

Protecting, maintaining and improving the health of all Minnesotans

November 16, 2011

Duncan White, Acting 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. White:

Enclosed is a copy of the final revisions to the Minnesota Radiological Health Rules Relating to Radiation Safety dated August 9, 2011. The final revision does not indicate the changes that were made to the rules. In order to easily identify the changes made by underlined and stricken text, I have included the revision dated August 20, 2010 and the Order of Adoption dated July 8, 2011. The Order of Adoption shows the final changes that were made to the August 20, 2010 revision. The Rules correspond to the following equivalent amendments to NRC's regulations.

Rats ID	Title	State Section
2009-1	Medical Use of Byproduct Material	4731.4411, 4731.4412, 4731.4414,
	- Authorized User Clarification	4731.4433, 4731.4436, 4731.4443,
		4731.4444, 4731.4445, 4731.4446,
		4731.4458, 4731.4459, 4731.4479

In addition to making the NRC initiated changes listed above, this rulemaking accomplished the following: expanded the exception to posting to include afterloaders and gamma stereotactic radiosurgery units; clarified the report requirements for leaking sources; deleted redundant language; removed the individual monitoring reporting requirement for industrial radiography licensees; clarified the notification and reporting requirements for industrial radiography events; added requirements for control of aerosols and gases; and added qualifications for nuclear medicine technologists.

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200.

If you have any questions, please feel free to contact me at 651-201-4522 or by email at sherrie.flaherty@state.mn.us.

Sincerely,

Sherrie Flaherty, MHP, DC, Supervisor

Minnesota Department of Health

Radioactive Materials Unit

PO Box 64975

St. Paul, MN 55164-0975

Enclosures: As stated

1.1	4731.2320 EXCEPTIONS TO POSTING REQUIREMENTS.
1.2	[For text of subps 1 to 3, see M.R.]
1.3	Subp. 4. Hospital; teletherapy, remote afterloader, or gamma stereotactic
1.4	radiosurgery units. A room in a hospital or clinic that is used for teletherapy, remote
1.5	afterloader, or gamma stereotactic radiosurgery units is exempt from the requirement
1.6	to post a caution sign if:
1.7	[For text of items A and B, see M.R.]
1.8	4731.2360 LEAK TEST REQUIREMENTS.
1.9	[For text of subps 1 to 4, see M.R.]
1.10	Subp. 5. Level of detection. The leak test must be capable of detecting the presence
1.11	of 0.005 microcurie (185 becquerel) of radioactive material on the test sample.
1.12	A. If the test reveals the presence of 0.005 microcurie (185 becquerel) or more
1.13	of removable contamination, the source must be removed immediately from service and
1.14	decontaminated, repaired, or disposed of according to this chapter.
1.15	B. The licensee must file a report with the commissioner within five days.
1.16	The report must include:
1.17	(1) the model number and serial number, if assigned, of the leaking source;
1.18.	(2) the identity of the radionuclide and its estimated activity;
1.19	(3) the results of the test;
1.20	(4) the date of the test; and
1.21	(5) the action taken.
1.22	[For text of subps 6 to 8, see M.R.]

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4731.2510 RECORDS; SURVEYS.

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2.1	Subpart 1. Record maintenance; three years. A licensee must maintain records
2.2	showing the results of surveys and calibrations required under parts 4731.2200 and
2.3	4731.2350, subpart 2, for three years after the record is made. The record must include:
2.4	A. the date of the measurements;
2.5	B. the manufacturer's name, model number, and serial number for the
2.6	instrument used to measure radiation or contamination levels;
2.7	C. the radiation or contamination level; and
2.8	D. the name or initials of the individual who performed the surveys or
2.9	calibrations.
2.10	[For text of subp 2, see M.R.]
2.11	Subp. 3. Instrument identification. To satisfy the requirements in subpart 1, item
2.12	B, licensees may assign a unique identification to an instrument provided:
2.13	A. the manufacturer's name, model number, and serial number for each
2.14	instrument is maintained and available for inspection by the department; and
2.15	B. the unique identification is indicated on each instrument.
2.16	4731.2520 DETERMINATION OF PRIOR OCCUPATIONAL DOSE.
2.17	[For text of subps 1 to 3, see M.R.]
2.18	Subp. 4. Record keeping. A licensee must record the exposure history of each
2.19	individual, as required by subpart 1 or 2, on a cumulative occupational exposure record
2.20,	form prescribed by the commissioner, or other clear and legible record including all of the
2.21, .	information required by the commissioner's form. The form or record must show each
2.22	period in which the individual received occupational exposure to radiation or radioactive
2.23	material and must be signed by the individual who received the exposure. For each period
2.24	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.

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

4731.2650 REPORTS; INDIVIDUAL MONITORING.

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

3.10	Radionuclide	Quantity of
3.11	K	adionuclide in curies
3.12	Cesium-137	1
3.13 . ,	Cobalt-60	1.
3.14	Gold-198	100
3.15	Iodine-131	1
3.16	Iridium-192	10
3.17	Krypton-85	1,000
3.18	Promethium-147	10
3.19	Technetium-99m	1,000

- B. The commissioner may require reports from licensees who are licensed to use radionuclides not listed under item A 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

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4.1	must use an NRC Form 5, or its equivalent, or electronic media containing all the
4.2	information required by the NRC form, to file the report.
4.3	D. A licensee must file the report required under item C, covering the preceding
4.4	year, on or before April 30 of each year. A licensee must submit the report to the
4.5	commissioner.
4.6 4.7	4731.4070 LEAK TESTING, REPLACEMENT, AND OTHER MODIFICATIONS OF SEALED SOURCES.
4.8	[For text of subps 1 and 2, see M.R.]
4.9	Subp. 3. Leaking source.
4.10	[For text of items A and B, see M.R.]
4.11	C. A report must be filed with the commissioner, within five days and must
4.12	include:
4:13	(1) the model number and serial number, if assigned, of the leaking source;
4.14	(2) the identity of the radionuclide and its estimated activity;
4.15	(3) the results of the test;
4.16	(4) the date of the test; and
4.17	(5) the action taken.
4.18	[For text of subp 4, see M.R.]
4.19	4731.4350 NOTIFICATIONS.
4.20 -	Subpart 1. Immediate notification required. A licensee must notify the
4.21	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

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5.1	that could exceed regulatory limits. Reportable events under this subpart include fires,
5.2	explosions, toxic gas release, or similar hazards.
5.3	Subp. 2. 24-hour notification required. A licensee must notify the commissioner
5.4	within 24 hours after discovery of any of the following events involving licensed material:
5.5	A. the occurrence of any of the following incidents involving radiographic
5.6	equipment:
5.7	(1) unintentional disconnection of the source assembly from the control
5.8	cable;
5.9	(2) inability to retract the source assembly to its fully shielded position and
5.10	secure it in the fully shielded position; or
5.11	(3) failure of any component, critical to safe operation of the device, to
5.12	properly perform its intended function;
5.13	B. an event in which equipment is disabled or fails to function as designed when:
5.14	(1) the equipment is required by rule or license condition to prevent
5.15	releases exceeding regulatory limits, to prevent exposure to radiation and radioactive
5.16	materials exceeding regulatory limits, or to mitigate the consequences of an accident;
5.17	(2) the equipment is required to be available and operable when it is
5.18	disabled or fails to function; and
5.19	(3) no redundant equipment is available and operable to perform the
5.20	required safety function;
5.21	C. an unplanned contamination event that:
5;22	(1) requires access to the contaminated area, by workers or the public, to
5.23	be restricted for more than 24 hours by imposing additional radiological controls or by
5.24	prohibiting entry into the areas;

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6.1	(2) involves a quantity of material greater than five times the lowest annual
6.2	limit on intake specified in part 4731.2750 for the material; and
6.3	(3) restricts access to the area for a reason other than to allow isotopes with
6.4	a half-life of less than 24 hours to decay prior to decontamination;
6.5	D. an event that requires unplanned medical treatment at a medical facility of
6.6	an individual with spreadable radioactive contamination on the individual's clothing or
6.7	body; or
6.8	E. an unplanned fire or explosion that damages any licensed material or any
6.9	device, container, or equipment containing licensed materials when:
6.10	(1) the quantity of material involved is five times the lowest annual limit
6.11	on intake specified in part 4731.2750; and
6.12	(2) the damage affects the integrity of the licensed material or its container
6.13	Subp. 3. Preparation and submission of notifications. A licensee must make
6.14	notifications required under subparts 1 and 2 by telephone to the commissioner. To the
6.15	extent the information is available at the time of notification, the information provided
6.16	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:				

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- 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

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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:

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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 in part 4731.4414, 4731.4458, or 4731.4479; and
10.8	[For text of item C, see M.R.]
10.9 10.10 10.11	4731.4414 TRAINING; EXPERIENCED RADIATION SAFETY OFFICER, TELETHERAPY OR MEDICAL PHYSICIST, AUTHORIZED USER, AND 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 individuals 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.

Subp. 3. Negative pressure required. A licensee must only administer radioactive

gases in rooms that are at negative pressure compared to surrounding rooms.

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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.

11.15 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;

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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
12.10	who meets the requirements in this part, part 4731.4414, 4731.4436, 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, 4731.4436, 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 is qualified as follows
12.24	under item A, B, or C:
12.25	A. The physician must:

13.1	(1) be certified by a medical specialty board whose certification process
13.2	has been recognized by the NRC or an agreement state;
13.3	(2) must also have obtained written attestation that the individual physician
13.4	has satisfactorily completed the requirements in subpart 2 and has achieved a level of
13.5	competency sufficient to function independently as an authorized user for the medical
13.6	uses authorized under parts 4731.4432 and 4731.4434. The attestation must be signed
13.7	by a preceptor authorized user who meets:
13.8	(a) the requirements in this part;
13.9	(b) the requirements in item C, subitem (1), unit (b), subunit vii, and
13.10	part 4731.4443;
13.11	(c) the requirements in part 4731.4414; or
13.12	(d) equivalent requirements of the NRC or an agreement state.
13.13	B. The physician must be an authorized user under part 4731.4443 and meet the
13.14	requirements in item C, subitem (1), unit (b), subunit vii, or equivalent requirements of the
13.15	NRC or an agreement state; or
13.16	C. The physician must have:
13.17	(1) completed 700 hours of training and experience, including a minimum
13.18	of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques
13.19	applicable to the medical use of unsealed radioactive material for imaging and localization
13.20	studies. The training and experience must include, at a minimum:
13.21	[For text of unit (a), see M.R.]
13.22	(b) work experience, under the supervision of an authorized user who
13.23	meets the requirements in this part, part 4731.4414, or in subunit vii and part 4731.4443,
13.24	or equivalent requirements of the NRC or an agreement state, involving:

14.1	[For text of subunits i to vii, see M.R.]
14.2	(2) obtained written attestation that the individual physician has
14.3	satisfactorily completed the requirements in this item and has achieved a level of
14.4	competency sufficient to function independently as an authorized user for the medical
14.5	uses authorized under parts 4731.4432 and 4731.4434. The attestation must be signed
14.6	by a preceptor authorized user who meets:
14.7	(a) the requirements in this part;
14.8	(b) the requirements in subitem (1), unit (b), subunit vii, and part
14.9	4731.4443;
14.10	(c) the requirements in part 4731.4414; or
14.11	(d) equivalent requirements of the NRC or an agreement state.
14.12	Subp. 2. Certification requirements. A specialty board shall require all candidates
14.13	for certification to:
14.14	A. complete 700 hours of training and experience in basic radionuclide handling
14.15	techniques and radiation safety applicable to the medical use of unsealed radioactive
14.16	material for imaging and localization studies that include the topics listed in subpart 1,
14.17	item C, subitem (1), units (a) and (b); and
14.18	B. pass an examination administered by diplomates of the specialty board,
14.19	which assesses knowledge and competence in radiation safety, radionuclide handling,
14,20	and quality control.
14.21 14.22	4731.4443 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE REQUIRED; TRAINING.
14.23	Subpart 1. Training and education requirements. Except as provided under part
14.24	4731.4414, a licensee must require an authorized user of unsealed radioactive material for
14.25	the uses authorized under part 4731.4440 to be a physician who:
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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

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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;

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

17.2 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

17.24 GREATER THAN 33 MILLICURIES (1.22 GBq); WRITTEN DIRECTIVE

17.25 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.]

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

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

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

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(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, 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.]

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(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:

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21.1	[For text of unit (a), see M.R.]
21.2	(b) 500 hours of work experience, under the supervision of an
21.3	authorized user who meets the requirements in this part, part 4731.4414, or equivalent
21.4	requirements of the NRC or an agreement state at a medical institution, involving:
21.5	[For text of subunits i to vi, see M.R.]
21.6.	(2) completed three years of supervised clinical experience in radiation.
21.7	oncology, under an authorized user who meets the requirements of this part, part
21.8	4731.4414, or equivalent requirements of the NRC or an agreement state, as part of a
21.9	formal training program approved by the Residency Review Committee for Radiation
-21.10	Oncology of the Accreditation Council for Graduate Medical Education, the Royal
21.11	College of Physicians and Surgeons of Canada, or the Committee on Postdoctoral Training
21.12	of the American Osteopathic Association. This experience may be obtained concurrently
21.13	with the supervised work experience required under subitem (1), unit (b); and
21.14	(3) obtained written attestation, signed by a preceptor authorized user
21.15	who meets the requirements of this part, part 4731.4414, or equivalent requirements
21.16	of the NRC or an agreement state, that the individual has satisfactorily completed the
21.17	requirements of this item and has achieved a level of competency sufficient to function
21.18	independently as an authorized user of manual brachytherapy sources for the medical user
21.19	authorized under part 4731.4450.
21.20	[For text of subp 2, see M.R.]
21.21	4731.4459 OPHTHALMIC USE OF STRONTIUM-90; TRAINING.
21.22	Except as provided under part 4731.4414, a licensee must require an authorized user
21.23	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

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NRC or an agreement state; or

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[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:

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23.1	[For text of unit (a), see M.R.]				
23.2	(b) 500 hours of work experience, under the supervision of an				
23.3	authorized user who meets the requirements of this part, part 4731.4414, or equivalent				
23.4	requirements of the NRC or an agreement state, at a medical institution involving:				
23.5	[For text of subunits i to vi, see M.R.]				
23.6	(2) completed three years of supervised clinical experience in radiation				
23.7	therapy, under an authorized user who meets the requirements of this part, part 4731.4414,				
23.8	or equivalent requirements of the NRC or an agreement state, as part of a formal training				
23.9	program approved by the Residency Review Committee for Radiation Oncology of				
23.10	the Accreditation Council for Graduate Medical Education, the Royal College of				
23.11	Physicians and Surgeons of Canada, or the Committee on Postdoctoral Training of the				
23.12	American Osteopathic Association. The experience may be obtained concurrently with				
23.13	the supervised work experience required under subitem (1), unit (b);				
23.14	(3) obtained written attestation that the individual has satisfactorily				
23.15	completed the requirements in this item and has achieved a level of competency sufficient				
23.16	to function independently as an authorized user of each type of therapeutic medical unit				
23.17	for which the individual is requesting authorized user status. The written attestation must				
23.18	be signed by a preceptor authorized user who meets the requirements of this part, part				
23.19	4731.4414, or equivalent requirements of the NRC or an agreement state for an authorized				
23.20	user for each type of therapeutic medical unit for which the individual is requesting				
23.21	authorized user status; and				
23.22	[For text of subitem (4), see M.R.]				
23.23	[For text of subp 2, see M.R.]				
23,24	4731.4525 MEDICAL EVENT; REPORT AND NOTIFICATION.				
23.25	[For text of subps 1 and 2, see M.R.]				

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24.1	Subp. 3. 24-hour notification required. A licensee must notify the commissioner
24.2	within 24 hours after discovery of a medical event.
24.3	[For text of subps 4 to 7, see M.R.]
24.4 24.5	4731.4526 DOSE TO AN EMBRYO/FETUS OR CHILD; REPORT AND NOTIFICATION.
24.6	[For text of subps 1 and 2, see M.R.]
24.7	Subp. 3. 24-hour notification required. A licensee must notify the commissioner
24.8	within 24 hours after discovery of a dose to an embryo/fetus or nursing child that requires
24.9	a report under subpart 1 or 2.
24.10	[For text of subps 4 to 6, see M.R.]
24.11	4731.4600 DEFINITIONS.
24.12	Subpart 1. Scope. The following definitions apply to parts 4731.4605 to 4731.4620.
24.13	Subp. 2. Accredited. "Accredited" means an individual who has satisfactorily
24.14	completed a nationally recognized examination in nuclear medicine and who maintains
24.15	the registration or certification of the examining organization. Nationally recognized
24.16	examinations are provided by the following organizations:
24.17	A. the American Registry of Radiologic Technologists (N) (ARRT);
24.18	B. the Nuclear Medicine Technology Certification Board (NMTCB); or
24.19	C. the American Society of Clinical Pathologists (NM) (ASCP).
24.20	Subp. 3. Nuclear medicine technologist. "Nuclear medicine technologist"
24.21	means a person other than a licensed practitioner of the healing arts who administers
24.22	radiopharmaceuticals and related drugs to human beings for diagnostic purposes,
24.23	performs in vivo and in vitro detection and measurement of radioactivity, and administers
24.24	radiopharmaceuticals to human beings for therapeutic purposes. A nuclear medicine

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25.1	technologist may perform such procedures only while under the general supervision of					
25.2	a licensed practitioner of the healing arts who is licensed to possess and use radioactive					
25.3	materials.					
25.4	Subp. 4. Direct supervision. "Direct supervision" means an accredited nuclear					
25.5	medicine technologist or an authorized user currently listed on an agreement state or					
25.6	United States Nuclear Regulatory Commission radioactive materials license is physically					
25.7	present in the facility and available to respond.					
25.8 25.9	4731.4605 MINIMUM STANDARDS FOR NUCLEAR MEDICINE TECHNOLOGISTS.					
25.10	Subpart 1. General requirements. Except as specified in part 4731.4610, any					
25.11	individual working as a nuclear medicine technologist in Minnesota must meet the					
25.12	following minimum eligibility requirements:					
25.13	A. graduation from high school or its equivalent;					
25.14	B. attainment of 18 years of age; and					
25.15	C. ability to adequately perform necessary duties without posing a hazard to the					
25.16	health or safety of patients, other employees, or members of the public.					
25.17	Subp. 2. Accreditation required. Except as specified in part 4731.4610, any					
25.18	individual working as a nuclear medicine technologist in Minnesota on or after January 1,					
25.19	2011, must be accredited.					
25.20	Subp. 3. Record retention. The licensee must retain documentation of accreditation					
25.21	for five years and make it available for inspection upon request by the department.					
25.22	4731.4610 EXCEPTIONS.					
25.23	The individuals in items A to D are exempt from the examination requirement in					
25.24	part 4731.4600, subpart 2:					

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Α.	a licensed practitions	er of the healing arts w	ho is listed as an	authorized
user on an a	agreement state or Unit	ed States Nuclear Regu	latory Commission	on radioactive
materials li	cense;			
В.	individuals working	as nuclear medicine tec	chnologists under	the direct
supervision	of: (1) an individual w	ho is accredited in nuc	lear medicine; or	(2) a physician
who appear	rs as an authorized user	on an agreement state	or United States	Nuclear
Regulatory	Commission radioactiv	ve materials license;		· · · · · · · · · · · · · · · · · · ·
C.	students enrolled in a	nd participating in an	accredited program	n for nuclear
medicine te	chnology or a school or	f medicine, osteopathy,	podiatry, or chire	practic who, a
a part of the	e students' course of stu	dy, administers radioac	tive material duri	ing supervised
clinical exp	perience; or			
D.	. an individual workin	g as a nuclear medicin	e technologist bef	ore January
1, 2011, wh	no is not accredited, pro	ovided the individual h	as completed the	training in
part 4731.4	612.			
•	TRAINING FOR IN E TECHNOLOGIST ITED.		_	
Subpar	rt 1. Training progra n	n. Individuals working	g as a nuclear me	dicine
technologis	st before January 1, 20	11, who are not accred	ited must comple	te a training

B. radiopharmaceutical characteristics including:

program designed to demonstrate competency in the following areas:

patient and personnel protection including:

(2) basic concepts of radiation protection; and

biological effects of radiation;

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

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27.1	·.	(1) half-life;		- -	
27.2		(2) method of localization	on; and		•
27.3		(3) biodistribution;	· · · · · · · · · · · · · · · · · · ·		
27.4	C.	proper handling of radioac	tive materials incl	uding:	
27.5		(1) inspection and survey	of packages;	<i>∴</i>	
27.6	•	(2) storage of radioactive	e material;		
27.7		(3) disposal of radioactiv	e waste; and		
27.8		(4) United States Departs	nent of Transporta	ation training r	equirements for
27.9	shippers;			•	
27.10	D.	factors affecting image qu	ality including:		
27.11		(1) equipment;	. • •	•	
27.12		(2) patient and detector of	orientation;		
27.13		(3) patient anatomical fac	ctors;	· · · · · · · · · · · · · · · · · · ·	
27.14	· ·	(4) anatomical landmark	S;		
27.15		(5) immobilization techn	iques; and	· , ·	
27.16	· · · · · ·	(6) radiopharmaceuticals	•	, .	
27.17	E.	facility monitoring including	ng:		
27.18		(1) survey equipment ope	eration and uses; a	nd	
27.19		(2) radioactive spill respo	onses; and	•	
27.20	F.	administration of radiophar	maceuticals during	g supervised cl	inical experience.
27.21.	Subp. 2	2. Clinical experience. Clin	nical experience n	ust be supervi	ised by an
27.22		ho is accredited in nuclear i	_		•

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authorized user on an agreement stat	e or United States N	uclear Regulatory	Commission
radioactive materials license.			
Subp. 3. Restrictions during t	raining. Individual	s in a training pro	gram
entrare to an income		4 .11	

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

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- 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 2; and
- 28.16 C. retain documentation of continuing education for five years and make it 28.17 available for inspection upon request 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 apply 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.

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29.1	Subp. 3. Procedures and	equipment. The docum	entation of compe	tency must		
29.2	specify the nature of procedures and the equipment the individual is competent to utilize					
29.3	and must be limited to work per	formed before January 1	, 2011.	•		
29.4	Subp. 4. Record retention	. The documentation of	competency must	be retained by		
29.5	the individual for inspection upo	on request by the departr	nent.			
29.6	4731.4620 REQUIREMENTS	FOR OPERATORS C	F FUSION IMA	GING		
29.7	DEVICES.		•	·		
29.8	Subpart 1. Accreditation r	equired. When a unit is	operated as a fus	ion imaging		
29.9	device or in a dual mode such as	s a SPECT/CT or PET/C	T device, the oper	rator must be		
29.10	accredited or must meet the requ	tirements in chapter 473	2.			

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.

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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. The licensee must file a report with the commissioner within five days.
1.20	The report must 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	4731.2510 RECORDS; SURVEYS.
2.4	Subpart 1. Record maintenance; three years. A licensee must maintain records
2.5	showing the results of surveys and calibrations required under parts 4731.2200 and
2.6	4731.2350, subpart 2, for three years after the record is made. The record must include:
2.7	A. the date of the measurements;
2.8	B. the manufacturer's name, model number, and serial number for the
2.9	instrument used to measure radiation or contamination levels;
2.10	C. the radiation or contamination level; and
2.11	D. the name or initials of the individual who performed the surveys or
2.12	calibrations.
2.13	[For text of subp 2, see M.R.]
2.14	Subp. 3. Instrument identification. To satisfy the requirements in subpart 1, item
2.15	B, licensees may assign a unique identification to an instrument provided:
2.16	A. the manufacturer's name, model number, and serial number for each
2.17	instrument is maintained and available for inspection by the department; and
2.18	B. the unique identification is indicated on each instrument.
2.19	4731,2520 DETERMINATION OF PRIOR OCCUPATIONAL DOSE.
2.20	[For text of subps 1 to 3, see M.R.]
2.21	Subp. 4. Record keeping.
2.22	A. A licensee must record the exposure history of each individual, as required
2.23	by subpart 1 or 2, on a cumulative occupational exposure record form prescribed by the

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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 historics 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
- 3.18 (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.

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4.1	A.	This part applies to	a person	licensed	I by the commissioner to:
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- (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:

4.8	Radionuclide	Quantity of
4.9		Radionuclide in curies
4.10	Cesium-137	1
4.11	Cobalt-60	1
4.12	Gold-198	100
4.13	Iodine-131	. 1
4.14	Iridium-192	10
4.15	Krypton-85	1,000
4.16	Promethium-147	10
4.17	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.

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5.1	D. A licensee must file	the report required unde	er item C, covering	the preceding
5.2	year, on or before April 30 of eac	h year. A licensee mus	t submit the report	to the
5.3	commissioner.			
5.4 5.5	4731.4070 LEAK TESTING, RUOF SEALED SOURCES.	EPLACEMENT, AND	OTHER MODIF	ICATIONS
5.6	[For tex	t of subps 1 and 2, see	<u>M.R.]</u>	
5.7	Subp. 3. Leaking source.			
5.8	[For tex	t of items A and B, see	<u>M.R.]</u>	
5.9	C. A report must be file	d with the commissione	r, within five days,	of any test
5.10	with results that exceed the thresho	old in item A, describin	g the equipment in	volved, the
5.11	test results, and corrective action t	aken. and must include	<u>:</u>	
5.12	(1) the model numb	per and serial number, if	assigned, of the le	aking source;
5.13	(2) the identity of the	he radionuclide and its	estimated activity;	
5.14	(3) the results of the	e test;		
5.15	(4) the date of the t	est; and		
5.16	(5) the action taken	<u>.</u>		
5.17	<u>[For</u>	text of subp 4, see M.I	<u> </u>	
5.18	4731.4350 NOTIFICATIONS.			
5.19	Subpart 1. Reports Immedia	te notification require	d. In addition to th	c reporting
5.20	required under part 4731.3110 and	under other parts of th	is chapter, a license	e e must
5.21	provide a written report to the com	ımissioner within 30 da	ys of the occurrenc	c of any of

A: unintentional disconnection of the source assembly from the control cable;

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the following incidents involving radiographic equipment:

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6.1	13. Inability to retract the source assembly to its fully-shielded position and
6.2	secure it in the fully shielded position; or
6.3	C. failure of any component, critical to safe operation of the device, to properly
6.4	perform its intended function.
6.5	A licensee must notify the commissioner as soon as possible but not later than four
6.6	hours after the discovery of any event that prevents immediate protective actions necessary
6.7	to avoid exposures to radiation or radioactive materials that could exceed regulatory limits
6.8	or releases of licensed material that could exceed regulatory limits. Reportable events
6.9	under this subpart include fires, explosions, toxic gas release, or similar hazards.
6.10	Subp. 2. 24-hour notification required information. A licensec must include the
6.11	following information in each report submitted under subpart 1 and in each report of
6.12	overexposure submitted under part 4731.2620 that involves failure of safety components
6.13	of radiography equipment:
6.14	Aa description of the equipment problem;
6.15	B: -the cause of each incident, if known;
6.16	C. the name of the manufacturer and model number of equipment involved
6.17	in the incident;
6.18	D. the place, date, and time of the incident;
5.19	E: -the actions taken to establish normal operations;
5.20	F: the corrective actions taken or planned to prevent recurrence; and
5.21	G: the qualifications of personnel involved in the incident:
5.22	A licensee must notify the commissioner within 24 hours after discovery of any of the
5.23	following events involving licensed material:
5.24	A. the occurrence of any of the following incidents involving radiographic
5.25	equipment:

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7.1	(1) uninte	entional disconnection of the sour	rce assembly from t	he control
7.2	cable;	:		
7.3	(2) inabili	ity to retract the source assembly	to its fully shielded	l position and
7.4	secure it in the fully shie	lded position; or		
7.5	(3) failure	of any component, critical to saf	e operation of the c	levice, to
7.6	properly perform its inte	nded function;	,	
7.7	B. an event in	which equipment is disabled or fa	ils to function as de	signed when:
7.8	(1) the eq	uipment is required by rule or lic	cense condition to p	revent
7.9	releases exceeding regula	atory limits, to prevent exposure	to radiation and rad	lioactive
7.10	materials exceeding regu	latory limits, or to mitigate the co	onsequences of an a	ccident;
7.11	(2) the eq	uipment is required to be availab	le and operable wh	en it is
7.12	disabled or fails to functi	on; and		
7.13	(3) no red	undant equipment is available ar	nd operable to perfo	orm the
7.14	required safety function;			
7.15	C. an unplanne	ed contamination event that:		
7.16	(1) require	es access to the contaminated are	a, by workers or the	public, to
7.17	be restricted for more tha	n 24 hours by imposing addition	al radiological cont	rols or by
7.18	prohibiting entry into the	areas;	, -	
7.19	(2) involve	es a quantity of material greater t	han five times the lo	owest annual
7.20	limit on intake specified i	n part 4731.2750 for the materia	l; and	
7.21	(3) restrict	s access to the area for a reason of	other than to allow i	sotopes with
22	a half-life of less than 24	hours to decay prior to decontar	nination.	,

8.1	D. an event that requires unpranted medical reatment at a medical racinty of
8.2	an individual with spreadable radioactive contamination on the individual's clothing or
8.3	body; or
8.4	E. an unplanned fire or explosion that damages any licensed material or any
8.5	device, container, or equipment containing licensed materials when:
8.6	(1) the quantity of material involved is five times the lowest annual limit
8.7	on intake specified in part 4731.2750; and
8.8	(2) the damage affects the integrity of the licensed material or its container
8.9	Subp. 3. Reporting unlisted use Preparation and submission of notifications. A
8.10	licensee conducting radiographic operations or storing radioactive material at any location
8.11	not listed on the license for a period in excess of 180 days in a calendar year must notify
8.12	the commissioner prior to exceeding the 180 days. must make notifications required
8.13	under subparts 1 and 2 by telephone to the commissioner. To the extent the information is
8.14	available at the time of notification, the information provided must include:
8.15	A. the caller's name and call-back telephone number;
8.16	B. a description of the event, including date and time;
8.17	C. the exact location of the event;
8.18	D. the isotopes, quantities, and chemical and physical form of the licensed
8.19	material involved; and
8.20	E. any personnel radiation exposure data available.
8.21	Subp. 4. Reports required. A licensee who makes a notification required under
8.22	subpart 1 or 2 must submit a written follow-up report within 30 days of the notification.
8.23	Written reports prepared as required by other rules may be submitted to fulfill this
8.24	requirement if the reports contain all of the necessary information and the appropriate
8.25	distribution is made. The reports must be sent to the commissioner and include:

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9.1	<u>A.</u>	a description of the incide	nt;		
9.2	<u>B.</u>	the cause of each incident	if known;		•
9.3	<u>C.</u>	the name of the manufactu	rer and model nu	mber of equipment in	avolved
9.4	in the incide	ent;			
9.5	<u>D.</u>	the place, date, and time of	f the incident;		
9.6	<u>E.</u>	the actions taken to establi	sh normal operati	ons;	
9.7	<u>F.</u>	the corrective actions taker	or planned to pre	event recurrence;	
9.8	<u>G.</u>	the qualifications of person	nnel involved in th	ne incident;	
9.9	<u>H.</u>	the isotopes, quantities, an	d chemical and pl	hysical form of the li	censed
9.10	material inv	olved;			
9.11	I.	the results of any evaluation	ns or assessments:	and	
9.12	<u>J.</u>	the extent of exposure of in	dividuals to radiat	tion or to radioactive	materials,
9.13	without ider	ntification of the individuals	by name.		
9.14	Subp. 5	. Reporting unlisted use.	A licensee conduc	ting radiographic ope	erations or
9.15	storing radio	pactive material at any location	on not listed on the	e license for a period	in excess of
9.16	180 days in	a calendar year must notify	the commissioner	prior to exceeding th	e 180 days.
9.17	4731.4411	RADIATION SAFETY OF	FICER TRAINI	NG.	
9.18		[For text of	of subp 1, see M.F	<u>₹.j</u>	
9.19	Subp. 2	. Certification requirement	its. A specialty be	oard under subpart 1,	item A,
9.20	shall require	all candidates for certificati	ion to:		•
D 21		For text of	if item A see M F	· ? T	

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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;

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- (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

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11.1	NRC or agreement state requirements for an authorized medical physicist for each type
11.2	of therapeutic medical unit for which the individual is requesting authorized medical
11.3	physicist status; and
11.4	[For text of subitem (2), see M.R.]
11.5	B. (1) holds a master's or doctor's degree in physics, medical physics, other
11.6	physical science, engineering, or applied mathematics from an accredited college or
11.7	university, and:
11.8	[For text of units (a) and (b), see M.R.]
11.9	(2) has obtained written attestation that the individual has satisfactorily
11.10	completed the requirements in this item and has achieved a level of competency sufficient
11.11	to function independently as an authorized medical physicist for each type of therapeutic
11.12	medical unit for which the individual is requesting authorized medical physicist status.
11.13	The written attestation must be signed by a preceptor authorized medical physicist who
11.14	meets the requirements in this part, part 4731.4414, or equivalent NRC or agreement state
11.15	requirements for an authorized medical physicist for each type of therapeutic medical unit
11.16	for which the individual is requesting authorized medical physicist status; and
11.17	[For text of subitem (3), see M.R.]
11.18	Subp. 2. Certification requirements. A specialty board under subpart 1, item A,
11.19	shall require all candidates for certification to:
11.20	[For text of item A, see M.R.]
11.21	B. have two years of full-time practical training or supervised experience in
11.22	medical physics:
11.23	(1) under the supervision of a medical physicist who is certified in medical
11:24	physics by a specialty board recognized by the commissioner, the NRC, or an agreement
11.25	state; or

12.1	(2) in clinical radiation facilities providing high-energy, external beam
12.2	therapy (photons and electrons with energies greater than or equal to 1,000,000 electron
12.3	volts) and brachytherapy services under the direction of physicians who meet the
12.4	requirements for authorized users in part 4731.4414, 4731.4458, or 4731.4479; and
12.5	[For text of item C, see M.R.]
12.6 12.7 12.8	4731.4414 TRAINING; EXPERIENCED RADIATION SAFETY OFFICER, TELETHERAPY OR MEDICAL PHYSICIST, AUTHORIZED USER, AND NUCLEAR PHARMACIST.
12.9	[For text of items A to D, see M.R.]
12.10	E. Individuals who need not comply with training requirements described in
12.11	this part may serve as preceptors for, and supervisors of, applicants seeking authorization
12.12	on licenses issued under this chapter for the same uses for which these individuals are
12.13	authorized.
12.14	4731.4430 CONTROL OF AEROSOLS AND GASES.
12.15	Subpart 1. Collection system. A licensee who administers radioactive aerosols or
12.16	gases must do so with a system that will keep airborne concentrations within the limits
12.17	prescribed by parts 4731.2020 and 4731.2090.
12.18	Subp. 2. System vented or system collection. The system must either be directly
12.19	vented to the atmosphere through an air exhaust or provide for collection and decay or
12.20	disposal of the aerosol or gas in a shielded container.
12.21	Subp. 3. Negative pressure required. A licensee must only administer radioactive
12.22	gases in rooms that are at negative pressure compared to surrounding rooms.
12.23	Subp. 4. Calculation of time needed after a release. Before receiving, using, or
12.24	storing a radioactive gas, the licensee must calculate the amount of time needed after a
12.25	release to reduce the concentration in the area of use to the occupational limit listed in

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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.
- 13.10 Subp. 7. Records retention. Records of these checks and measurements must be

 13.11 maintained for three years.
- 13.12 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
- 13.25 C. has:

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14.1	(1) completed 60 hours of training and experience, including a minimum of
14.2	eight hours of classroom and laboratory training, in basic radionuclide handling techniques
14.3	applicable to the medical use of unsealed radioactive material for uptake, dilution, and
14.4	excretion studies. The training and experience must include:
14.5	[For text of unit (a), see M.R.]
14.6	(b) work experience, under the supervision of an authorized user who
14.7	meets the requirements under in this part, part 4731.4414, 4731.4436, or 4731.4443, or
14.8	equivalent requirements of the NRC or an agreement state, involving:
14.9	[For text of subunits i to vi, see M.R.]
14.10	(2) obtained written attestation, signed by a preceptor authorized user
14.11	who meets the requirements of this part, part 4731.4414, 4731.4436, or 4731.4443,
14.12	or equivalent requirements of the NRC or an agreement state, that the individual has
14.13	satisfactorily completed the requirements in this item and has achieved a level of
14.14	competency sufficient to function independently as an authorized user for the medical uses
14.15	authorized under part 4731.4432.
14.16	[For text of subp 2, see M.R.]
14.17	4731.4436 IMAGING AND LOCALIZATION STUDIES; TRAINING.
14.18	Subpart 1. Training and education requirements. Except as provided under part
14.19	4731.4414, a licensee must require an authorized user of unsealed radioactive material for
14.20	the uses authorized under part 4731.4434 to be a physician who is qualified as follows
14.21	under item A, B, or C:
14.22	A. The physician must:
14.23	(1) is be certified by a medical specialty board whose certification process
14.24	has been recognized by the NRC or an agreement state and has;

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15.1	(2) must also have obtained written attestation, signed by a preceptor
15.2	authorized user who meets the requirements in this part; or in item C, subitem (1), unit (b)
15.3	subunit vii, and part 4731:4443; or equivalent requirements of the NRC or an agreement
15.4	state, that the individual physician has satisfactorily completed the requirements in subpart
15.5	2 and has achieved a level of competency sufficient to function independently as an
15.6	authorized user for the medical uses authorized under parts 4731.4432 and 4731.4434;
15.7	The attestation must be signed by a preceptor authorized user who meets:
15.8	(a) the requirements in this part; or
15.9	(b) the requirements in item C, subitem (1), unit (b), subunit vii, and
15.10	part 4731.4443;
15.11	(c) the requirements in part 4731.4414; or
15.12	(d) equivalent requirements of the NRC or an agreement state.
15.13	B. is The physician must be an authorized user under part 4731.4443 and
15.14	meets meet the requirements in item C, subitem (1), unit (b), subunit vii, or equivalent
15.15	requirements of the NRC or an agreement state; or
15.16	C. has The physician must have:
15.17	(1) completed 700 hours of training and experience, including a minimum
15.18	of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques
15.19	applicable to the medical use of unsealed radioactive material for imaging and localization
15.20	studies. The training and experience must include, at a minimum:
15.21	[For text of unit (a), see M.R.]
15.22	(b) work experience, under the supervision of an authorized user who
15.23	meets the requirements under in this part; part 4731.4414, or in subunit vii and part
15.24	4731.4443; or equivalent requirements of the NRC or an agreement state, involving:
15.25	[For text of subunits i to vii, see M.R.]

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(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.

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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:

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(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:

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

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(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

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(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:

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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.

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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.]

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[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:

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[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:

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[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

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B. has:

23.1	(1) completed a structured educational program in basic radionuclide
23.2	handling techniques applicable to the use of manual brachytherapy sources that includes:
23.3	[For text of unit (a), see M.R.]
23.4	(b) 500 hours of work experience, under the supervision of an
23.5	authorized user who meets the requirements under in this part, part 4731.4414, or
23.6	equivalent requirements of the NRC or an agreement state at a medical institution,
23.7	involving:
23.8	[For text of subunits i to vi, see M.R.]
23.9	(2) completed three years of supervised clinical experience in radiation
23.10	oncology, under an authorized user who meets the requirements of this part, part
23.11	4731.4414, or equivalent requirements of the NRC or an agreement state, as part of a
23.12	formal training program approved by the Residency Review Committee for Radiation
23.13	Oncology of the Accreditation Council for Graduate Medical Education, the Royal College
23,14	of Physicians and Surgeons of Canada, or the Committee on Postgraduate Postdoctoral
23.15	Training of the American Osteopathic Association. This experience may be obtained
23.16	concurrently with the supervised work experience required under subitem (1), unit (b); and
23.17	(3) obtained written attestation, signed by a preceptor authorized user
23.18	who meets the requirements of this part, part 4731.4414, or equivalent requirements
23.19	of the NRC or an agreement state, that the individual has satisfactorily completed the
23.20	requirements of this item and has achieved a level of competency sufficient to function
23.21	independently as an authorized user of manual brachytherapy sources for the medical uses
23.22	authorized under part 4731.4450.
23.23	[For text of subp 2, see M.R.]
23.24	4731.4459 OPHTHALMIC USE OF STRONTIUM-90; TRAINING.

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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:

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[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 <u>4731.4414</u>, or <u>4731.4458</u>, 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

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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:

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[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

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27.1	B. the Nuclear Medicine Technology Certification Board (NMTCB); or
27.2	C. the American Society of Clinical Pathologists (NM) (ASCP).
27.3	Subp. 3. Nuclear medicine technologist. "Nuclear medicine technologist"
27.4	means a person other than a licensed practitioner of the healing arts who administers
27.5	radiopharmaceuticals and related drugs to human beings for diagnostic purposes,
27.6	performs in vivo and in vitro detection and measurement of radioactivity, and administers
27.7	radiopharmaceuticals to human beings for therapeutic purposes. A nuclear medicine
27.8	technologist may perform such procedures only while under the general supervision of
27.9	a licensed practitioner of the healing arts who is licensed to possess and use radioactive
27.10	materials.
27.11 27.12	4731.4605 MINIMUM STANDARDS FOR NUCLEAR MEDICINE TECHNOLOGISTS.
27.13	Subpart 1. General requirements. Except as specified in part 4731.4610, any
27.14	individual working as a nuclear medicine technologist in Minnesota must meet the
27.15	following minimum eligibility requirements:
27.16	A. graduation from high school or its equivalent;
27.17	B. attainment of 18 years of age; and
27.18	C. ability to adequately perform necessary duties without posing a hazard to the
27.19	health or safety of patients, other employees, or members of the public.
27.20	Subp. 2. Accreditation required. Except as specified in part 4731.4610, any
27.21	individual working as a nuclear medicine technologist in Minnesota after January 1,
27.22	2011, must be accredited.
27.23	Subp. 3. Record retention. The licensee must retain documentation of accreditation
27.24	for five years and make it available for inspection by the department.
27 25	4731 4610 FYCEPTIONS

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28.1	The individuals in items A to E are exempt from the examination requirement in
28.2	part 4731.4600, subpart 3:
28.3	A. a licensed practitioner of the healing arts who is listed as an authorized
28.4	user on an agreement state or United States Nuclear Regulatory Commission radioactive
28.5	materials license;
28,6	B. individuals working as nuclear medicine technologists under the direct
28.7	supervision of an individual who is accredited in nuclear medicine or by a physician who
28.8	appears as an authorized user on an agreement state or United States Nuclear Regulatory
28.9	Commission radioactive materials license;
28.10	C. students enrolled in and participating in an accredited program for nuclear
28.11	medicine technology or a school of medicine, osteopathy, podiatry, or chiropractic who, as
28.12	a part of the students' course of study, administers radioactive material during supervised
28.13	clinical experience; or
28.14	D. an individual working as a nuclear medicine technologist before January
28.15	1, 2011, who is not accredited, provided the individual has completed the training in
28.16	part 4731.4612.
28.17 28.18 28.19	4731.4612 TRAINING FOR INDIVIDUALS FUNCTIONING AS A NUCLEAR MEDICINE TECHNOLOGIST BEFORE JANUARY 1, 2011, WHO ARE NOT ACCREDITED.
28.20	Subpart 1. Training program. Individuals working as a nuclear medicine
28.21	technologist before January 1, 2011, who are not accredited must complete a training
28.22	program designed to demonstrate competency in the following areas:
28.23	A. patient and personnel protection including:
28.24	(1) biological effects of radiation;
28.25	(2) basic concepts of radiation protection; and

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29.1	(3) Minnesota Department of Health rules for radiation exposure;
29.2	B. radiopharmaceutical characteristics including:
29.3	(1) half-life;
29.4	(2) method of localization; and
29.5	(3) biodistribution;
29.6	C. proper handling of radioactive materials including:
29.7	(1) inspection and survey of packages;
29.8	(2) storage of radioactive material;
29.9	(3) disposal of radioactive waste; and
29.10	(4) United States Department of Transportation training requirements for
29.11	shippers;
29.12	D. factors affecting image quality including:
29.13	(1) equipment;
29.14	(2) patient and detector orientation;
29.15	(3) patient anatomical factors;
29,16	(4) anatomical landmarks;
29.17	(5) immobilization techniques; and
29.18	(6) radiopharmaceuticals;
29.19	E. facility monitoring including:
29.20	(1) survey equipment operation and uses; and
29.21	(2) radioactive spill responses; and

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30.1	F. administration of radio	opharmaceuticals as de	etermined during sur	pervised
30.2	clinical experience.			
30.3	Subp. 2. Clinical experience	. Clinical experience	must be supervised b	y an
30.4	individual who is accredited in nuc	lear medicine or by a	physician who appea	us as an
30.5	authorized user on an agreement sta	ate or United States No	iclear Regulatory Co	ommission
30.6	radioactive materials license.			
30.7	Subp. 3. Restrictions during	training. Individuals	in a training progra	<u>m</u>
30.8	indicated in subpart 1 cannot work	as a nuclear medicine	technologist before o	obtaining
30.9	documentation of competency as re	quired in part 4731.46	15 unless the individ	lual works
30.10	under the direct supervision of:			
30.11	A. an individual who is a	ccredited in nuclear m	edicine; or	
30.12	B. a physician who appear	ars as an authorized us	er on an agreement	state or
30.13	United States Nuclear Regulatory C	Commission radioactive	e materials license.	
30.14	Subp. 4. Continuing education	on. Individuals worki	ng as nuclear medici	ne
30.15	technologists before January 1, 201	1, who are not accredit	ted must:	
30.16	A. obtain 24 hours of cor	ntinuing education on	nuclear medicine eve	ery 24
30.17	months;			
30.18	B. have the continuing ed	lucation training appro	ved by any of the or	ganizations
30.19	listed in part 4731.4600, subpart 3;	and		
30.20	C. retain documentation of	of continuing education	n for five years and r	nake it
30.21	available for inspection by the depa	rtment.	,	
30.22	4731.4615 DOCUMENTATION O	OF COMPETENCY.		
30.23	Subpart 1. Nuclear medicine	technologist; January	, 1, 2011. An individ	dual

functioning as a nuclear medicine technologist prior to January 1, 2011, and who is

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31.1	not accredited must obtain documer	itation that the indivi	dual is competent to	applying
31.2	ionizing radiation to human beings.			
31.3	Subp. 2. Who can document of	competency. The doc	cumentation of comp	etency mus
31.4	be provided by a licensed practitione	er of the healing arts	under whose general	. supervision
31.5	the individual is employed or has be	een employed.		
31.6	Subp. 3. Procedures and equi	pment. The docume	ntation of competen	cy must
31.7	specify the nature of procedures and	the equipment the in	dividual is competer	at to utilize
31.8	and must be limited to work perform	ned before January 1,	2011.	
31.9	Subp. 4. Record retention. Th	e documentation of c	competency must be	retained by
31.10	the individual for inspection by the	department.		
31.11	4731.4620 REQUIREMENTS FO	R OPERATORS O	F FUSION IMAGI	<u>NG</u>
31.12	DEVICES.			
31.13	Subpart 1. Accreditation requ	ired. When a unit is	operated as a fusion	imaging
31.14	device or in a dual mode such as a S	PECT/CT or PET/CT	device, the operato	r must be
31.15	accredited or must meet the requiren	nents in chapter 4732	• •	
31.16	Subp. 2. Diagnostic CT imagin	ng device. When the	unit is operated as a	stand-alone
31.17	diagnostic CT imaging device, the or	perator must meet the	requirements in cha	pter 4732.

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Department of Health

Adopted Permanent Rules Relating to Radiation Safety

The rules proposed and published at State Register, Volume 35, Number 11, pages 1.3 421-437, September 13, 2010 (35 SR 421), are adopted with the following modifications: 1.4

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:

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

C. The physician must have:

- obtained written attestation that the individual physician has satisfactorily completed the requirements in this item and has achieved a level of competency sufficient to function independently 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

4731.4600 DEFINITIONS.

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2.1	Subp. 4. Direct supervision. "Direct supervision" means an accredited nuclear	
2.2	medicine technologist or an authorized user currently listed on an agreement state or	
2.3	United States Nuclear Regulatory Commission radioactive materials license is physically	
2.4	present in the facility and available to respond.	
2.5 2.6	4731.4605 MINIMUM STANDARDS FOR NUCLEAR MEDICINE TECHNOLOGISTS.	
2.7	Subp. 2. Accreditation required. Except as specified in part 4731.4610, any	
2.8	individual working as a nuclear medicine technologist in Minnesota on or after January 1,	•
2.9	2011, must be accredited.	
2.10	Subp. 3. Record retention. The licensee must retain documentation of accreditation	
2.11	for five years and make it available for inspection upon request by the department.	
2.12	4731.4610 EXCEPTIONS.	
2.13	The individuals in items A to $\underline{E}\underline{D}$ are exempt from the examination requirement	
2.14	in part 4731.4600, subpart <u>3_2</u> :	
2.15	B. individuals working as nuclear medicine technologists under the direct	
2.16	supervision of: (1) an individual who is accredited in nuclear medicine; or by (2) a	
2.17	physician who appears as an authorized user on an agreement state or United States	
2.18	Nuclear Regulatory Commission radioactive materials license;	
2.19 2.20 2.21	4731.4612 TRAINING FOR INDIVIDUALS FUNCTIONING AS A NUCLEAR MEDICINE TECHNOLOGIST BEFORE JANUARY 1, 2011, WHO ARE NOT ACCREDITED.	
2.22	Subpart 1. Training program. Individuals working as a nuclear medicine	
2.23	technologist before January 1, 2011, who are not accredited must complete a training	
2.24	program designed to demonstrate competency in the following areas:	
1 25	E administration of radionharmacouticals as determined during supervised	

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clinical experience.

2.26 .

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3.1	Subp. 4. Continuing education	tion. Individuals worki	ng as nuclear medic	ine .
3.2	technologists before January 1, 20	11, who are not accred	ited must:	
3.3	B. have the continuing of	education training appro	oved by any of the or	ganizations
3.4	listed in part 4731.4600, subpart 3	<u>2</u> ; and		
3.5	C. retain documentation	of continuing education	on for five years and	make it
3.6	available for inspection upon requ	est by the department.		
3.7	4731.4615 DOCUMENTATION	OF COMPETENCY		
3.8	Subpart 1. Nuclear medicine	e technologist; Januar	y 1, 2011. An indiv	idual
3.9	functioning as a nuclear medicine	technologist prior to Ja	nuary 1, 2011, and v	vho is not

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 apply ionizing radiation to human beings.

Subp. 4. **Record retention.** The documentation of competency must be retained by the individual for inspection <u>upon request</u> by the department.

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3.10

3.11

3.12