Department of Health

Proposed Permanent Rules Relating to Radiation Safety

4731.2320 EXCEPTIONS TO POSTING REQUIREMENTS.

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

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

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

4731.2360 LEAK TEST REQUIREMENTS.

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

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

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

B. The licensee must file a report with the commissioner within five days. The report must include:

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

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

(3) the results of the test;

(4) the date of the test; and

(5) the action taken.

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

4731.2510 RECORDS; SURVEYS.

Subpart 1. **Record maintenance; three years.** A licensee must maintain records showing the results of surveys and calibrations required under parts 4731.2200 and 4731.2350, subpart 2, for three years after the record is made. The record must include:

A. the date of the measurements;

B. the manufacturer's name, model number, and serial number for the instrument used to measure radiation or contamination levels;

C. the radiation or contamination level; and

D. the name or initials of the individual who performed the surveys or calibrations.

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

Subp. 3. **Instrument identification.** To satisfy the requirements in subpart 1, item B, licensees may assign a unique identification to an instrument provided:

A. the manufacturer's name, model number, and serial number for each instrument is maintained and available for inspection by the department; and

B. the unique identification is indicated on each instrument.

4731.2520 DETERMINATION OF PRIOR OCCUPATIONAL DOSE.

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

Subp. 4. **Record keeping.**

~~A.~~ A licensee must record the exposure history of each individual, as required by subpart 1 or 2, on a cumulative occupational exposure record form prescribed by the

commissioner, or other clear and legible record including all of the information required by the commissioner's form. The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee obtains reports, the licensee must use the dose shown in the report in preparing the exposure record. For any period in which the licensee does not obtain a report, the licensee must place a notation on the record indicating the periods and time for which data are not available.

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

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

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

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

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

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

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

4731.2650 REPORTS; INDIVIDUAL MONITORING.

A. This part applies to a person licensed by the commissioner to~~:~~

~~(1) possess or use radioactive material for purposes of radiography according to parts 4731.3000 to 4731.3175 and 4731.4000 to 4731.4360; or~~

~~(2)~~ possess or use at any time for processing or manufacturing for distribution according to parts 4731.3000 to 4731.3175, 4731.3300 to 4731.3580, or 4731.4400 to 4731.4527, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Quantity of Radionuclide in curies
Cesium-137	1
Cobalt-60	1
Gold-198	100
Iodine-131	1
Iridium-192	10
Krypton-85	1,000
Promethium-147	10
Technetium-99m	1,000

B. The commissioner may require ~~as a license condition or by order according to part 4731.0200,~~ reports from licensees who are licensed to use radionuclides not listed under item A~~, subitem (2),~~ in quantities sufficient to cause comparable radiation levels.

C. A licensee under item A must submit an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required under part 4731.2210 during that year. The licensee may include additional data for individuals for whom monitoring was provided but not required. The licensee must use an NRC Form 5, or its equivalent, or electronic media containing all the information required by the NRC form, to file the report.

D. A licensee must file the report required under item C, covering the preceding year, on or before April 30 of each year. A licensee must submit the report to the commissioner.

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

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

Subp. 3. **Leaking source.**

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

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

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

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

(3) the results of the test;

(4) the date of the test; and

(5) the action taken.

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

4731.4350 NOTIFICATIONS.

Subpart 1. **~~Reports~~ Immediate notification required.** ~~In addition to the reporting required under part 4731.3110 and under other parts of this chapter, a licensee must provide a written report to the commissioner within 30 days of the occurrence of any of the following incidents involving radiographic equipment:~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. an unplanned contamination event that:

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

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

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

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

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

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

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

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

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

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

C. the exact location of the event;

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

E. any personnel radiation exposure data available.

Subp. 4. **Reports required.** A licensee who makes a notification required under subpart 1 or 2 must submit a written follow-up report within 30 days of the notification. Written reports prepared as required by other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. The reports must be sent to the commissioner and include:

A. a description of the incident;

B. the cause of each incident, if known;

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

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

E. the actions taken to establish normal operations;

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

G. the qualifications of personnel involved in the incident;

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

I. the results of any evaluations or assessments; and

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

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

4731.4411 RADIATION SAFETY OFFICER TRAINING.

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

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

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

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

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

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

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

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

4731.4412 AUTHORIZED MEDICAL PHYSICIST TRAINING.

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

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

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

NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4731.4430 CONTROL OF AEROSOLS AND GASES.

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

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

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

Subp. 4. **Calculation of time needed after a release.** Before receiving, using, or storing a radioactive gas, the licensee must calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in

part 4731.2750. The calculation must be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

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

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

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

4731.4433 UPTAKE, DILUTION, AND EXCRETION STUDIES; TRAINING.

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

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

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

C. has:

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

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

(b) work experience, under the supervision of an authorized user who meets the requirements ~~under~~ in this part, part 4731.4414, 4731.4436, or 4731.4443, or equivalent requirements of the NRC or an agreement state, involving:

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

(2) obtained written attestation, signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, 4731.4436, or 4731.4443, or equivalent requirements of the NRC or an agreement state, that the individual has satisfactorily completed the requirements in this item and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under part 4731.4432.

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

4731.4436 IMAGING AND LOCALIZATION STUDIES; TRAINING.

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

A. The physician must:

(1) ~~is~~ be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state ~~and has~~;

(2) must also have obtained written attestation~~, signed by a preceptor authorized user who meets the requirements in this part; or in item C, subitem (1), unit (b), subunit vii, and part 4731.4443; or equivalent requirements of the NRC or an agreement state,~~ that the individual physician has satisfactorily completed the requirements in subpart 2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under parts 4731.4432 and 4731.4434~~;~~. The attestation must be signed by a preceptor authorized user who meets:

(a) the requirements in this part; or

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

(c) the requirements in part 4731.4414; or

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

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

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

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

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

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

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

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

(a) the requirements in this part; or

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

(c) the requirements in part 4731.4414; or

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

Subp. 2. **Certification requirements.** A specialty board shall require all candidates for certification to:

A. complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies that include the topics listed in subpart 1, item C, subitem (1), units (a) and (b); and

B. pass an examination administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control.

4731.4443 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE REQUIRED; TRAINING.

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

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

B. has:

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

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

(b) work experience, under the supervision of an authorized user who meets the requirements in this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state. A supervising authorized user who meets the requirements in this item must also have experience in administering dosages in the same dosage category

or categories under subunit vi as the individual requesting authorized user status. The work experience must involve:

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

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

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

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

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

A. is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and includes all of the requirements of item C, subitems (1) and (2), and who has obtained written attestation that the individual has satisfactorily completed the requirements of item C, subitems (1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under part 4731.4440. The written attestation must be signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, 4731.4443, or 4731.4445, or equivalent requirements of the NRC or an agreement state. A

preceptor authorized user who meets the requirement in part 4731.4443, subpart 1, item B, must also have experience in oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide (I-131) for which a written directive is required or oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide (I-131) as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi;

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

C. has:

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

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

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

(3) obtained written attestation that the individual has satisfactorily completed the requirements of this item and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under part 4731.4440. The written attestation must be signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, 4731.4443, or 4731.4445, or equivalent requirements of the NRC or an agreement state. A preceptor authorized user who meets the requirement in part 4731.4443, subpart 1, item B, must also have experience in oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide

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

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

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

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

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

C. has:

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

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

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

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

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

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

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

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

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

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

electron volts for which a written directive is required or parenteral administration of any other radionuclide for which a written directive is required as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi. The work experience must involve:

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

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

4731.4458 MANUAL BRACHYTHERAPY TRAINING.

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

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

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

B. has:

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

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

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

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

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

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

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

4731.4459 OPHTHALMIC USE OF STRONTIUM-90; TRAINING.

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

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

B. has:

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

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

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

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

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

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

B. has:

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

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

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

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

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

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

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

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

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

4731.4525 MEDICAL EVENT; REPORT AND NOTIFICATION.

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

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

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

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

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

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

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

4731.4600 DEFINITIONS.

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

Subp. 2. **Accredited.** "Accredited" means an individual who has satisfactorily completed a nationally recognized examination in nuclear medicine and who maintains

the registration or certification of the examining organization. Nationally recognized examinations are provided by the following organizations:

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

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

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

Subp. 3. **Nuclear medicine technologist.** "Nuclear medicine technologist" means a person other than a licensed practitioner of the healing arts who administers radiopharmaceuticals and related drugs to human beings for diagnostic purposes, performs in vivo and in vitro detection and measurement of radioactivity, and administers radiopharmaceuticals to human beings for therapeutic purposes. A nuclear medicine technologist may perform such procedures only while under the general supervision of a licensed practitioner of the healing arts who is licensed to possess and use radioactive materials.

4731.4605 MINIMUM STANDARDS FOR NUCLEAR MEDICINE TECHNOLOGISTS.

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

A. graduation from high school or its equivalent;

B. attainment of 18 years of age; and

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

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

Subp. 3. **Record retention.** The licensee must retain documentation of accreditation for five years and make it available for inspection by the department.

4731.4610 EXCEPTIONS.

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

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

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

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

D. an individual working as a nuclear medicine technologist before January 1, 2011, who is not accredited, provided the individual has completed the training in part 4731.4612.

4731.4612 TRAINING FOR INDIVIDUALS FUNCTIONING AS A NUCLEAR MEDICINE TECHNOLOGIST BEFORE JANUARY 1, 2011, WHO ARE NOT ACCREDITED.

Subpart 1. **Training program.** Individuals working as a nuclear medicine technologist before January 1 , 2011, who are not accredited must complete a training program designed to demonstrate competency in the following areas:

A. patient and personnel protection including:

(1) biological effects of radiation;

(2) basic concepts of radiation protection; and

(3) Minnesota Department of Health rules for radiation exposure;

B. radiopharmaceutical characteristics including:

(1) half-life;

(2) method of localization; and

(3) biodistribution;

C. proper handling of radioactive materials including:

(1) inspection and survey of packages;

(2) storage of radioactive material;

(3) disposal of radioactive waste; and

(4) United States Department of Transportation training requirements for shippers;

D. factors affecting image quality including:

(1) equipment;

(2) patient and detector orientation;

(3) patient anatomical factors;

(4) anatomical landmarks;

(5) immobilization techniques; and

(6) radiopharmaceuticals;

E. facility monitoring including:

(1) survey equipment operation and uses; and

(2) radioactive spill responses; and

F. administration of radiopharmaceuticals as determined during supervised clinical experience.

Subp. 2. **Clinical experience.** Clinical experience must be supervised by an individual who is accredited in nuclear medicine or by a physician who appears as an authorized user on an agreement state or United States Nuclear Regulatory Commission radioactive materials license.

Subp. 3. **Restrictions during training.** Individuals in a training program indicated in subpart 1 cannot work as a nuclear medicine technologist before obtaining documentation of competency as required in part 4731.4615 unless the individual works under the direct supervision of:

A. an individual who is accredited in nuclear medicine; or

B. a physician who appears as an authorized user on an agreement state or United States Nuclear Regulatory Commission radioactive materials license.

Subp. 4. **Continuing education.** Individuals working as nuclear medicine technologists before January 1, 2011, who are not accredited must:

A. obtain 24 hours of continuing education on nuclear medicine every 24 months;

B. have the continuing education training approved by any of the organizations listed in part 4731.4600, subpart 3; and

C. retain documentation of continuing education for five years and make it available for inspection by the department.

4731.4615 DOCUMENTATION OF COMPETENCY.

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

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

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

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

4731.4620 REQUIREMENTS FOR OPERATORS OF FUSION IMAGING DEVICES.

Subpart 1. **Accreditation required.** When a unit is operated as a fusion imaging device or in a dual mode such as a SPECT/CT or PET/CT device, the operator must be accredited or must meet the requirements in chapter 4732.

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