosages in the same dosage
15.12 category or categories under subitem (1), unit (b), subunit vi, as the individual requesting
15.13 authorized user status.

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

15.15 **4731.4444 ORAL ADMINISTRATION OF SODIUM IODIDE I-131; QUANTITIES**
15.16 **LESS THAN OR EQUAL TO 33 MILLICURIES (1.22 GBq); WRITTEN**
15.17 **DIRECTIVE REQUIRED; TRAINING.**

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

15.21 A. is certified by a medical specialty board whose certification process has been
15.22 recognized by the NRC or an agreement state and includes all of the requirements of
15.23 item C, subitems (1) and (2), and who has obtained written attestation that the individual
15.24 has satisfactorily completed the requirements of item C, subitems (1) and (2), and has
15.25 achieved a level of competency sufficient to function independently as an authorized user
15.26 for medical uses authorized under part 4731.4440. The written attestation must be signed

16.1 by a preceptor authorized user who meets the requirements of this part, part 4731.4414,
16.2 4731.4443₂ or 4731.4445, or equivalent requirements of the NRC or an agreement state. A
16.3 preceptor authorized user who meets the requirement in part 4731.4443, subpart 1, item B,
16.4 must also have experience in oral administration of less than or equal to 33 millicuries
16.5 (1.22 GBq) of sodium iodide (I-131) for which a written directive is required or oral
16.6 administration of greater than 33 millicuries (1.22 GBq) of sodium iodide (I-131) as
16.7 specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi;

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

16.9 C. has:

16.10 [For text of subitem (1), see M.R.]

16.11 (2) work experience under the supervision of an authorized user who meets
16.12 the requirements of this part, part 4731.4414, 4731.4443₂ or 4731.4445, or equivalent
16.13 requirements of the NRC or an agreement state. A supervising authorized user who meets
16.14 the requirements in part 4731.4443, subpart 1, item B, must also have experience in
16.15 oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide
16.16 (I-131) for which a written directive is required or oral administration of greater than 33
16.17 millicuries (1.22 GBq) of sodium iodide (I-131) as specified in part 4731.4443. The
16.18 work experience must involve:

16.19 [For text of units (a) to (f), see M.R.]

16.20 (3) obtained written attestation that the individual has satisfactorily
16.21 completed the requirements of this item and has achieved a level of competency sufficient
16.22 to function independently as an authorized user for medical uses authorized under
16.23 part 4731.4440. The written attestation must be signed by a preceptor authorized user
16.24 who meets the requirements of this part, part 4731.4414, 4731.4443₂ or 4731.4445, or
16.25 equivalent requirements of the NRC or an agreement state. A preceptor authorized user
16.26 who meets the requirement in part 4731.4443, subpart 1, item B, must also have experience

17.1 in oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide
17.2 (I-131) for which a written directive is required or oral administration of greater than 33
17.3 millicuries (1.22 GBq) of sodium iodide (I-131) as specified in part 4731.4443.

17.4 **4731.4445 ORAL ADMINISTRATION OF SODIUM IODIDE; QUANTITIES**
17.5 **GREATER THAN 33 MILLICURIES (1.22 GBq); WRITTEN DIRECTIVE**
17.6 **REQUIRED; TRAINING.**

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

17.10 A. is certified by a medical specialty board whose certification process has
17.11 been recognized by the NRC or an agreement state and includes all the requirements in
17.12 item C, subitems (1) and (2), and who has obtained written attestation that the individual
17.13 has satisfactorily completed the requirements of this item and has achieved a level of
17.14 competency sufficient to function independently as an authorized user for medical uses
17.15 authorized under part 4731.4440. The written attestation must be signed by a preceptor
17.16 authorized user who meets the requirements in this part, part 4731.4414 or 4731.4443,
17.17 or equivalent requirements of the NRC or an agreement state. A preceptor authorized
17.18 user who meets the requirements in part 4731.4443, subpart 1, item B, must also have
17.19 experience in the oral administration of I-131 in quantities greater than 33 millicuries as
17.20 specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi;

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

17.22 C. has:

17.23 [For text of subitem (1), see M.R.]

17.24 (2) has work experience, under the supervision of an authorized user who
17.25 meets the requirements ~~under~~ of this part, part 4731.4414 or 4731.4443, subpart 1, item
17.26 A or B, or equivalent requirements of the NRC or an agreement state. A supervising

18.1 authorized user who meets the requirements in part 4731.4443, subpart 1, item B, must
18.2 also have experience in the oral administration of I-131 in quantities greater than 33
18.3 millicuries under part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi. The
18.4 work experience must involve:

18.5 [For text of units (a) to (f), see M.R.]

18.6 (3) obtained written attestation that the individual has satisfactorily
18.7 completed the requirements of this item and has achieved a level of competency sufficient
18.8 to function independently as an authorized user for medical uses authorized under
18.9 part 4731.4440. The written attestation must be signed by a preceptor authorized user
18.10 who meets the requirements in this part, part 4731.4414 or 4731.4443, or equivalent
18.11 requirements of the NRC or an agreement state. A preceptor authorized user who meets
18.12 the requirements in part 4731.4443, subpart 1, item B, must also have experience in the
18.13 oral administration of I-131 in quantities greater than 33 millicuries under part 4731.4443,
18.14 subpart 1, item B, subitem (1), unit (b), subunit vi.

18.15 **4731.4446 PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE**
18.16 **MATERIAL; WRITTEN DIRECTIVE REQUIRED; TRAINING.**

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

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

18.19 [For text of subitem (1), see M.R.]

18.20 (2) work experience, under the supervision of an authorized user who
18.21 meets the requirements in this part ~~or~~, part 4731.4414 or 4731.4443, or equivalent
18.22 requirements of the NRC or agreement state, in the parenteral administration, for which a
18.23 written directive is required, of any beta emitter, or any photon-emitting radionuclide with
18.24 a photon energy less than 150 keV or parenteral administration of any other radionuclide
18.25 for which a written directive is required. A supervising authorized user who meets the
18.26 requirements in part 4731.4443 must have experience in parenteral administration of any

19.1 beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 kilo
19.2 electron volts for which a written directive is required or parenteral administration of any
19.3 other radionuclide for which a written directive is required as specified in part 4731.4443,
19.4 subpart 1, item B, subitem (1), unit (b), subunit vi. The work experience must involve:

19.5 [For text of units (a) to (f), see M.R.]

19.6 (3) obtained written attestation that the individual has satisfactorily
19.7 completed the requirements in this item and item A, subitem (2) or (3), and has achieved
19.8 a level of competency sufficient to function independently as an authorized user for the
19.9 parenteral administration of unsealed radioactive material requiring a written directive.
19.10 The written attestation must be signed by a preceptor authorized user who meets the
19.11 requirements in this part, part 4731.4414 or 4731.4443, or equivalent requirements of the
19.12 NRC or agreement state. A preceptor authorized user who meets the requirements in part
19.13 4731.4443 must have experience in parenteral administration of any beta emitter, or a
19.14 photon-emitting radionuclide with a photon energy less than 150 kilo electron volts for
19.15 which a written directive is required or parenteral administration of any other radionuclide
19.16 for which a written directive is required as specified in part 4731.4443, subpart 1, item B,
19.17 subitem (1), unit (b), subunit vi.

19.18 **4731.4458 MANUAL BRACHYTHERAPY TRAINING.**

19.19 Subpart 1. **Training and education requirements.** Except as provided under part
19.20 4731.4414, a licensee must require an authorized user of a manual brachytherapy source
19.21 for the uses authorized under part 4731.4450 to be a physician who:

19.22 A. is certified by a medical specialty board whose certification has been
19.23 recognized by the NRC or an agreement state and has obtained written attestation,
19.24 signed by a preceptor authorized user who meets the requirements of this part, part
19.25 4731.4414, or equivalent requirements of the NRC or an agreement state, that the
19.26 individual has satisfactorily completed the requirements of subpart 2 and has achieved a

20.1 level of competency sufficient to function independently as an authorized user of manual
20.2 brachytherapy sources for the medical uses authorized under part 4731.4450; or

20.3 B. has:

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

20.6 [For text of unit (a), see M.R.]

20.7 (b) 500 hours of work experience, under the supervision of an
20.8 authorized user who meets the requirements ~~under~~ in this part, part 4731.4414, or
20.9 equivalent requirements of the NRC or an agreement state at a medical institution,
20.10 involving:

20.11 [For text of subunits i to vi, see M.R.]

20.12 (2) completed three years of supervised clinical experience in radiation
20.13 oncology, under an authorized user who meets the requirements of this part, part
20.14 4731.4414, or equivalent requirements of the NRC or an agreement state, as part of a
20.15 formal training program approved by the Residency Review Committee for Radiation
20.16 Oncology of the Accreditation Council for Graduate Medical Education, the Royal College
20.17 of Physicians and Surgeons of Canada, or the Committee on Postgraduate Training of the
20.18 American Osteopathic Association. This experience may be obtained concurrently with
20.19 the supervised work experience required under subitem (1), unit (b); and

20.20 (3) obtained written attestation, signed by a preceptor authorized user
20.21 who meets the requirements of this part, part 4731.4414, or equivalent requirements
20.22 of the NRC or an agreement state, that the individual has satisfactorily completed the
20.23 requirements of this item and has achieved a level of competency sufficient to function
20.24 independently as an authorized user of manual brachytherapy sources for the medical uses
20.25 authorized under part 4731.4450.

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

21.2 **4731.4459 OPHTHALMIC USE OF STRONTIUM-90; TRAINING.**

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

21.5 A. is an authorized user under part 4731.4458 or equivalent requirements of the
21.6 NRC or an agreement state; or

21.7 B. has:

21.8 [For text of subitems (1) and (2), see M.R.]

21.9 (3) obtained written attestation, signed by a preceptor authorized user
21.10 who meets the requirements of this part, part 4731.4414 or 4731.4458, or equivalent
21.11 requirements of the NRC or an agreement state, that the individual has satisfactorily
21.12 completed the requirements in this item and has achieved a level of competency sufficient
21.13 to function independently as an authorized user of strontium-90 for ophthalmic use.

21.14 **4731.4479 REMOTE AFTERLOADER UNITS, TELE THERAPY UNITS, AND**
21.15 **GAMMA STEREOTACTIC RADIOSURGERY UNITS; TRAINING.**

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

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

22.1 this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state for
22.2 an authorized user for each type of therapeutic medical unit for which the individual is
22.3 requesting authorized user status; or

22.4 B. has:

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

22.8 [For text of unit (a), see M.R.]

22.9 (b) 500 hours of work experience, under the supervision of an
22.10 authorized user who meets the requirements of this part, part 4731.4414, or equivalent
22.11 requirements of the NRC or an agreement state, at a medical institution involving:

22.12 [For text of subunits i to vi, see M.R.]

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

22.21 (3) obtained written attestation that the individual has satisfactorily
22.22 completed the requirements in this item and has achieved a level of competency sufficient
22.23 to function independently as an authorized user of each type of therapeutic medical unit
22.24 for which the individual is requesting authorized user status. The written attestation must
22.25 be signed by a preceptor authorized user who meets the requirements of this part, part

23.1 4731.4414, or equivalent requirements of the NRC or an agreement state for an authorized
23.2 user for each type of therapeutic medical unit for which the individual is requesting
23.3 authorized user status; and

23.4 [For text of subitem (4), see M.R.]

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

23.6 **4731.4525 MEDICAL EVENT; REPORT AND NOTIFICATION.**

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

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

23.11 [For text of subps 4 to 7, see M.R.]

23.12 **4731.4526 DOSE TO AN EMBRYO/FETUS OR CHILD; REPORT AND**
23.13 **NOTIFICATION.**

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

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

23.19 [For text of subps 4 to 6, see M.R.]

23.20 **4731.4600 DEFINITIONS.**

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

23.22 Subp. 2. **Nuclear medicine technologist.** "Nuclear medicine technologist"
23.23 means a person other than a licensed practitioner of the healing arts who administers
23.24 radiopharmaceuticals and related drugs to human beings for diagnostic purposes,

24.1 performs in vivo and in vitro detection and measurement of radioactivity, and administers
24.2 radiopharmaceuticals to human beings for therapeutic purposes. A nuclear medicine
24.3 technologist may perform such procedures only while under the general supervision of
24.4 a licensed practitioner of the healing arts who is licensed to possess and use radioactive
24.5 materials.

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

24.10 A. the American Registry of Radiologic Technologists (N) (ARRT);

24.11 B. the Nuclear Medicine Technology Certification Board (NMTCB); or

24.12 C. the American Society of Clinical Pathologists (NM) (ASCP).

24.13 **4731.4605 MINIMUM STANDARDS FOR NUCLEAR MEDICINE**
24.14 **TECHNOLOGISTS.**

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

24.18 A. graduation from high school or its equivalent;

24.19 B. attainment of 18 years of age; and

24.20 C. ability to adequately perform necessary duties without constituting a hazard
24.21 to the health or safety of patients, other employees, or members of the public.

24.22 Subp. 2. **Accreditation required.** Except as specified in part 4731.4610, any
24.23 individual functioning as a nuclear medicine technologist in Minnesota after January 1,
24.24 2011, must be accredited.

25.1 **4731.4610 EXCEPTIONS.**

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

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

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

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

25.15 D. an individual functioning as a nuclear medicine technologist prior to January
25.16 1, 2011, who is not accredited, provided the individual has completed a training program
25.17 designed to prepare students to demonstrate competency in the following areas:

25.18 (1) patient and personnel protection including:

25.19 (a) biological effects of radiation;

25.20 (b) basic concepts of radiation protection; and

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

25.22 (2) radiopharmaceutical characteristics including:

25.23 (a) half-life;

25.24 (b) method of localization; and

- 26.1 (c) biodistribution;
- 26.2 (3) proper handling of radioactive materials including:
- 26.3 (a) inspection and survey of packages;
- 26.4 (b) storage of radioactive material;
- 26.5 (c) disposal of radioactive waste; and
- 26.6 (d) United States Department of Transportation training requirements
- 26.7 for shippers;
- 26.8 (4) factors effecting image quality including:
- 26.9 (a) equipment;
- 26.10 (b) patient and detector orientation;
- 26.11 (c) patient anatomical factors;
- 26.12 (d) anatomical landmarks;
- 26.13 (e) immobilization techniques; and
- 26.14 (f) radiopharmaceutical;
- 26.15 (5) facility monitoring including:
- 26.16 (a) survey equipment operation and uses; and
- 26.17 (b) radioactive spill responses; and
- 26.18 (6) administration of radiopharmaceuticals as determined during supervised
- 26.19 clinical experience.
- 26.20 E. Clinical experience must be supervised by an individual who is accredited in
- 26.21 nuclear medicine or by a physician who appears as an authorized user on an agreement
- 26.22 state or United States Nuclear Regulatory Commission radioactive materials license.
- 26.23 **4731.4615 DOCUMENTATION OF COMPETENCY.**

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

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

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

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

27.13 **4731.4620 REQUIREMENTS FOR OPERATORS OF DUAL IMAGING DEVICES.**

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

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