Minnesota Rules, Chapter 4731 Draft Rule Document

4731.0100 DEFINITIONS.

[For text of subparts 1 to 19 see M.R.]

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

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

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

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

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

[For text of subparts 20 to 157 see M.R.]

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

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

B. is identified as an ophthalmic physicist on a:

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

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

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

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

[For text of subparts 158 to 173 see M.R.]

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

[For text of subparts 175 to 269 see M.R.]

4731.0406 GENERAL LICENSE; NRC-APPROVED PACKAGE.

[For text of subparts 1 to 2 see M.R.]

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

A. maintain a copy of the certificate of compliance or other approval of the package and have the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;

B. comply with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of this chapter and Code of Federal Regulations, title 10, part 71, subpart H; and

C. submit in writing to the NRC, before the licensee's first use of the package, the licensee's name and license number and the package identification number specified in the package approval. For the submittal to the NRC, the licensee must use an approved method listed in the Code of Federal

Regulations, title 10, section 71.1(a), addressed to: ATTN: Document Control Desk, Director, Division of ~~Spent~~ Fuel Management ~~Storage and Transportation~~, Office of Nuclear Material Safety and Safeguards.

[For text of subparts 4 to 5 see M.R.]

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

[For text of subparts 1 to 2 see M.R.]

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

A. The notification required under this part must:

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

(2) if delivered by mail, be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur; and

(3) if delivered by any other means than mail, reach the office of the commissioner and the governor or governor's designee or the Tribal official or Tribal official's designee at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

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

C. The licensee must retain a copy of the notification as a record for three years.

[For text of subparts 4 to 5a see M.R.]

Subp. 6. **Cancellation notice.**

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

B. The licensee must state in the notice that it is a cancellation and identify the advance notification that is being canceled.

C. The licensee must retain a copy of the notice as a record for three years.

4731.0422 A1 AND A2 VALUES FOR RADIONUCLIDES.

[For text of subparts 1a see M.R.]

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

Element and Atomic Number and Symbol of Radionuclide	Specific Activity (TBq/g)	Specific Activity (Ci/g)

[For text of Actinium (89) to Silicon (14) see M.R.]

Samarium (62)

Sm-145	9.8×10^{1}	2.6×10^{3}
Sm-147	~~8.5×10^{-1}~~ 8.5×10^{-10}	2.3×10^{-8}
Sm-151	9.7×10^{-1}	2.6×10^{1}
Sm-153	1.6×10^{4}	4.4×10^{5}

[For text of Tin (50) to Zirconium (40) see M.R.]

[For text of subpart 3 see M.R.]

4731.2750 ANNUAL LIMITS ON INTAKE AND DERIVED AIR CONCENTRATIONS.

[For text of subpart 1 to 6 see M.R.]

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

[For text of AN 1 to AN 55 see M.R.]

AN 56						
Barium-126[2]						
D, all compounds	6E+3	2E+4	6E-6	2E-8	8E-5	8E-4
Barium-128						
D, all compounds	5E+2	2E+3	7E-7	2E-9	7E-6	7E-5
Barium-131m[2]						
D, all compounds	4E+5	1E+6	6E-4	2E-6	---	---
	Stom					
	(5E+5)	---	---	---	7E-3	7E-2
Barium-131						
D, all compounds	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
Barium-133m ~~Barium-133~~						
D, all compounds	2E+3	9E+3	4E-6	1E-8	---	---
	LLI (3E+3)	---	---	---	4E-5	4E-4
Barium-133						
D, all compounds	2E+3	7E+2	3E-7	9E-10	2E-5	2E-4
Barium-135m						
D, all compounds	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
Barium-139[2]						
D, all compounds	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
Barium-140						
D, all compounds	5E+2	1E+3	6E-7	2E-9	---	---
	LLI (6E+2)	---	---	---	8E-6	8E-5
Barium-141[2]						
D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
Barium-142[2]						

D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3

[For text of AN 57 to subpart 8 see M.R.]

4731.3075 TERMS AND CONDITIONS OF LICENSES.

[For text of subparts 1 to 6 see M.R.]

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

[For text of subparts 8 to 9 see M.R.]

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

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

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

A. a copy of the general license issued under part 4731.3215. If part 4731.3215, subpart 3, items B to D, or 3a, do not apply to the particular device, those items may be omitted;

B. a copy of parts 4731.2600, 4731.2610, 4731.3115, and ~~4731.3205~~ 4731.3200 item B;

C. a list of the services that can only be performed by a specific licensee;

D. information on acceptable disposal options, including estimated costs of disposal; and

E. an indication that the commissioner's policy is to issue high civil penalties for improper disposal.

[For text of subparts 5 to 11 see M.R.]

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

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

A. satisfies the general requirements specified in part 4731.3070;

B. submits evidence that the applicant is at least one of the following:

(1) registered or licensed with the United States Food and Drug Administration as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under Code of Federal Regulations, title 21, section 207.20(a);

(2) registered or licensed with a state agency as a drug manufacturer;

(3) licensed as a pharmacy by a state board of pharmacy;

(4) operating as a nuclear pharmacy within a federal medical institution; or

(5) a positron emission tomography (PET) drug production facility registered with a state agency;

C. submits the following information regarding the radionuclide:

(1) the chemical and physical form;

(2) the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and

(3) the shielding provided by the packaging to show it is appropriate for safe handling and storage of the radioactive drugs by medical use licensees; and

D. ~~satisfies~~ The applicant commits to the following labeling requirements:

(1) a label must be affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution and include the radiation symbol, the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specific date and time. For a radioactive drug with a half-life greater than 100 days, the time may be omitted; and

(2) a label must be affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol, the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

Subp. 2. **Pharmacy licensees.**

A. A licensee described in subpart 1, item B, subitem (3) or (4) may:

(1) prepare radioactive drugs for medical use, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in subitem (2) or item C, or an individual under the supervision of an authorized nuclear pharmacist, as specified in part 4731.4407; and

(2) allow a pharmacist to work as an authorized nuclear pharmacist if:

(a) the individual qualifies as an authorized nuclear pharmacist;

(b) the individual meets the requirements under parts 4731.4413 and 4731.4415 and the licensee has received an approved license amendment identifying the individual as an authorized nuclear pharmacist; or

(c) the individual is designated as an authorized nuclear pharmacist according to item C.

B. The actions authorized in item A are permitted notwithstanding more restrictive language in license conditions.

C. A licensee described in subpart 1, item B, subitem (3) or (4), may designate a pharmacist as an authorized nuclear pharmacist if the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and the individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

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

(1) the individual's certification by a specialty board whose certification process has been recognized as specified in part 4731.4413, subpart 1~~, with the written attestation signed by a preceptor as required by part 4731.4413, subpart 1~~; or

(2) the NRC or agreement state license, or the permit issued by an NRC master materials licensee, or the permit issued by a licensee of broad scope, or the authorization from a commercial nuclear pharmacy authorized to issue its own authorized nuclear pharmacist; or

(3) documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC; and

(4) a copy of the individual's state pharmacy licensure or registration.

Subp. 3. **Measuring radioactivity.** A licensee under this part must:

A. possess and use instrumentation to measure the radioactivity of radioactive drugs;

B. have procedures for use of the instrumentation;

C. measure, by direct measurement or a combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution;

D. perform tests before initial use, periodically, and following repair on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments when necessary; and

E. check each instrument for constancy and proper operation at the beginning of each day of use.

Subp. 4. **Labeling Requirements.** A licensee must satisfy the labeling requirements of subpart 1, item D.

~~Subp. 4.~~Subp. 5. **Other law.** Nothing in this part relieves a licensee from complying with applicable United States Food and Drug Administration, other federal, or state requirements governing radioactive drugs.

4731.4170 PERSONNEL MONITORING.

Subpart 1. **Monitoring requirements.**

A. A licensee may not permit an individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of direct reading dosimeter, an operating alarm ratemeter, and a personnel dosimeter~~ that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~.

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

D. Each personnel dosimeter must be assigned to and worn by only one individual.

E. Film badges must be replaced at periods not to exceed one month and other personnel dosimeters that require replacement ~~processed and evaluated by an accredited NVLAP processor~~ must be replaced at periods not to exceed three months. All personnel dosimeters must be evaluated at periods not to exceed three months or promptly after replacement, whichever is more frequent.

~~F. After replacement, each personnel dosimeter must be processed as soon as possible.~~

[For text of subparts 2 and 3 see M.R.]

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

[For text of subpart 5 see M.R.]

Subp. 6. **Report retention.** Dosimetry results ~~reports received from the accredited NVLAP personnel dosimeter processor~~ must be retained according to part 4731.4310.

[For text of subpart 7 see M.R.]

4731.4310 RECORDS; PERSONNEL MONITORING.

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

A. direct reading dosimeter readings and yearly operability checks according to part 4731.4170, subparts 2 and 3, for three years after the record is made;

B. alarming ratemeter calibrations for three years after the record is made;

C. personnel dosimeter results ~~received from the accredited NVLAP processor~~ until the commissioner terminates the license; and

D. estimates of exposures as a result of off-scale personal direct reading dosimeters or lost or damaged personnel dosimeters until the commissioner terminates the license.

4731.4403 SPECIFIC LICENSE; MEDICAL USE OF RADIOACTIVE MATERIALS.

[For text of subpart 1 see M.R.]

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

A. An application for a specific license under subpart 1 must be signed by the applicant's or licensee's management.

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

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

(2) the procedures required under parts 4731.4466 and 4731.4472 to 4731.4474, as applicable.

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

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

(2) the procedures required under parts 4731.4466 and 4731.4472 to 4731.4474, as applicable.

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

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

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

(3) any additional ~~The applicant must provide~~ specific information on:

(a)~~(1)~~ radiation safety precautions and instructions;

(b)~~(2)~~ methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(c)~~(3)~~ calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

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

E. An applicant that satisfies the requirements under part 4731.3530 may apply for a Type A specific license of broad scope.

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

A. before the licensee receives, prepares, or uses radioactive material for a type of use that is permitted under this chapter, but not authorized under the licensee's current license issued under parts 4731.4400 to 4731.4527;

B. before the licensee permits anyone to work as an authorized user, authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or ophthalmic physicist under the license, except that the licensee may permit an individual to work as an authorized user, ~~an~~ authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or ophthalmic physicist for 60 days before being authorized on a license if the individual is an authorized user, authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or ophthalmic physicist for the same type of use:

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

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

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

(4) by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

C. before the licensee changes radiation safety officers, except as provided under part 4731.4405, subpart 1, item C;

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

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

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

G.~~F.~~ before the licensee changes an address identified in the application or on the license;~~ and~~

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

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

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

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

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

(2) the licensee's mailing address changes;

(3) the licensee's name changes, but the name change does not constitute a transfer of control of the license as described under part 4731.3075, subpart 2;

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

(5) the licensee permits ~~an authorized user or~~ an individual qualified to be a radiation safety officer under parts 4731.4411 and 4731.4415, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer as described under part 4731.4405, subpart 1, item C~~.~~; or

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

B. A licensee must mail required documents to the address under part 4731.0200, subpart 4.

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

A. subpart 2, item D, regarding the need to file an amendment to the license for medical use of radioactive materials under part 4731.4404;

B. subpart 3, item B;

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

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

E. subpart 4, item A, subitem (4), regarding additions to or changes in the areas of use identified in the application or license where radioactive material is used under part 4731.4432 or 4731.4434; and

F. part 4731.4410, item A.

[For text of subparts 6 and 7 see M.R.]

4731.4405 RADIATION PROTECTION PROGRAM.

Subpart 1. **Authority and responsibilities.**

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

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

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

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

[For text of subpart 2 see M.R.]

4731.4408 WRITTEN DIRECTIVES.

[For text of subpart 1 see M.R.]

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

A. for an administration of quantities greater than 30 microcuries (1.11 MBq) of sodium iodide I-131, the dosage;

B. for an administration of a therapeutic dosage of an unsealed radioactive material other than sodium iodide I-131, the radioactive drug, dosage, and route of administration;

C. for gamma stereotactic radiosurgery, the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

D. for teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;

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

F. for permanent implant brachytherapy:

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

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

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

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

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

Subp. 3. **Revisions.**

A. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

B. If, because of a patient's condition, a delay to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

[For text of subpart 4 see M.R.]

4731.4409 PROCEDURES FOR ADMINISTRATIONS REQUIRING WRITTEN DIRECTIVE.

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

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

(1) verifying the identity of the patient or human research subject;

(2) verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

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

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

(5) Determining if a medical event, as defined in 4731.4525, has occurred; and

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

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

4731.4411 RADIATION SAFETY OFFICER AND ASSOCIATE RADIATION SAFETY OFFICER TRAINING.

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

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

~~(1) has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in this item and subpart 2 and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and~~

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

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

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

i. radiation physics and instrumentation;

ii. radiation protection;

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

iv. radiation biology; and

v. radiation dosimetry;

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

i. shipping, receiving, and performing related radiation surveys;

ii. using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

iii. securing and controlling radioactive material;

iv. using administrative controls to avoid mistakes in the administration of radioactive material;

v. using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

vi. using emergency procedures to control radioactive material; and

vii. disposing of radioactive material;

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

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

C. (1) is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC or an agreement state under part 4731.4412, ~~and~~ has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking approval of the individual as radiation safety officer or associate radiation safety officer, and~~:~~

~~(1) has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in this item and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and~~

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

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

~~(1) has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in this item and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and~~

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

E. has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license, and has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, associate radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval.

[For text of subpart 2 see M.R.]

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

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

(2) has training for the types of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the types of use for which the individual is seeking authorization; or

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:

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

(b) has completed an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the types of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1,000,000 electron volts) and brachytherapy services and must include:

i. performing sealed source leak tests and inventories;

ii. performing decay corrections;

iii. performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

iv. conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable;

(2) has obtained written attestation that the individual has satisfactorily completed the requirements in this item and is able to independently fulfill the radiation safety-related duties ~~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

(3) has training for the types of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the types of use for which the individual is seeking authorization.

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

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

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

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

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

C. pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery.

4731.4413 AUTHORIZED NUCLEAR PHARMACIST TRAINING.

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

A. is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit Web page ~~and has obtained written attestation signed by a preceptor authorized nuclear pharmacist, 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 nuclear pharmacist~~; or

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

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

i. radiation physics and instrumentation;

ii. radiation protection;

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

iv. chemistry of radioactive material for medical use; and

v. radiation biology; and

(b) supervised practical experience in a nuclear pharmacy involving:

i. shipping, receiving, and performing related radiation surveys;

ii. using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

iii. calculating, assaying, and safely preparing dosages for patients or human research subjects;

iv. using administrative controls to avoid medical events in the administration of radioactive material; and

v. using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) has obtained written attestation signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in this item and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

[For text of subpart 2 see M.R.]

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

A. An individual identified as a radiation safety officer, a teletherapy or medical physicist, or a nuclear pharmacist on a license issued by the NRC or an agreement state; a permit issued by an NRC or agreement state broad scope licensee; a master material license permit; or a permit issued by a master material license permittee of broad scope before ~~October 24, 2002~~ January 14, 2019, need not comply with the training requirements under parts 4731.4411, 4731.4412, or 4731.4413, respectively, except a radiation safety officer or authorized medical physicist identified in this item must meet the training requirements in 4731.4411 subpart 1, item A, subitem (2) or 4731.4412 subpart 1, item A, subitem (2), as appropriate, for any material or uses for which they were not authorized prior to this date.

B. An individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear

Medicine before October 24, 2005, need not comply with the training requirements of 4731.4411 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed before October 24, 2005.

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

~~B. An individual identified as a radiation safety officer, an authorized medical physicist, or an authorized nuclear pharmacist on an NRC or agreement state license; a permit issued by an NRC or agreement state broad scope licensee; an NRC or agreement state master material license permit; or a permit issued by a master material license permittee of broad scope between October 24, 2002, and April 29, 2005, need not comply with the training requirements of part 4731.4411, 4731.4412, or 4731.4413.~~

~~C.~~D. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or an agreement state; a permit issued by an NRC master material licensee; a permit issued by an NRC or agreement state broad scope licensee; or a permit issued by an NRC master material license broad scope permittee before ~~October 24, 2002~~ January 14, 2019, who perform only those medical uses for which they were authorized on that date, need not comply with the training requirements of parts 4731.4432 to 4731.4479.

~~D. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the commissioner, the NRC, or an agreement state; a permit issued by an NRC master material licensee; a permit issued by an NRC or agreement state broad scope licensee; or a permit issued by an NRC master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002, and April 29, 2005, need not comply with the training requirements of parts 4731.4432 to 4731.4479.~~

E. Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the NRC or an agreement state; a permit issued by an NRC master material licensee; a permit issued by an NRC or agreement state broad scope licensee; or a permit issued by an NRC master material license broad scope permittee before October 24, 2005, need not comply with the training requirements of parts 4731.4432 to 4731.4479 for those materials and uses that these individuals performed before October 24, 2005, as follows:

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

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

(3) For uses authorized under 4731.4450 or 4731.4463, a physician who was certified before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal

College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

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

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

4731.4423 AUTHORIZATION FOR CHECK, CALIBRATION, TRANSMISSION, AND REFERENCE USE.

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

A. sealed sources that do not exceed 30 millicuries (1.11 GBq) each and that are manufactured and distributed by a person licensed under part 4731.3400 or equivalent requirements of the NRC or an agreement state;

B. sealed sources that do not exceed 30 millicuries (1.11 GBq) each and that are redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under part 4731.3400, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

C. any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 millicuries (0.56 GBq);

D. any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 200 microcuries (7.4 MBq) or 1,000 times the quantities in part 4731.3160; and

E. technetium-99m in amounts as needed.

Subpart 2. **Restriction of use.** Byproduct material in sealed sources authorized by this provision must not be:

A. Used for medical use as defined in 4731.0100 except in accordance with the requirements in 4731.4460; or

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

Subpart 3. **Listing on license.** A licensee using calibration, transmission, and reference sources in accordance with the requirements in subparts 1 or 2 of this part need not list these sources on a specific medical use license.

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. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit Web page ~~and has obtained written attestation, signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, 4731.4436, or 4731.4443, or equivalent requirements of the NRC or an agreement state, that the individual has satisfactorily completed the requirements in subpart 2 and has achieved a~~

~~level of competency sufficient to function independently as an authorized user for the medical uses authorized under part 4731.4432~~;

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

C. has:

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

(a) classroom and laboratory training in the following areas:

i. radiation physics and instrumentation;

ii. radiation protection;

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

iv. chemistry of radioactive material for medical use; and

v. radiation biology; and

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

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

ii. performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

iii. calculating, measuring, and safely preparing patient or human research subject dosages;

iv. using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

v. using procedures to safely contain spilled radioactive material and using proper decontamination procedures; and

vi. administering dosages of radioactive drugs to patients or human research subjects; and

(2) obtained written attestation~~, signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, 4731.4436, or 4731.4443, or equivalent requirements of the NRC or an agreement state,~~ that the individual has satisfactorily completed the requirements in this item and <u>is able to</u> ~~has achieved a level of competency sufficient to function~~ independently <u>fulfill the radiation safety-related duties</u> as an authorized user for the medical uses authorized under part 4731.4432. <u>The attestation must be obtained from either:</u>

<u>(a) A preceptor authorized user who meets the requirements in part 4731.4414, 4731.4433, 4731.4436, or 4731.4443, or equivalent requirements of the NRC or an agreement state; or</u>

<u>(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in part 4731.4414, 4731.4433, 4731.4436, or 4731.4443, or equivalent requirements of the NRC or an agreement state, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review</u>

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

[For text of subpart 2 see M.R.]

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

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

(1) more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m); ~~or~~

(2) more than 0.02 microcuries of strontium-82 per millicurie of rubidium-82 chloride injection (0.02 kBq of strontium-82 per MBq of rubidium-82 chloride); or

(3) more than 0.2 microcuries of strontium-85 per millicurie of rubidium-82 chloride injection (0.2 kBq of strontium-85 per MBq of rubidium-82).

B. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical must measure the molybdenum-99 concentration in each eluate from ~~of the first eluate after receipt of~~ a generator to demonstrate compliance with item A.

C. A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical must, before the first patient use of the day, measure the concentration of strontium-82 and strontium-85 radionuclides to demonstrate compliance with item A.

D. If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee must retain a record of each measurement according to part 4731.4509.

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

4731.4436 IMAGING AND LOCALIZATION STUDIES; TRAINING.

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

A. ~~The physician must:~~

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

~~(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;~~

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

~~(c) the requirements in part 4731.4414; or~~

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

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

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

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

(a) classroom and laboratory training in the following areas:

i. radiation physics and instrumentation;

ii. radiation protection;

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

iv. chemistry of radioactive material for medical use; and

v. radiation biology; and

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

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

ii. performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

iii. calculating, measuring, and safely preparing patient or human research subject dosages;

iv. using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

v. using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

vi. administering dosages of radioactive drugs to patients or human research subjects; and

vii. eluting generator systems, appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) obtained written attestation that the individual physician has satisfactorily completed the requirements in this item and is able to independently fulfill the radiation safety-related duties ~~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 obtained from either ~~signed by a preceptor authorized user who meets~~:

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

(b) ~~the requirements in subitem (1), unit (b), subunit vii, and part 4731.4443;~~ A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this part, part 4731.4414, or in subitem 1, unit (b), subunit vii and part 4731.4443, or equivalent requirements of the NRC or an agreement state, and concurs with the attestation provided

by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in this item.

~~(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 under subpart 1, item A, 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.

4731.4440 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE REQUIRED.

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

A. obtained from a manufacturer or preparer licensed under part 4731.3395 or equivalent requirements of the NRC or an agreement state or a PET radioactive drug producer licensed according to part 4731.3065, subpart 7, or equivalent requirements of the NRC or an agreement state;

B. excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and meets the requirements under part 4731.4436 or 4731.4443, or an individual under the supervision of either, as specified under part 4731.4407;

C. obtained from and prepared by a commissioner, NRC, or agreement state licensee for use in research according to an investigational new drug protocol accepted by the Food and Drug Administration; or

D. prepared by the licensee for use in research according to an investigational new drug protocol accepted by the Food and Drug Administration.

4731.4443 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE REQUIRED; TRAINING.

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

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

(a) classroom and laboratory training in:

i. radiation physics and instrumentation;

ii. radiation protection;

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

iv. chemistry of radioactive material for medical use; and

v. radiation biology; and

(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:

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

ii. performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

iii. calculating, measuring, and safely preparing patient or human research subject dosages;

iv. using administrative controls to prevent a medical event involving the use of radioactive material;

v. using procedures to safely contain spilled radioactive material and using proper decontamination procedures; and

vi. administering dosages of radioactive drugs to patients or human research subjects from the three categories in this paragraph. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under part 4731.4404. This work experience must involve ~~involving~~ a minimum of three cases in each of the following categories for which the individual is requesting authorized user status: 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; oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide (I-131) (experience with at least three cases also satisfies the requirement of oral administration of less than or equal to 33 millicuries of I-131); parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics ~~emitter~~, alpha radiation characteristics, or a photon~~-emitting radionuclide with a photon~~ energy of 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;~~ and

(2) obtained written attestation that the individual has satisfactorily completed the requirements in this item and is able to independently fulfill the radiation safety-related duties ~~has achieved a level of competency sufficient to function independently~~ as an authorized user for the medical uses authorized under part 4731.4440 for which the individual is requesting authorized user status. The attestation must be obtained from either:

(a)~~. The written attestation must be signed by a~~ 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~~ and has 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~~.~~; or

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

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

A. successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in subpart 1, item B, subitem (1), units (a) and (b), subunits i to v. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the ~~Committee on Postgraduate Training~~ Council on Postdoctoral Training of the American Osteopathic Association; and

B. pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required.

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). The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit Web page~~, 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~~;

B. is an authorized user under part 4731.4443, for 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) under part 4731.4443 or 4731.4445, or under equivalent requirements of the NRC or an agreement state; or

C. has:

(1) successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide (I-131) for procedures requiring a written directive. The training must include:

(a) radiation physics and instrumentation;

(b) radiation protection;

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

(d) chemistry of radioactive material for medical use; and

(e) radiation biology;

(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:

(a) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for the proper operation of survey meters;

(c) calculating, measuring, and safely preparing patient or human research subject dosages;

(d) using administrative controls to prevent a medical event involving the use of radioactive materials;

(e) using procedures to safely contain spilled radioactive material and using proper decontamination procedures; and

(f) administering dosages to patients or human research subjects that include at least three cases involving the oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide I-131; and

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

(a)~~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 and has ~~. 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; or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this part, 4731.4414, 4731.4443, or 4731.4731.4445, or equivalent requirements of the NRC or an agreement state, has 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, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subitems (1) and (2).

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). The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit Web page~~, 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~~;

B. is an authorized user ~~under part 4731.4443, subpart 1, item A; 4731.4443, subpart 1, item B,~~ for 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; or equivalent requirements of the NRC or an agreement state; or

C. has:

(1) successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of I-131 for procedures requiring a written directive. The training must include:

(a) radiation physics and instrumentation;

(b) radiation protection;

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

(d) chemistry of radioactive materials for medical use; and

(e) radiation biology;

(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:

(a) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) calculating, measuring, and safely preparing patient or human research subject dosages;

(d) using administrative controls to prevent a medical event involving the use of radioactive material;

(e) using procedures to safely contain spilled radioactive material and using proper decontamination procedures; and

(f) administering dosages to patients or human research subjects, including at least three cases involving the oral administration of greater than 33 millicuries (1.22 GBq) of I-131; and

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

(a)~~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, and has~~. 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 (1.22 GBq) ~~under~~ as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi; or

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an 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, has experience in the oral administration of I-131 in quantities greater than 33 millicuries (1.22 GBq) as specified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subitems (1) and (2).

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

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

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

(2) an authorized user under part 4731.4458 or 4731.4479 or equivalent requirements of the NRC or an agreement state and meets the requirements in item B; or

(3) certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state under part 4731.4458 or 4731.4479 and meets the requirements in item B.

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

(1) successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or a photon-energy

of less than 150 kilo electron volts for which a written directive is required ~~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~~. The training must include:

(a) radiation physics and instrumentation;

(b) radiation protection;

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

(d) chemistry of radioactive material for medical use; and

(e) radiation biology;

(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 of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or a photon-energy of less than 150 kilo electron volts for which a written directive is required ~~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 this part or part 4731.4443, or equivalent requirements of the NRC or agreement state, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. ~~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:

(a) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) calculating, measuring, and safely preparing patient or human research subject dosages;

(d) using administrative controls to prevent a medical event involving the use of unsealed radioactive materials;

(e) using procedures to contain spilled radioactive materials safely and using proper decontamination procedures; and

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

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

(a) ~~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 this part or part 4731.4443, or equivalent requirements of the NRC or agreement state, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or ~~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.~~

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is 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, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subitems (1) and (2).

4731.4450 USE OF BRACHYTHERAPY SOURCES.

A licensee must use only brachytherapy sources ~~for therapeutic medical uses~~:

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

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

4731.4456 DECAY OF STRONTIUM-90 SOURCES FOR OPHTHALMIC TREATMENTS.

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

(1) An authorized medical physicist; or

(2) An individual who:

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

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

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

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

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

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

(c) has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(d) Has documented training in:

i. The creation, modification, and completion of written directives;

ii. Procedures for administrations requiring a written directive; and

iii. Performing the calibration measurements of brachytherapy sources as detailed in 4731.4455.

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

(1) ~~Only an authorized medical physicist shall~~ calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under part 4731.4455~~.~~; and

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

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

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. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit Web page ~~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:

(a) 200 hours of classroom and laboratory training in:

i. radiation physics and instrumentation;

ii. radiation protection;

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

iv. radiation biology; and

(b) 500 hours of 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 at a medical institution authorized to use radioactive materials under 4731.4450, involving:

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

ii. checking survey meters for proper operation;

iii. preparing, implanting, and removing brachytherapy sources;

iv. maintaining running inventories of material on hand;

v. using administrative controls to prevent a medical event involving the use of radioactive material; and

vi. using emergency procedures to control radioactive material;

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

(3) obtained written attestation~~, signed by a preceptor authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state,~~ that the individual has satisfactorily completed the requirements of this item and is able to ~~has achieved a level of competency sufficient to function~~ independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under part 4731.4450. The attestation must be obtained from either:

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

(b) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this part, part 4731.4414, or equivalent requirements of the NRC or an agreement state, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subitems (1) and (2).

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

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

B. pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy.

4731.4459 OPHTHALMIC USE OF STRONTIUM-90; TRAINING.

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

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

B. has:

(1) completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

(a) radiation physics and instrumentation;

(b) radiation protection;

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

(d) radiation biology;

(2) had supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. The supervised clinical training must involve:

(a) examination of each individual to be treated;

(b) calculation of the dose to be administered;

(c) administration of the dose; and

(d) follow up and review of each individual's case history; and

(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 subitems (1) and (2) ~~this item~~ and is able to ~~has achieved a level of competency sufficient to function~~ independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

4731.4460 USE OF SEALED SOURCES AND MEDICAL DEVICES FOR DIAGNOSIS.

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

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

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

4731.4461 USE OF SEALED SOURCES FOR DIAGNOSIS; TRAINING.

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

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

B. Is an authorized user for uses listed in 4731.4434 or equivalent requirements of the NRC or an agreement state; or

C. ~~B.~~ has~~:~~

~~(1)~~ completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

(1)~~(a)~~ radiation physics and instrumentation;

(2)~~(b)~~ radiation protection;

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

(4)~~(d)~~ radiation biology; and

D.~~(2)~~ completed training in the use of the device for the uses requested.

4731.4463 USE OF A SEALED SOURCE; REMOTE AFTERLOADER UNIT, TELETHERAPY UNIT, OR GAMMA STEREOTACTIC RADIOSURGERY UNIT.

A. A licensee must only use sealed sources:

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

~~B.~~ (2) in research~~,~~ involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units according to an active investigational device exemption application accepted by the U.S. Food and Drug Administration, provided the requirements of 4731.4410, item A, are met.

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

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

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

4731.4466 REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS; SAFETY PROCEDURES AND INSTRUCTIONS.

A. This part applies to remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

B. A licensee must:

(1) secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with the source;

(3) prevent dual operation of more than one radiation-producing device in a treatment room, if applicable; and

(4) develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source in the shielded position or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

(a) instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(b) the process for restricting access to and posting the treatment area to minimize the risk of inadvertent exposure; and

(c) the names and telephone numbers of the authorized user, authorized medical physicist, and radiation safety officer to be contacted if the unit or console operates abnormally.

C. A copy of the procedures required under item B, subitem (4), must be physically located at the unit console.

D. A licensee must post instructions at the unit console to inform the operator of:

(1) the location of the procedures required under item B, subitem (4); and

(2) the names and telephone numbers of the authorized user, authorized medical physicist, and radiation safety officer to be contacted if the unit or console operates abnormally.

E. A licensee must:

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

(2) provide operational and safety instructions, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties. The instructions must include instruction in:

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

(b) the operating procedures of the unit.

F. A licensee must ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

G. A licensee must retain a record of individuals receiving instruction required under item E according to part 4731.4510.

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

4731.4477 TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS; FULL-INSPECTION SERVICING~~FIVE-YEAR INSPECTION~~.

Subpart 1. **Inspection and servicing required.** A licensee must have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement to assure proper functioning of the source exposure mechanism and other safety components. ~~or at intervals~~ The interval between each full-inspection servicing must not ~~to~~ exceed five years for each teletherapy unit, and must not exceed seven years for each gamma stereotactic radiosurgery unit~~, whichever comes first, to ensure proper functioning of the source exposure mechanism~~.

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

[For text of subpart 3 see M.R.]

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, and meets the requirements in item B, subitem (4). The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Use Licensee Toolkit Web page~~, 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:

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

i. radiation physics and instrumentation;

ii. radiation protection;

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

iv. radiation biology; and

(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 that is authorized to use radioactive material in 4731.4463, involving:

i. reviewing full calibration measurements and periodic spot checks;

ii. preparing treatment plans and calculating treatment doses and times;

iii. using administrative controls to prevent a medical event involving the use of radioactive materials;

iv. implementing emergency procedures to be followed in the event of an abnormal operation of the medical unit or console;

v. checking and using survey meters; and

vi. selecting the proper dose and how it is to be administered;

(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 Postdoctoral Training~~ Council on 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~~ subitems (1), (2), and (4), and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties 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 obtained from either:

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

(4) received training in device operation, safety procedures, and clinical use for the types of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the types of use for which the individual is seeking authorization.

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

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

B. pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy.

[For text of subpart 2 see M.R.]

4731.4500 RADIATION PROTECTION PROGRAM RECORDS.

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

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

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

C. for each associate radiation safety officer appointed under 4731.4405, subpart 1, item B, the licensee shall retain, for 5 years after the associate radiation safety officer is removed from the license, a copy of the written document appointing the associate radiation safety officer signed by the licensee's management.

Subp. 2. **Protection program changes.** A licensee must retain a record of each radiation protection program change made under part 4731.4405, subpart 2, for five years. The record must include a copy of the old and new procedures, the effective date of the change, and the signature of the licensee's management that reviewed and approved the change.

4731.4510 SAFETY INSTRUCTION RECORDS.

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

A. a list of the topics covered;

B. the date of the instruction;

C. the names of the attendees; and

D. the names of the individuals who provided the instruction.

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

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

A. the inspector's radioactive material license number;

B. the date of inspection;

C. the manufacturer's name, model number, and serial number for both the treatment unit and source;

D. a list of components inspected and serviced, and the type of service; and

E. the signature of the inspector.

4731.4525 MEDICAL EVENT; REPORT AND NOTIFICATION.

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

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

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

~~(1)~~(a) the total dose delivered differs from the prescribed dose by 20 percent or more;

~~(2)~~(b) the total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

~~(3)~~(c) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more;

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

~~(1)~~(a) an administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;

~~(2)~~(b) an administration of a radioactive drug containing radioactive material by the wrong route of administration;

~~(3)~~(c) an administration of a dose or dosage to the wrong individual or human research subject;

~~(4)~~(d) an administration of a dose or dosage delivered by the wrong mode of treatment; or

~~(5)~~(e) a leaking sealed source; or

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

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

(b) 50 percent or more ~~of~~ the ~~dose~~ expected dose to that site from the procedure if the administration ~~defined in~~ had been given in accordance with the written directive prepared or revised before administration~~, excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site~~.

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

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

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

(3) An administration that includes any of the following:

(a) The wrong radionuclide;

(b) The wrong individual or human research subject;

(c) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

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

[For text of subpart 2 to 6 see M.R.]

Subpart 7. **Individual identification.** A licensee must:

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

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

(2) ~~the social security number or other identification number, if one has been assigned,~~ Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and

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

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

[For text of subpart 1 to 5 see M.R.]

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

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

(1) the name of the pregnant individual ~~woman~~ or the nursing child who is the subject of the event; and

(2) ~~the Social Security number or other identification number, if one has been assigned, of the pregnant woman or the nursing child~~ Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and

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

4731.4528 REPORT AND NOTIFICATION FOR AN ELUATE EXCEEDING PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82, AND STRONTIUM-85 CONCENTRATIONS.

Subpart 1. **Telephone notification.** The licensee must notify, by telephone, the commissioner and the distributor of the generator, within seven days after discovery, that an eluate exceeded the permissible concentration listed in 4731.4435, item A, at the time of generator elution. The telephone report to the commissioner must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

Subpart 2. **Written Report.** The licensee must submit a written report to the commissioner within 30 days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by subpart 1.

4731.6180 PERSONNEL MONITORING.

Subpart 1. **Irradiator Operators.** Irradiator operators must wear a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~ while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter must be capable of detecting ~~processor must be accredited for~~ high energy photons in the normal and accident dose ranges ~~under part 4731.2200, subpart 3~~. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced ~~processed~~ at least monthly and other personnel dosimeters that require replacement must be replaced ~~processed~~ at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

[For text of subpart 2 see M.R.]

4731.7220 PERSONNEL MONITORING.

A. A licensee may not permit an individual to act as a logging supervisor or logging assistant unless the individual wears a personnel dosimeter~~,~~ at all times during the handling of licensed radioactive materials~~, a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and other personnel dosimeters that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent. ~~After replacement, each personnel dosimeter must be promptly processed.~~

B. A licensee must provide bioassay services to individuals using licensed materials in subsurface tracer studies if required by the license.

C. A licensee must retain records of personnel dosimeters required under item A and bioassay results for inspection until the commissioner authorizes disposition of the records.

4731.8015 ACCESS AUTHORIZATION PROGRAM REQUIREMENTS.

[For text of subpart 1 see M.R.]

Subp. 2. **Reviewing officials.**

A. Reviewing officials are the only individuals authorized to make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.

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

C. Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive materials or access to safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling.

D. Reviewing officials cannot approve other individuals to act as reviewing officials.

E. A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(1) the individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(2) the individual is subject to a category listed in part 4731.8030, subpart 1.

[For text of subpart 3 to 8 see M.R.]

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

[For text of subpart 1 to 2 see M.R.]

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

A. For the purpose of complying with parts 4731.8010 to 4731.8040, licensees must submit to the U.S. Nuclear Regulatory Commission, Director, Division of Physical and Cyber Security Policy ~~Facilities and Security~~, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-8B20 ~~TWB-05 B32M~~, Rockville, MD 20852~~-2738~~, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by emailing MAILSVS.Resource@nrc.gov. ~~writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling (630) 829-9565, or by e-mail to FORMS.Resource@nrc.gov.~~ Guidance on submitting electronic fingerprints can be found at https://www.nrc.gov/security/chp.html ~~http://www.nrc.gov/site-help/e-submittals.html~~.

B. Fees for the processing of fingerprint checks are due upon application. Licensees must submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." For guidance on

making electronic payments, contact the ~~Security Branch,~~ Division of Physical ~~Facilities~~ and Cyber Security Policy by emailing Crimhist.Resource@nrc.gov ~~at (301) 492-3531~~. Combined payment for multiple applications is acceptable. The NRC ~~commission~~ publishes the amount of the fingerprint check application fee on the NRC public website. To find the current fee amount, go to the Licensee Criminal History Records Checks & Firearms Background Check information page at https://www.nrc.gov/security/chp.html and see the link for "How do I determine how much to pay for the request?" ~~Electronic Submittals page at http://www.nrc.gov/site-help/e-submittals.html and see the link for the Criminal History Program under Electronic Submission Systems.~~

C. The commission must forward to the submitting licensee all data received from the FBI as a result of the licensee's applications for criminal history records checks.

4731.8055 GENERAL SECURITY PROGRAM REQUIREMENTS.

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

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

A. Licensees authorized to possess category 1 or category 2 quantities of radioactive material must limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

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

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

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

(2) if the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination must be conducted by the reviewing official and must include the background investigation elements contained in part 4731.8020, subpart 1, item A, subitems (2) to (6), and item B.

D. Licensees need not subject the following individuals to the background investigation elements for protection of information:

(1) the categories of individuals listed in part 4731.8030, subpart 1, items A to M; or

(2) security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in part 4731.8020, subpart 1, item A, subitems (2) to (6), and item B, has been provided by the security service provider.

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

F. Licensees must maintain a list of persons currently approved for access to the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access, or no longer meets the access authorization requirements for access to the information, the licensee must remove the person from the approved list as soon as possible, but no later than seven working days, and take

prompt measures to ensure that the individual is unable to obtain the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access.

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

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

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

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

4731.8115 ADVANCE NOTIFICATION OF SHIPMENT OF CATEGORY 1 QUANTITIES OF RADIOACTIVE MATERIAL.

[For text of subpart 1 see M.R.]

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

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

B. A notification delivered by mail must be postmarked at least seven days before transport of the shipment commences at the shipping facility.

C. A notification delivered by any means other than mail must reach the commissioner at least four days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least four days before transport of a shipment within or through the state.

[For text of subpart 3 to 7 see M.R.]