

641—41.2(136C) Use of radionuclides in the healing arts.**41.2(1) Purpose and scope.**

a. This rule establishes requirements and provisions for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this rule are in addition to, and not in substitution for, the applicable portions of 641—Chapters 38 to 40. The requirements and provisions of these rules apply to applicants and licensees subject to this rule unless specifically exempted.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 22, 2020.

41.2(2) Definitions. For the purpose of this chapter, the definitions of 641—Chapters 38 to 40 may also apply. As used in 41.2(136C), the following definitions apply:

“*Area of use*” means a portion of a physical structure that has been set aside for the purpose of receiving, using, or storing radioactive material.

“*Associate radiation safety officer*” means an individual who:

a. Meets the requirements of 41.2(65) and 41.2(77); and
 b. Is currently identified as an associate radiation safety officer for the types of use of byproduct material for which the duties and tasks by the radiation safety officer on:

1. A specific medical use license issued by the NRC or an agreement state; or
2. A medical use permit issued by an NRC master material licensee.

“*Authorized medical physicist*” means an individual who:

- a. Meets the requirements of 41.2(74) and 41.2(77); or
- b. Is identified as an authorized medical physicist or teletherapy physicist on:
 1. A specific medical use license issued by this agency, the NRC, or an agreement state;
 2. A medical use permit issued by an NRC master material licensee;
 3. A permit issued by an NRC or agreement state broad scope medical use licensee; or
 4. A permit issued by an NRC master material license broad scope medical use permittee.

“*Authorized nuclear pharmacist*” means a pharmacist who:

a. Has met the appropriate requirements of 41.2(77) and 41.2(78), or before May 3, 2006, meets the requirements in 10 CFR 35.980(a) and 10 CFR 35.59; or

b. Is identified as an authorized nuclear pharmacist on:

1. A specific license issued by the agency, NRC or agreement state that authorizes medical use or the practice of nuclear pharmacy;
2. A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

3. A permit issued by the NRC or agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

4. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

c. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

d. Is designated as an authorized nuclear pharmacist in accordance with 641—39.4(29) “j”(2)“3.”

“*Authorized user*” means a physician, dentist, or podiatrist who has met the appropriate requirements of 41.2(67) “a,” 41.2(68) “a,” 41.2(69) “a,” 41.2(70) “a,” 41.2(72) “a,” 41.2(73) “a,” 41.2(81) “a,” or 41.2(82) “a,” or before May 3, 2006, meets the requirements in 10 CFR 35.910(a), 35.920(a), 35.930(c), 35.940(a), 35.950(a), or 35.960(a) and 10 CFR 35.59; or who is identified on:

1. A current Iowa, NRC, or agreement state license that authorizes the medical use of radioactive material;

2. A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

3. A permit issued by an NRC, agreement state, or Iowa-specific licensee of broad scope that is authorized to permit medical use of radioactive material; or

4. A permit issued by an NRC master material license broad scope permittee that is authorized to permit medical use of radioactive material.

“Dedicated check source” means a radioactive source that is used to ensure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

“Management” means the chief executive officer or that individual’s designee.

“Medical institution” means an organization in which several medical disciplines are practiced.

“Mobile nuclear medicine service” means the transportation and medical use of radioactive material.

“Ophthalmic physicist” means an individual who:

- a. Meets the requirements of 41.2(85)“a”(2) and 41.2(77); and
- b. Is identified as an ophthalmic physicist on a:
 1. Specific medical use license issued by an NRC or an agreement state;
 2. Permit issued by an 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.

“Output” means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

“Pharmacist” means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

“Radiation safety officer” means an individual who, in addition to the definition in 641—38.2(136C):

- a. Meets the requirements of 41.2(65) and 41.2(77); and
- b. Is identified as a radiation safety officer on:
 1. A specific medical use license issued by the NRC or an agreement state; or
 2. A medical use permit issued by an NRC master material licensee.

“Stereotactic radiosurgery” means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

“Teletherapy” means therapeutic irradiation in which the source of radiation is at a distance from the body.

“Unit dosage” means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

“Visiting authorized user” means an authorized user who is not identified on the license of the licensee being visited.

41.2(3) License required.

a. No person shall manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to these rules.

b. Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with these rules under the supervision of an authorized user as provided in 41.2(11).

c. An individual may prepare unsealed radioactive material for medical use in accordance with these rules under the supervision of an authorized nuclear pharmacist or authorized user as provided in 41.2(11) unless prohibited by license condition.

d. A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by another federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an Institutional Review Board in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

Nothing in this subrule relieves the licensee from complying with applicable FDA, federal, and other state requirements governing radioactive drugs or devices.

e. An applicant that satisfies the requirements of 641—paragraph 39.4(28) “*b*” may apply for a Type A specific license of broad scope.

41.2(4) License amendments.

a. A licensee shall apply for and receive a license amendment:

(1) Before using byproduct material for a method or type of medical use not permitted by the license issued under this rule;

(2) Before permitting anyone to work as an authorized user or authorized nuclear pharmacist under the license unless the individual meets “visiting” status in accordance with 41.2(12);

(3) Before changing a radiation safety officer;

(4) Before permitting 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;

(5) Before receiving byproduct material in excess of the amount authorized on the license;

(6) Before adding to or changing the address or addresses of use identified in the application or on the license; and

(7) Before it 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.

b. License amendment exemptions regarding Type A specific licenses of broad scope. A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(1) The provision of 41.2(4) “*a*”(2);

(2) The provisions of 41.2(4) “*a*”(6) regarding additions to or changes in the areas of use only at the addresses specified in the license.

41.2(5) Notifications.

a. A licensee shall notify the agency no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, a radiation safety officer, an associate radiation safety officer, an authorized medical physicist, or an ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

(2) The licensee permits an individual qualified to be a radiation safety officer under 41.2(65) and 41.2(77) to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with 41.2(10) “*c*”;

(3) The licensee’s mailing address changes;

(4) The licensee’s name changes but the name change does not constitute a transfer of control of the license as described in 641—paragraph 39.4(32) “*b*”; or

(5) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used.

b. Notifications requiring agency approval prior to implementation for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units include:

(1) Revisions to procedures required by 41.2(52), 41.2(59) “*a*,” 41.2(59) “*b*,” and 41.2(59) “*c*” as applicable, where such revision reduces radiation safety;

(2) Changes that could impact radiation levels in adjacent spaces, such as shielding or location of device.

c. The licensee shall mail the documents required in this subrule to the agency in accordance with 641—38.7(136C).

d. Notification exemptions regarding Type A specific licenses of broad scope. A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(1) The provisions of 41.2(5) “*a*”(1) for an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, or an ophthalmic physicist.

(2) The provisions of 41.2(5) “*a*”(5).

41.2(6) Maintenance of records.

a. Each record required by this rule must be legible throughout the retention period specified by each subrule. The record may be original or reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period.

b. The record may also be stored on electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures.

c. The licensee shall maintain adequate safeguards against tampering with and loss of records specified in 41.2(6)“*a*” and “*b*.”

41.2(7) ALARA program.

a. Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with 641—subrule 40.1(3).

b. To satisfy the requirement of 41.2(7)“*a*”:

(1) The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these rules or the radiation safety committee; or

(2) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.

c. The ALARA program shall include an annual review by the radiation safety committee for licensees that are medical institutions, or management and the radiation safety officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

d. The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

(1) A commitment by management to keep occupational doses as low as reasonably achievable;

(2) A requirement that the radiation safety officer brief management once each year on the radiation safety program;

(3) Personnel exposure investigational levels as established in accordance with 41.2(9)“*b*”(8) that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure; and

(4) Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the radiation safety officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

41.2(8) Radiation safety officer.

a. A licensee shall appoint a radiation safety officer responsible for implementing the radiation safety program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee’s radioactive material program.

b. The radiation safety officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Implement written policy and procedures for:

1. Authorizing the purchase of radioactive material;

2. Receiving and opening packages of radioactive material;

3. Storing radioactive material;

4. Keeping an inventory record of radioactive material;

5. Using radioactive material safely;
 6. Taking emergency action if control of radioactive material is lost;
 7. Performing periodic radiation surveys;
 8. Performing checks and calibrations of survey instruments and other safety equipment;
 9. Disposing of radioactive material;
 10. Training personnel who work in or frequent areas where radioactive material is used or stored;
- and
11. Keeping a copy of all records and reports required by the agency rules, a copy of these rules, a copy of each licensing request and license and amendments, and the written policy and procedures required by the rules; and

(3) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the agency for licensing action; or

(4) For medical use sited at a medical institution, assist the radiation safety committee in the performance of its duties.

41.2(9) Radiation safety committee. Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.

a. The committee shall meet the following administrative requirements:

(1) Membership must consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. Other members may be included as the licensee deems appropriate.

(2) The committee shall meet at least once each calendar quarter.

(3) Reserved.

(4) The minutes of each radiation safety committee meeting shall include:

1. The date of the meeting;

2. Members present;

3. Members absent;

4. Summary of deliberations and discussions;

5. Recommended actions and the numerical results of all ballots; and

6. Document any reviews required in 41.2(7) "c" and 41.2(9) "b."

(5) The committee shall provide each member with a copy of the meeting minutes and retain one copy until the agency authorizes its disposition.

b. To oversee the use of licensed material, the committee shall:

(1) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

(2) Review:

1. Review, on the basis of safety and with regard to the training and experience standards of this rule, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the radiation safety officer, or teletherapy physicist before submitting a license application or request for amendment or renewal;

2. Review on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist.

(3) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

(4) Review on the basis of safety, and approve with the advice and consent of the radiation safety officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the agency for licensing action;

(5) Review quarterly, with the assistance of the radiation safety officer, occupational radiation exposure records of all personnel working with radioactive material;

(6) Review quarterly, with the assistance of the radiation safety officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;

(7) Review annually, with the assistance of the radiation safety officer, the radioactive material program; and

(8) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the radiation safety officer.

41.2(10) Authority and responsibilities for the radiation protection program.

a. In addition to the radiation protection program requirements of 641—40.10(136C), a licensee's management shall approve in writing:

(1) Requests for a license application, renewal, or amendment before submittal to this agency;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment.

b. A licensee's management shall 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, shall ensure that the radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. 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 the 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 individual qualified to be a radiation safety officer under 41.2(65) or 41.2(75) to function as a temporary radiation safety officer to perform the functions of radiation safety officer, as provided in 41.2(10) "g," if the licensee takes the actions required in 41.2(10) "b," "e," "g," and "h" and notifies this agency in accordance with 41.2(5).

d. A licensee may simultaneously appoint more than one temporary radiation safety officer in accordance with 41.2(10) "c" if needed to ensure that the licensee has a temporary radiation safety officer who satisfies the requirements to be a radiation safety officer for each of the different types of byproduct material permitted on the license.

e. A licensee shall establish the authority, duties, and responsibilities of the radiation safety officer in writing.

f. Licensees that are authorized for two or more different types of uses of radioactive materials or two or more types of units under this rule shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license.

g. A licensee shall provide the radiation safety officer sufficient authority, organizational freedom, time, resources, and management prerogative to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective solutions;

(3) Verify implementation of corrective actions; and

(4) Stop unsafe operations.

h. A licensee shall retain a record of actions taken under 41.2(10) in accordance with 641—40.80(136C).

41.2(11) Supervision.

a. A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 41.2(3) shall, in addition to the requirements in 641—40.111(136C):

(1) Instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, rules of this chapter, and license conditions appropriate to that individual's use of radioactive material;

(2) Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;

(3) Require the authorized user to be immediately available to communicate with the supervised individual;

(4) Require the authorized user to be able to be physically present and available to the supervised individual on one hour's notice (the supervising authorized user need not be present for each use of radioactive material); and

(5) Require that only those individuals certified and issued a current permit to practice in accordance with 641—Chapter 42 as a nuclear medicine technologist or a radiation therapist, as applicable, or an Iowa-licensed physician and designated by the authorized user, shall be permitted to administer radionuclides (sealed sources only for radiation therapists) or radiation to patients or human research subjects. For a nuclear medicine technologist or a radiation therapist, the individual's permit to practice shall be made available at the individual's place of employment. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

b. A license shall require the supervised individual receiving, possessing, using or transferring radioactive material under 41.2(3) to:

(1) Follow the instructions of the supervising authorized user for the medical uses of byproduct material;

(2) Follow the written radiation protection and written directive procedures established by the radiation safety officer; and

(3) Comply with these rules and the license conditions with respect to the use of radioactive material.

c. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 41.2(3) "c," shall, in addition to the requirements in 641—40.111(136C):

(1) Instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee's written procedures for maintaining written directives, as appropriate to that individual's use of radioactive material;

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter and license conditions; and

(3) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.

d. A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

41.2(12) *Visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, and visiting authorized nuclear pharmacist.*

a. A licensee may permit any visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, or visiting authorized nuclear pharmacist to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

(1) The visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, or visiting authorized nuclear pharmacist has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;

(2) The licensee has a copy of the NRC or agreement state license that identifies the visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, or visiting authorized nuclear pharmacist by name for the medical use being utilized by the licensee; and

(3) Only those procedures for which the visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, or visiting authorized nuclear pharmacist is specifically authorized by an NRC or agreement state license are performed by that individual.

b. A licensee need not apply for a license amendment in order to permit a visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, or visiting authorized nuclear pharmacist to use licensed material as described in 41.2(12)“a.”

c. A licensee shall retain copies of the records specified in 41.2(12)“a” for five years from the date of the last visit.

41.2(13) *Mobile nuclear medicine service administrative requirements.*

a. The agency will only license mobile nuclear medicine services in accordance with this rule and other applicable requirements of these rules.

b. Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material and clearly delineates the authority of the licensee and client.

c. If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for ensuring that services are conducted in accordance with the rules in this chapter while the mobile nuclear medicine service is under the client’s direction.

d. A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client’s address of use.

e. Mobile nuclear medicine service licensees shall also perform the following:

(1) Check instruments used to measure the activity of unsealed radioactive material for proper function before use at each client’s address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this rule must include a constancy check;

(2) Check survey instruments for proper operation with a dedicated check source before use at each client’s address;

(3) Before leaving a client’s address, survey all areas of use to ensure compliance with the requirements of 641—Chapters 40 and 41.

41.2(14) *Records and reports of reportable medical events.*

a. When a reportable medical event, as defined in 641—38.2(136C), occurs, the licensee shall notify the agency by telephone. The licensee shall also notify the referring physician of the affected patient or human research subject and the patient or human research subject or a responsible relative or guardian, unless the referring physician agrees to inform the patient or human research subject or believes, based on medical judgment, that telling the patient or human research subject or the patient’s or human research subject’s responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the reportable medical event. If the referring physician, patient or human research subject, or the patient’s or human research subject’s responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or human research subject or the patient’s or human research subject’s responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient or human research subject because of this notification requirement including remedial care as a result of the reportable medical event because of any delay in notification.

b. Written reports.

(1) The licensee shall submit a written report to the agency within 15 days after discovery of the reportable medical event. The written report must include the licensee’s name, the prescribing physician’s name, a brief description of the event, why the event occurred, the effect on the patient or the human research subject, what improvements are needed to prevent recurrence, actions taken to prevent recurrence, whether the licensee notified the patient or the human research subject or the patient’s or the human research subject’s responsible relative or guardian (this individual will subsequently be referred to as “the patient or the human research subject”), and if not, why not, and if the patient or the human research subject was notified, what information was provided to that individual. The report must not include the patient’s or the human research subject’s name or other information that could lead to identification of the patient or the human research subject.

(2) If the patient or the human research subject was notified, the licensee shall also furnish, within 15 days after discovery of the reportable medical event, a written report to the patient or the human research subject and the referring physician by sending either:

1. A copy of the report that was submitted to the agency; or
2. A brief description of both the event and the consequences as they may affect the patient or the human research subject, provided a statement is included that the report submitted to the agency can be obtained from the licensee.

c. Reserved.

d. Each licensee shall retain a record of each reportable medical event for three years. The record shall contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient or human research subject, and the patient's or human research subject's referring physician, the patient's or human research subject's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient or human research subject, what improvements are needed to prevent recurrence, and the action taken, if any, to prevent recurrence.

e. Aside from the notification requirement, nothing in 41.2(14) "a" to 41.2(14) "d" shall affect any rights or duties of licensees and physicians in relation to each other, patients or human research subjects, or responsible relatives or guardians.

f. Report and notification of a dose to an embryo/fetus or a nursing child.

(1) A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding individual that:

1. Is greater than 5 rem (50 mSv) total effective dose equivalent; or
2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify this agency by telephone no later than the next calendar day after a dose to the embryo/fetus or nursing child that requires a report in 41.2(14) "f"(1) or (2).

(4) The licensee shall submit a written report to the agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 41.2(14) "f"(1) or (2).

1. The written report must include:

- The licensee's name;
- The name of the prescribing physician;
- A brief description of the event;
- Why the event occurred;
- The effect, if any, on the embryo/fetus or the nursing child;
- What actions, if any, have been taken or are planned to prevent recurrence; and
- Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under 41.2(14) "f"(1) or (2), unless the referring physician personally informs the licensee either that the physician will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in

notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) A licensee shall:

1. Annotate a copy of the report provided to the agency with the:
 - Name of the pregnant individual or the nursing child who is the subject of the event; and
 - Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and
2. 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.

41.2(15) Suppliers. A licensee shall use for medical use only:

- a. Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to these rules or the equivalent regulations of another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission; and
- b. Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Food and Drug Administration;
- c. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to these rules, or the equivalent regulations of another agreement state, a licensing state, or the U.S. Nuclear Regulatory Commission.

41.2(16) Quality control of imaging equipment. Each licensee shall establish written quality control procedures for all equipment used to obtain images from radionuclide studies. As a minimum, the procedures shall include quality control procedures recommended by equipment manufacturers or procedures which have been approved by the agency. The licensee shall conduct quality control procedures in accordance with written procedures.

41.2(17) Possession, use, calibration, and check of dose calibrators.

a. A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient or human research subject.

b. A licensee shall:

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on frequently used settings with a sealed source of not less than 10 microcuries (370 kBq) of radium-226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days;

(2) Test each dose calibrator for accuracy upon installation and at 12-month intervals thereafter by assaying at least two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at 3-month intervals thereafter over the range of use between 30 microcuries (1.1 megabecquerels) and the highest dosage that will be administered; and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

c. A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

d. A licensee shall also perform checks and tests required by 41.2(17) "b" following adjustment or repair of the dose calibrator.

e. A licensee shall retain a record of each check and test required by 41.2(17) for three years, except the geometry dependence test which shall be retained in accordance with 41.2(17) “*b*”(4). The records required by 41.2(17) “*b*” shall include:

(1) For 41.2(17) “*b*”(1), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

(2) For 41.2(17) “*b*”(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, the identity of the individual performing the test, and the signature of the radiation safety officer;

(3) For 41.2(17) “*b*”(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, the identity of the individual performing the test, and the signature of the radiation safety officer; and

(4) For 41.2(17) “*b*”(4), the model and serial number of the dose calibrator, the configuration calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, the identity of the individual performing the test, and the signature of the radiation safety officer.

41.2(18) Calibration and check of survey instruments.

a. A licensee shall ensure that the survey instruments used to show compliance with this rule have been calibrated before first use, annually, and following repair.

b. To satisfy the requirements of 41.2(18) “*a*,” the licensee shall:

(1) Calibrate all required scale readings up to 1000 millirems (10 mSv) per hour with a radiation source;

(2) For each scale that shall be calibrated, calibrate two readings separated by at least 50 percent of scale rating; and

(3) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

c. To satisfy the requirements of 41.2(18) “*b*,” the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent and shall conspicuously attach a correction chart or graph to the instrument. A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

d. A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.

e. The licensee shall retain a record of each calibration required in 41.2(18) “*a*” for three years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

f. To meet the requirements of 41.2(18) “*a*,” “*b*,” and “*c*,” the licensee may obtain the services of individuals licensed by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations which contain information required by 41.2(18) “*e*” shall be maintained by the licensee.

41.2(19) Assay of radiopharmaceutical dosages. A licensee shall:

a. Assay, prior to medical use, the activity of each radiopharmaceutical dosage that contains a photon-emitting radionuclide;

b. Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29) “*j*” or equivalent NRC or agreement state requirements;

c. Not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent unless otherwise directed by the authorized user; and

d. Retain a record of the assays required by 41.2(19)“a” for three years. To satisfy this requirement, the record shall contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(2) Patient’s or human research subject’s name and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of assay, or a notation that the total activity is less than 30 microcuries (1.1 megabecquerels);

(4) Date and time of the assay and administration; and

(5) Initials of the individual who performed the assay.

41.2(20) Authorization for calibration and reference sources.

a. Any person authorized by 41.2(3) for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration and reference use:

(1) Sealed sources manufactured and distributed by persons specifically licensed pursuant to 641—Chapter 39 or equivalent provisions of the NRC, agreement state or licensing state and that do not exceed 30 millicuries (1.11 GBq) each;

(2) Any byproduct material listed in 41.2(31) or 41.2(33) with a half-life of 120 days or less in individual amounts not to exceed 15 millicuries (555 MBq);

(3) Any byproduct material listed in 41.2(31) or 41.2(33) with a half-life greater than 120 days in individual amounts not to exceed 200 microcuries (7.4 MBq) or 1,000 times quantities in Appendix C of 641—Chapter 40 each; and

(4) Technetium-99m amounts as needed.

b. Byproduct material in sealed sources authorized by this provision shall not be:

(1) Used for medical use as defined in 641—38.2(136C) except in accordance with the requirements in 41.2(41); or

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

c. A licensee using calibration, transmission, and reference sources in accordance with the requirements in 41.2(20)“a” or “b” need not list these sources on a specific medical use license.

41.2(21) Requirements for possession of sealed sources and brachytherapy sources.

a. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.

b. A licensee in possession of a sealed source shall ensure that:

(1) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) The source is tested for leakage at intervals not to exceed six months or at intervals approved by the agency, another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission.

c. To satisfy the leak test requirements of 41.2(21)“b,” the licensee shall ensure that:

(1) Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) per 24 hours;

(2) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(3) Test samples are taken when the source is in the “off” position.

d. A licensee shall retain leak test records for five years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels),

a description of the method used to measure each test sample, the date of the test, the signature of the radiation safety officer and the signature of the individual performing the leak test.

e. If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store it in accordance with the requirements of these rules; and

(2) File a report with the agency within five days of receiving the leak test results. The report shall describe the equipment involved, the model and serial number of the leaking source, the radionuclide and its estimated activity, the test results, the date of the test, and the action taken.

f. A licensee need not perform a leak test on the following sources:

- (1) Sources containing only radioactive material with a half-life of less than 30 days;
- (2) Sources containing only radioactive material as a gas;
- (3) Sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material; [and]
- (4) Seeds of iridium-192 encased in nylon ribbon; and
- (5) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.

g. A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at 6-month intervals. The licensee shall retain each inventory record for five years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, the signature of the radiation safety officer and the signature of the individual performing the physical inventory.

h. A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

i. A licensee shall retain a record of each survey required in 41.2(21) "h" for three years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the radiation safety officer.

41.2(22) Syringe shields.

a. A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

b. Unless otherwise approved by this agency, a licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

41.2(23) Syringe labels. Unless utilized immediately, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to be performed, or the patient's or human research subject's name.

41.2(24) Vial shields. A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

41.2(25) Vial shield labels. A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

41.2(26) Surveys for contamination and ambient radiation dose rate.

a. A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

b. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

c. A licensee shall conduct the surveys required by 41.2(26)“a” and “b” so as to be able to measure dose rates as low as 0.1 millirem (1 μ Sv) per hour.

d. A licensee shall establish dose rate action levels for the surveys required by 41.2(26)“a” and “b” and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.

e. A licensee shall survey for removable contamination each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.

f. A licensee shall conduct the surveys required by 41.2(26)“e” so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute (33.3 Bq).

g. A licensee shall establish removable contamination action levels for the surveys required by 41.2(26)“e” and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.

h. A licensee shall retain a record of each survey required by 41.2(26)“a,” “b,” and “e” for two years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

i. A licensee does not need to perform the surveys required in this subrule in an area where the patient or human research subject is confined and cannot be released under 41.2(27).

41.2(27) *Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.*

a. The licensee may authorize the release from its control of any individual who has been administered unsealed radioactive materials or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv). (NUREG-1556, Vol. 9, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses,” describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).)

b. The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (1 mSv). If the dose to a breast-feeding infant or child could exceed 0.1 rem (1 mSv) assuming there were no interruption of breast feeding, the instructions shall also include:

- (1) Guidance on the interruption or discontinuation of breast feeding, and
- (2) Information on the consequences of failure to follow the guidance.

c. The licensee shall maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

- (1) Using the retained activity rather than the activity administered,
- (2) Using an occupancy factor less than 0.25 at 1 meter,
- (3) Using the biological or effective half-life, or
- (4) Considering the shielding by tissue.

d. The licensee shall maintain a record for three years after the date of release that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast feeding could result in a total effective dose equivalent exceeding 0.5 rem (5 mSv). IDPH Regulatory Guide, Release of Patients Administered Radioactive Materials describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).

41.2(28) *Mobile nuclear medicine service technical requirements.* A licensee providing mobile nuclear medicine service shall:

a. Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

b. Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

c. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use;

d. Check survey instruments and dose calibrators as required in 41.2(17) “b”(1) “d” and “e” and 41.2(18) “d” and check all other transported equipment for proper function before medical use at each location of use;

e. Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material and, before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and

f. Retain a record of each survey required by 41.2(28) “e” for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

41.2(29) Storage of volatiles and gases.

a. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers’ radiation shield and container.

b. A licensee shall store and use a multidose container in a properly functioning fume hood.

41.2(30) Decay-in-storage.

a. A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

(1) Holds radioactive material for decay a minimum of ten half-lives;

(2) Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

(3) Removes or obliterates all radiation labels; and

(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

b. For radioactive material disposed in accordance with 41.2(30) “a,” the licensee shall retain a record of each disposal for three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

41.2(31) Use of unsealed radioactive material for uptake, dilution, or excretion studies for which a written directive is not required. Except for quantities that require a written directive under 41.2(87), a licensee may use for uptake, dilution, or excretion studies any unsealed radioactive material prepared for medical use that:

a. Is obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29) “j” or equivalent NRC or agreement state requirements or from a PET radioactive drug producer licensed pursuant to 641—paragraph 39.4(24) “h” or equivalent NRC or agreement state requirements; or

b. Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69) and has work experience in 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; or

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(31) “b”(1) or the physician who is an authorized user in 41.2(31) “b”(2); or

c. Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. Is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

41.2(32) Reserved.

41.2(33) *Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.* Except for quantities that require a written directive under 41.2(87), a licensee may use for imaging and localization studies any unsealed byproduct material prepared for medical use that:

a. Is obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29) “j” or equivalent NRC or agreement state requirements or a PET radioactive drug producer licensed pursuant to 641—paragraph 39.4(24) “h” or equivalent NRC or agreement state requirements; or

b. Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69);

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(33) “b”(1) or the physician who is an authorized user in 41.2(33) “b”(2); or

c. Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. Is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

41.2(34) *Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.*

a. A licensee shall 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 microcurie of strontium-82 per millicurie of rubidium-82 chloride injection (0.02 kilobecquerel strontium-82 per megabecquerel rubidium-82 chloride); or more than 0.2 microcurie of strontium-85 per millicurie of rubidium-82 chloride injection (0.2 kilobecquerel strontium-85 per megabecquerel rubidium-82 chloride).

b. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with 41.2(34) “a.”

c. A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with 41.2(34) “a.”

d. A licensee who must measure molybdenum-99, strontium-82, or strontium-85 concentration shall retain a record of each measurement for three years. The record shall include:

(1) For each elution or extraction of technetium-99m, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium), the date of the test, and the initials of the individual who performed the test.

(2) For each elution or extraction of rubidium-82, the ratio of the measures expressed as microcuries of strontium-82 per millicurie of rubidium-82 (kilobecquerels of strontium-82 per megabecquerel of rubidium-82), microcuries of strontium-85 per millicurie of rubidium-82 (kilobecquerels of strontium-85 per millicurie of rubidium-82), the date of the test, and the initials of the individual who performed the test.

e. A licensee shall report any measurement that exceeds the limits in 41.2(34) “a” at the time of generator elution, in accordance with the following:

(1) The licensee shall notify by telephone the agency and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in 41.2(34)“a” at the time of generator elution. The telephone report to the agency 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.

(2) By an appropriate method listed in 641—38.7(136C), the licensee shall submit a written report to the agency within 30 calendar 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 41.2(34)“a.”

41.2(35) Control of aerosols and gases.

a. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by 641—40.15(136C) and 641—40.26(136C) of these rules.

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

c. A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

d. Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix B of 641—Chapter 40. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

e. A licensee shall post the time calculated in 41.2(35)“a” at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

f. A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements shall be maintained for three years.

g. A copy of the calculations required in 41.2(35)“d” shall be recorded and retained for the duration of the license.

41.2(36) Reserved.

41.2(37) Use of unsealed byproduct material for which a written directive is required. A licensee may use any unsealed byproduct material identified in 41.2(69)“b”(1)“2,” seventh bulleted paragraph, prepared for medical use and for which a written directive is required that:

a. Is obtained from:

(1) A manufacturer or preparer licensed under 641—paragraph 39.4(29)“j” or equivalent NRC or agreement state requirements; or

(2) A PET radioactive drug producer licensed under 641—paragraph 39.4(24)“h” or equivalent NRC or agreement state requirements; or

b. Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements of 41.2(68) or 41.2(69);

or

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(37)“b”(1) or the physician who is an authorized user in 41.2(37)“b”(2); or

c. Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with the Investigational New Drug (IND) protocol accepted by FDA; or

d. Is prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

41.2(38) *Safety instruction for radiopharmaceutical therapy and hospitalization.*

a. A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy and hospitalized for compliance with 41.2(27). Refresher training shall be provided initially and at 12-month intervals or as required for patient care.

b. To satisfy 41.2(38)“a,” the instruction shall describe the licensee’s procedures for:

- (1) Patient or human research subject control;
- (2) Visitor control;
- (3) Contamination control;
- (4) Waste control;
- (5) Notification of the radiation safety officer, radiation safety officer designee, or authorized user in case of the patient’s or human research subject’s death or medical emergency; and
- (6) Training requirements specified in 641—40.110(136C) and 641—40.116(136C) and adopted by reference and included herein.

c. A licensee shall maintain a record of safety instructions required by 41.2(38) for three years. The records must include a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the agency for three years.

41.2(39) *Safety precautions for radiopharmaceutical therapy and hospitalization.*

a. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 41.2(27), a licensee shall:

- (1) Provide a private room with a private sanitary facility or a room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under 41.2(27);
- (2) Post the patient’s or human research subject’s door with a “Caution: Radioactive Material” sign and note on the door or on the patient’s or human research subject’s chart where and how long visitors may stay in the patient’s or human research subject’s room;
- (3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;
- (4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 641—subrule 40.26(1) which is adopted by reference and included herein and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems (μSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;
- (5) Either monitor material and items removed from the patient’s or human research subject’s room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;
- (6) Provide the patient or human research subject with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient or human research subject;
- (7) Survey the patient’s or human research subject’s room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters; and

b. A licensee shall notify the radiation safety officer or the authorized user immediately if the patient or human research subject dies or has a medical emergency.

41.2(40) Reserved.

41.2(41) *Use of sealed sources 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 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 FDA provided the requirements in 41.2(15) “*a*” are met.

41.2(42) Reserved.

41.2(43) *Use of sources for manual brachytherapy.* A licensee shall use only brachytherapy sources:

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 in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15) are met.

41.2(44) *Safety instruction for manual brachytherapy.*

a. The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient or human research subject receiving manual brachytherapy and cannot be released under 41.2(27). Refresher training shall be provided initially and at 12-month intervals or as required for patient care.

b. To satisfy 41.2(44) “*a*,” the instruction shall describe:

- (1) Size and appearance of the brachytherapy sources;
- (2) Safe handling and shielding instructions in case of a dislodged source;
- (3) Procedures for patient or human research subject control;
- (4) Procedures for visitor control, to include routine visitation of hospitalized individuals in accordance with 641—40.26(136C) and visitation authorized in accordance with 641—40.26(136C);
- (5) Procedures for notification of the radiation safety officer, radiation safety officer designee, or authorized user if the patient or human research subject dies or has a medical emergency; and
- (6) Training requirements specified in 641—40.110(136C) and 40.116(136C) as adopted by reference and included herein.

c. A licensee shall maintain a record of safety instructions required by 41.2(44) for three years. The records must include a description of the instruction, the date of instruction, the name of the attendee(s), and the name of the individual who gave the instruction for three years.

41.2(45) *Safety precautions for manual brachytherapy.*

a. For each patient or human research subject receiving manual brachytherapy a licensee shall:

- (1) Not place the patient or human research subject in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirement of 641—40.26(136C) as adopted by reference and included herein at a distance of 1 meter from the implant;
- (2) Post the patient’s or human research subject’s door with a “Caution: Radioactive Materials” sign and note on the door or the patient’s or human research subject’s chart where and how long visitors may stay in the patient’s or human research subject’s room;
- (3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;
- (4) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with 641—40.26(136C) as adopted by reference and included herein; and retain for three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed,

the measured dose rate at several points expressed in millirems (mSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(5) Provide the patient or human research subject with radiation safety guidance that will help keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient or human research subject if the patient or human research subject was administered a permanent implant; and

(6) Have applicable emergency response equipment available near each treatment room to respond to a source dislodged from the patient or lodged within the patient following removal of the source applicators.

b. A licensee shall notify the radiation safety officer, radiation safety officer designee, or authorized user immediately if the patient or human research subject dies or has a medical emergency.

41.2(46) Brachytherapy sources inventory.

a. Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

b. A licensee shall make a record of brachytherapy source utilization which includes:

(1) The names of the individuals permitted to handle the sources;

(2) The number and activity of sources removed from storage, the room number of use and patient's or human research subject's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

(3) The number and activity of sources returned to storage, the room number of use and patient's or human research subject's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

c. Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

d. A licensee shall maintain the records required in 41.2(46) "b" and "c" for three years.

e. A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use. As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

41.2(47) Release of patients or human research subjects treated with temporary implants.

a. Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall perform a radiation survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed and, for remote afterloaders, returned to the safe shielded position. The licensee shall not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.

b. A licensee shall maintain a record of patient or human research subject surveys which demonstrate compliance with 41.2(47) "a" for three years. Each record shall include the date of the survey, the name of the patient or human research subject, the dose rate from the patient or human research subject expressed as millirems (microsieverts) per hour and measured within 1 meter from the patient or human research subject, and the initials of the individual who made the survey.

41.2(48) Reserved.

41.2(49) Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

a. A licensee must only use sealed sources:

(1) Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

(2) In research involving photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15)“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 in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15)“a” are met.

41.2(50) *Installation, maintenance, adjustment, and repair.*

a. Only a person specifically licensed by the NRC or an agreement state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), or reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

b. Except for low-dose-rate remote afterloader units, only a person specifically licensed by the NRC or an agreement state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

c. For low-dose-rate remote afterloader units, only a person specifically licensed by the NRC or an agreement state or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

d. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units for three years. The record must include the date, description of the service, and the name of the individual who performed the work.

41.2(51) *Amendments.* In addition to the requirements specified in 41.2(4), a licensee shall apply for and receive a license amendment before:

- a. Making any change in the treatment room shielding;
- b. Making any change in the location of the teletherapy unit within the treatment room;
- c. Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;
- d. Relocating the teletherapy unit; or
- e. Allowing an individual not listed on the licensee’s license to perform the duties of the teletherapy physicist.

41.2(52) *Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.*

a. A licensee shall:

(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 to remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

b. A copy of the procedures required by 41.2(52)“a”(4) must be physically located at the unit console.

c. A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by 41.2(52)“a”(4); and

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

d. A licensee shall:

(1) Ensure that vendor operational and safety training is provided to all individuals who will operate the unit 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. 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.

(2) Provide operational and safety instruction, initially and at least annually, to all individuals who operate the unit, appropriate to the individual’s assigned duties, in:

1. The procedures identified in 41.2(52)“a”(4); and

2. The operating procedures for the unit.

e. The licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of emergency procedures, initially and at least annually.

f. A licensee shall retain a record for three years of individuals receiving instruction required by 41.2(52), a description of the instruction, the date of instruction, the name of the attendee(s), and the name of the individual who gave the instruction.

g. A copy of the procedures required in 41.2(52)“d”(2) shall be retained until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

41.2(53) *Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.*

a. A licensee shall control access to the teletherapy room by a door at each entrance.

b. A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:

(1) Prevent the operator from turning the primary beam of radiation “on” unless each treatment room entrance door is closed;

(2) Turn the beam of radiation “off” immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned “on” following an interlock interruption until all treatment room entrance doors are closed and the beam “on-off” control is reset at the console.

c. A licensee shall require any individual entering the treatment room to ensure, through the use of appropriate monitors, that radiation levels have returned to ambient levels.

d. Except for low-dose-rate remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or human research subject from the treatment console during irradiation.

e. For licensed activities where sources are placed within the patient’s or human research subject’s body, the licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

f. In addition to the requirements specified in 41.2(53)“a” through “e,” a licensee shall:

(1) For medium-dose-rate and pulsed-dose-rate remote afterloader units, require:

1. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation of and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who have been trained to remove the source applicator in the event

of an emergency involving the unit to be immediately available during continuation of all patient treatments involving the unit.

(2) For high-dose-rate remote afterloader units, require:

1. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation and emergency response for the unit, to be physically present during the continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit. As used in this subparagraph, “physically present” means to be within hearing distance of normal voice.

(4) Notify the radiation safety officer, or the radiation safety officer designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

g. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source remaining in the unshielded position or lodged within the patient following completion of the treatment.

41.2(54) Reserved.

41.2(55) *Radiation monitoring device.*

a. A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

b. Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.

c. Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

d. A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

e. A licensee shall maintain a record of the check required by 41.2(55) “d” for three years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

f. If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in 41.2(55) “e.”

g. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

41.2(56) *Viewing system.* A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.

41.2(57) *Dosimetry equipment.*

a. Except for low-dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies, or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of

the intercomparison must indicate that the calibration factor of the licensee's system has not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, if applicable, and sources of the same radionuclide as the source used at the licensee's facility.

b. The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.2(57) "a." This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in 41.2(57) "a."

c. The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.2(57) "a" and "b," the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

41.2(58) *Full calibration measurements on teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.*

a. Teletherapy units.

(1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements for each teletherapy unit:

1. Before the first medical use of the unit; and
2. Before medical use under the following conditions:
 - Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output of the last full calibration corrected mathematically for radioactive decay;
 - Following replacement of the source or following reinstallation of the teletherapy unit in a new location;
 - Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
3. At intervals not exceeding one year.

(2) To satisfy the requirements of 41.2(58) "a"(1), full calibration measurements must include determination of:

1. The output within ± 3 percent for the range of field sizes and for the distance or range of distances used for medical use;
2. The coincidence of the radiation field and the field indicated by the light beam localizing device;
3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;
4. Timer accuracy and linearity over the range of use;
5. On-off error; and
6. The accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 41.2(58) "a"(2)"1" may be made using the dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by 41.2(58) "a" in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in 41.2(58) "a"(2)"1" for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1 percent of all other radionuclides.

(6) Full calibration measurements required by 41.2(58) "a"(1) and physical decay corrections required in 41.2(58) "a"(5) must be performed by the authorized medical physicist.

(7) A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration; the manufacturer's name, model number, and serial number for

both the unit and the source; tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the measured timer accuracy for a typical treatment time; the calculated “on-off” error; the estimated accuracy of each distance measuring or localization device; and the signature of the authorized medical physicist.

b. Remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements for each unit:

1. Before the first medical use of the unit; and

2. Before medical use under the following conditions:

- Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

- Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one quarter of a year for high-dose-rate, medium-dose-rate, and pulsed-dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

4. At intervals not exceeding one year for low-dose-rate remote afterloader units.

(2) To satisfy the requirements of 41.2(58) “b”(1), full calibration measurements must include, as applicable, determination of:

1. The output within ± 5 percent;

2. Source positioning accuracy to within ± 1 millimeter;

3. Source retraction with backup battery upon power failure;

4. Length of the source transfer tubes;

5. Timer accuracy and linearity over the typical range of use;

6. Length of the applicators; and

7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output.

(4) A licensee shall make full calibration measurements required by 41.2(58) “b”(1) in accordance with published protocols accepted by nationally recognized bodies.

(5) In addition to the requirements for full calibrations for low-dose-rate remote afterloader units in 41.2(58) “b”(2), a licensee shall perform an autoradiograph of the source to verify inventory and source arrangement at intervals not exceeding one quarter of a year.

(6) For low-dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 41.2(58) “b.”

(7) A licensee shall mathematically correct the outputs determined in 41.2(58) “b”(2) “1” for physical decay intervals consistent with 1 percent physical decay.

(8) Full calibration measurements required by 41.2(58) “b”(1) and physical decay corrections required by 41.2(58) “b”(7) must be performed by the authorized medical physicist.

(9) A licensee shall retain a record of each calibration in accordance with 41.2(58) “a”(7).

c. Gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;

2. Before medical use under the following conditions:

- Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

- Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

- Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

3. At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) To satisfy the requirement of 41.2(58)“c”(1), full calibration measurements must include determination of:

1. The output within ± 3 percent;
2. Relative helmet factors;
3. Isocenter coincidence;
4. Timer accuracy and linearity over the range of use;
5. On-off error;
6. Trunnion centricity;
7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
8. Helmet microswitches;
9. Emergency timing circuits; and
10. Stereotactic frames and localizing devices (trunnions).

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 41.2(58)“c”(2)“1” may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by 41.2(58)“c”(1) in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in 41.2(58)“c”(2)“1” at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(6) Full calibration measurements required by 41.2(58)“c”(1) and physical decay corrections required in 41.2(58)“c”(5) must be performed by the authorized medical physicist.

(7) A licensee shall retain a record of each calibration in accordance with 41.2(58)“a”(7).

41.2(59) Periodic spot checks for teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.

a. Teletherapy units.

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month that include determination of:

1. Timer accuracy and timer linearity over the range of use;
2. On-off error;
3. The coincidence of the radiation field and the field indicated by the light beam localizing device;
4. The accuracy of all distance measuring and localization devices used for medical use;
5. The output for one typical set of operating conditions measured with the dosimetry system described in 41.2(57); and
6. The difference between the measurement made in 41.2(59)“a”(1)“5” and the anticipated output expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(2) A licensee shall perform measurements required by 41.2(59)“a”(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the result of each spot check.

(4) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility once in each calendar month and after each source installation to ensure proper operation of:

1. Electrical interlocks at each teletherapy room entrance;
2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

4. Viewing and intercom systems;

5. Treatment room doors from inside and outside the treatment room; and

6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(5) If the results of the spot checks required in 41.2(59) "a"(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) A licensee shall retain for three years a record of each spot check required in 41.2(59) "a." The record must include:

1. The date of the spot check;

2. The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

3. An assessment of timer linearity and constancy;

4. The calculated on-off error;

5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

6. The determined accuracy of each distance measuring and localization device;

7. The difference between the anticipated output and the measured output;

8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical source exposure indicator light, and the viewing and intercom system and doors; and

9. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(7) A licensee shall retain a copy of the procedures required by 41.2(59) "a"(2) until the licensee no longer possesses the teletherapy unit.

b. Remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform spot checks of each remote afterloader facility and on each unit:

1. Before the first use of a high-dose-rate, medium-dose-rate, or pulsed-dose-rate remote afterloader unit on a given day;

2. Before each patient treatment with a low-dose-rate remote afterloader unit; and

3. After each source installation.

(2) A licensee shall perform the measurements required by 41.2(59) "b"(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(4) To satisfy the requirements of 41.2(59) "b"(1), spot checks must, at a minimum, ensure proper operation of:

1. Electrical interlocks at each remote afterloader unit room entrance;

2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

3. Viewing and intercom systems in each high-dose-rate, medium-dose-rate, and pulsed-dose-rate remote afterloader facility;

4. Emergency response equipment;

5. Radiation monitors used to indicate the source position;

6. Timer accuracy;

7. Clock (date and time) in the unit's computer; and

8. Decayed source(s) activity in the unit's computer.

(5) If the results of the spot checks required in 41.2(59) "b"(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or spot check the malfunctioning system.

(6) A licensee shall retain for three years a record of each spot check required in 41.2(59) "b"(4). The record must include:

1. The date of the spot check;
2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
3. An assessment of timer accuracy;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
5. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(7) A licensee shall retain a copy of the procedures required in 41.2(59) "b"(2) until the licensee no longer possesses the remote afterloader unit.

c. Gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot checks for the gamma stereotactic radiosurgery facility and on each unit:

1. Monthly;
2. Before the first use of the unit on a given day; and
3. After each source installation.

(2) A licensee shall:

1. Perform the measurements required by 41.2(59) "c"(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

2. Have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(3) To satisfy the requirements of 41.2(59) "c"(1)"1," spot checks must, at a minimum:

1. Ensure proper operation of treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off; helmet microswitches; emergency timing circuits; and stereotactic frames and localizing devices (trunnions).

2. Determine:

- The output for one typical set of operating conditions measured with the dosimetry system described in 41.2(57);

- The difference between the measurement made in the above bulleted point and the anticipated output expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

- Source output against computer calculation;
- Timer accuracy and linearity over the range of use;
- On-off error; and
- Trunnion centricity.

(4) To satisfy the requirements of 41.2(59) "c"(1)"2" and "3," spot checks must ensure proper functioning of:

1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
3. Viewing and intercom systems;
4. Timer termination;
5. Radiation monitors used to indicate room exposures; and
6. Emergency off buttons.

(5) A licensee shall arrange as soon as possible for the repair of any system identified in 41.2(59)“c”(3) that is not operating properly.

(6) If the results of the spot checks required in 41.2(59)“c”(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(7) A licensee shall retain for three years a record of each spot check required by 41.2(59)“c”(3) and (4). The record shall include:

1. The date of the spot check;
2. The manufacturer’s name, model number, and serial number for the gamma stereotactic radiosurgery unit and the survey instrument used to measure the output of the unit;
3. An assessment of timer linearity and accuracy;
4. The calculated on-off error;
5. A determination of trunnion centricity;
6. The difference between the anticipated output and the measured output;
7. An assessment of source output against computer calculations;
8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, on-off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
9. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(8) A licensee shall retain a copy of the procedures required in 41.2(59)“c”(2) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

41.2(60) Radiation surveys for teletherapy facilities.

a. In addition to the survey requirements in 641—40.36(136C), a person licensed under 641—41.2(136C) shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

b. The licensee shall make the survey required in 41.2(60)“a” at installation of a new source, and following repairs to the source shielding, the source driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the source.

c. A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer’s name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the “off” position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirems (μSv) per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the radiation safety officer.

41.2(61) Safety spot checks for teletherapy facilities.

a. A licensee shall promptly check all systems listed in 41.2(59)“g” for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by 41.2(51).

b. If the results of the safety spot checks required in 41.2(61)“a” indicate the malfunction of any system specified in 41.2(59), the licensee shall lock the control console in the “off” position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

c. A licensee shall maintain a record of the safety spot checks following installation of a source for three years. The record shall include notations indicating the operability of each entrance door interlock,

each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer.

41.2(62) *Modification of teletherapy unit or room before beginning a treatment program.* If the survey required by 41.2(60) indicates that any individual member of the public is likely to receive a dose greater than those permitted by 641—40.26(136C) before beginning the treatment program, the licensee shall:

- a. Either equip the unit with stops or add additional radiation shielding to ensure compliance with 641—40.26(136C);
- b. Perform the survey required by 41.2(60) again; and
- c. Include in the report required by 41.2(63) the results of the initial survey, a description of the modification made to comply with 41.2(62) “a,” and the results of the second survey; or
- d. Request and receive a license amendment under 641—40.26(136C) that authorizes radiation levels in unrestricted areas greater than those permitted by 641—40.26(136C).

41.2(63) *Reports of teletherapy surveys, checks, tests, and measurements.* A licensee shall furnish a copy of the records required in 41.2(60), 41.2(61), and 41.2(62) and the output from the teletherapy source expressed as rems (sieverts) per hour at 1 meter from the source as determined during the full calibration required in 41.2(58) to the agency within 30 days following completion of the action that initiated the record requirement.

41.2(64) *Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.*

a. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full inspection shall not exceed five years for each teletherapy unit and shall not exceed seven years for each gamma stereotactic radiosurgery unit.

b. This inspection and servicing shall be performed only by persons specifically licensed to do so by the NRC or an agreement state.

c. A licensee shall maintain a record of the full inspection and servicing for the duration of the use of the unit. The record shall contain the inspector’s name, the inspector’s license number, the date of inspection, the manufacturer’s name and model number and serial number for both the teletherapy unit and gamma stereotactic radiosurgery unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

41.2(65) *Training for radiation safety officer.* Except as provided in 41.2(75), the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer or an individual assigned duties and tasks as an associate radiation safety officer as provided in 41.2(8) to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in 41.2(65) “d.” The names of the board certifications that have been recognized by the NRC or an agreement state are posted on the NRC’s Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall:

(1) Require all candidates for certification to:

1. Hold a bachelor’s or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

2. Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

3. Pass an examination administered by diplomats of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2) Require all candidates for certification to:

1. Hold a master’s or doctor’s degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

2. Have two years of either full-time practical training or supervised experience in medical physics under the supervision of a medical physicist who is certified in medical physics by a specialty

board recognized by the NRC or an agreement state, or in clinical nuclear medicine facilities providing either diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in 41.2(68), 41.2(69), or 41.2(75); and

3. Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

b. Has:

(1) Completed a structured educational program consisting of both:

1. 200 hours of classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Radiation biology; and
- Radiation dosimetry; and

2. One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on an NRC or agreement state license or permit issued by the NRC master material licensee that authorizes similar types of use of byproduct 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 the following:

- Shipping, receiving, and performing related radiation surveys;
- Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
- Securing and controlling byproduct material;
- Using administrative controls to avoid mistakes in the administration of byproduct material;
- Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
- Using emergency procedures to control byproduct material; and
- Disposing of byproduct material; and

(2) This individual must obtain a 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 byproduct 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 41.2(65)“*b*”(1) and 41.2(65)“*d*” and is able to independently fulfill the radiation safety-related duties as a radiation safety officer or as an associate radiation safety officer for a medical use license; or

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 41.2(74)“*a*,” has experience in radiation safety aspects of similar types of use of byproduct material for which the licensee is seeking the approval of the individual as a radiation safety officer or an associate radiation safety officer, and meets the requirements in 41.2(65)“*d*”; or

(2) 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, has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the radiation safety officer or associate radiation safety officer and meets the requirements in 41.2(65)“*d*”; or

(3) 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 or new medical use permit issued by an NRC master material licensee. The individual must also meet the requirements in 41.2(65)“*d*”; and

d. Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the 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 type of use for which the licensee is seeking approval.

41.2(66) Reserved.

41.2(67) *Training for uptake, dilution, and excretion studies.* Except as provided in 41.2(75), the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under 41.2(31) 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 agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in 41.2(67) "c"(1) "1" and "2"; and

(2) Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

b. Is an authorized user under 41.2(68) or 41.2(69) or meets equivalent NRC or agreement state requirements; or

c. (1) Has completed 60 hours of training and experience, including a minimum of 8 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:

1. Classroom and laboratory training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material for medical use, and radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(67), 41.2(68), 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements, involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

- Calculating, measuring, and safely preparing patient or human research subject dosages;

- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

- Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(67) "c"(1) and is able to independently fulfill the radiation safety-related duties as an authorized user under 41.2(31). The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(67), 41.2(68), 41.2(69), or 41.2(75) or equivalent NRC or agreement state requirements; or

2. 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 41.2(67), 41.2(68), 41.2(69), or 41.2(75), or equivalent NRC or agreement state requirements, 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 41.2(67) "c"(1).

41.2(68) *Training for imaging and localization studies.* Except as provided in 41.2(75), the licensee shall require the authorized user of unsealed byproduct material for the uses authorized under 41.2(33) 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 agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) 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 as described in 41.2(68) "c"(1)"1" and "2"; and

(2) Pass an examination administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

b. Is an authorized user under 41.2(69) and meets the requirements in 41.2(68) "c"(1)"2," seventh bulleted paragraph, or equivalent NRC or agreement state requirements; or

c. (1) Has 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:

1. Classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Chemistry of radioactive material for medical use;
- Radiation biology, and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(68); 41.2(69) and 41.2(68) "c"(1)"2," seventh bulleted paragraph; 41.2(75); or equivalent NRC or agreement state requirements. An authorized nuclear pharmacist who meets the requirements in 41.2(75) or 41.2(78) may provide the supervised work experience for the seventh bulleted paragraph of 41.2(68) "c"(1)"2." Work experience must involve:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

- Calculating, measuring, and safely preparing patient or human research subject dosages;

- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

- Administering dosages of radioactive drugs to patients or human research subjects; and

- 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) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(68) "c"(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 41.2(31) and 41.2(33). The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(68); 41.2(69) and 41.2(68) "c"(1)"2," seventh bulleted paragraph; or 41.2(75), or equivalent NRC or agreement state requirements; or

2. 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 41.2(68); 41.2(69) and 41.2(68) "c"(1)"2," seventh bulleted paragraph; or

41.2(75); or equivalent NRC or agreement state requirements, 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 41.2(68) “c”(1).

41.2(69) Training for use of unsealed byproduct material for which a written directive is required. Except as provided in 41.2(75), the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under 41.2(37) 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 who meets the requirements in 41.2(69) “b”(1)“2,” seventh bulleted paragraph. The names of the board certificates that have been recognized by the NRC or agreement state are posted on the NRC’s Medical Uses License Toolkit web page. To be recognized, a specialty board shall require all candidates for certification to:

(1) 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 41.2(69) “b”(1)“1” through 41.2(69) “b”(1)“2,” fifth bulleted paragraph. 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 Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, which 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; or

b. (1) Has 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:

1. Classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Chemistry of radioactive material for medical use; and
- Radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69) “b” must also have experience in administering dosages in the same dosage category or categories (i.e., 41.2(69) “b”(1)“2,” seventh bulleted paragraph) as the individual requesting authorized user status. The work experience must involve:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

- Calculating, measuring, and safely preparing patient or human research subject dosages;

- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

- Reserved.

- Administering dosages of radioactive drugs to patients or human research subjects from the three categories in this bulleted paragraph. Radioactive drugs containing radionuclides in categories not included are regulated under 41.2(88). This work experience must involve 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 gigabecquerels) of sodium iodide I-131, for which a written directive is required;
- Oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 (experience with at least three cases in this category also satisfies the requirement in the above category);
- Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emissions, beta radiation characteristics, alpha radiation characteristics, or photon energy less than 150 keV for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(69)“b”(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 41.2(37) for which the individual is requesting authorized user status. The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(69), 41.2(75) or equivalent NRC or agreement state requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

2. 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 41.2(69), 41.2(75) or equivalent NRC or agreement state requirements, 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 41.2(69)“b”(1).

c. For training only for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) or quantities greater than 33 millicuries (1.22 gigabecquerels), see 41.2(81) or 41.2(82).

41.2(70) Training for use of manual brachytherapy sources. Except as provided in 41.2(75), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 41.2(43) 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 the board certifications that have been recognized by the NRC or agreement state must be posted on the NRC’s Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) 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 or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

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

1. 200 hours of classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity; and
- Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(70) or 41.2(75) or equivalent NRC or agreement state requirements at a medical facility authorized to use byproduct materials under 41.2(43), involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- Checking survey meters for proper operation;
- Preparing, implanting, and removing brachytherapy sources;
- Maintaining running inventories of material on hand;
- Using administrative controls to prevent a medical event involving the use of radioactive material; and

- Using emergency procedures to control radioactive material; and

(2) Has completed three years of supervised clinical experience in radiation oncology under an authorized user who meets the requirements in 41.2(70) or 41.2(75) or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required in 41.2(70) “b”(1)“2”; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(70) “b”(1) and (2) and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under 41.2(43). The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(70), 41.2(75), or equivalent NRC or agreement state requirements; or

2. 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 41.2(70), 41.2(75), or equivalent NRC or agreement state requirements, 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 41.2(70) “b”(1) and (2).

41.2(71) Training for ophthalmic use of strontium-90. Except as provided in 41.2(75), the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

a. Is an authorized user under 41.2(70) or equivalent NRC or agreement state requirements; or

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

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and
4. Radiation biology; and

(2) Has completed 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. This supervised clinical training must involve:

1. Examination of each individual to be treated;
2. Calculation of the dose to be administered;
3. Administration of the dose; and
4. Follow-up and review of each individual’s case history; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(70), 41.2(71) or 41.2(75) or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(71) “b”(1) and (2) and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

41.2(72) Training for use of sealed sources for diagnosis. Except as provided in 41.2(75), the licensee shall require the authorized user of a diagnostic sealed source or a device authorized under 41.2(41) to be a physician, dentist, or podiatrist who:

a. Is certified by a specialty board whose certification process includes all of the requirements in 41.2(72) “c” and “d” and whose certification has been recognized by the NRC or an agreement state. The names of the board certificates that have been recognized by the NRC or agreement state must be posted on the NRC’s Medical Uses Licensee Toolkit web page; or

b. Is an authorized user for uses listed in 41.2(33) or equivalent NRC or agreement state requirements; or

c. Has 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) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity; and
- (4) Radiation biology; and

d. Has completed training in the use of the device for the uses requested.

41.2(73) *Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.* Except as provided in 41.2(75), the licensee shall require an authorized user of a sealed source for a use authorized under 41.2(49) 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 who meets the requirements in 41.2(73) “c.” The names of board certification that have been recognized by the NRC or agreement state are posted on the NRC’s Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) 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 or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, which 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; or

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

1. 200 hours of classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity; and
- Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(73) or 41.2(75) or equivalent NRC or agreement state requirements at a medical facility that is authorized to use byproduct material in 41.2(49), involving:

- Reviewing full calibration measurements and periodic spot checks;
- Preparing treatment plans and calculating treatment doses and times;
- Using administrative controls to prevent a medical event involving the use of radioactive material;

● Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

- Checking and using survey meters; and
- Selecting the proper dose and how it is to be administered; and

(2) Has completed three years of supervised clinical experience in radiation therapy under an authorized user who meets the requirements in 41.2(73) or 41.2(75) or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the

American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 41.2(73)“b”(1)“2”; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(73)“b”(1) and (2) and 41.2(73)“c” and 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 attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(73) or 41.2(75) or equivalent NRC or agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; or

2. 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 41.2(73), 41.2(75), or equivalent NRC or agreement state requirements, 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 41.2(73)“b”(1) and (2); and

c. Has received training in device operation, safety procedures, and clinical use for the type 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 type of use for which the individual is seeking authorization.

41.2(74) Training for an authorized medical physicist. Except as provided in 41.2(75), the licensee shall require the authorized medical physicist to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(74)“c.” The names of the board certifications that have been recognized by the NRC or agreement state are posted on the NRC’s Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

(2) Have two years of either 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 under this rule by 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 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 41.2(70), 41.2(73), or 41.2(75); and

(3) Pass an examination, administered by diplomats 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; 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 has completed one year of full-time training in medical physics and 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 type 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 million electron volts) and brachytherapy services and must include:

1. Performing sealed source leak tests and inventories;

2. Performing decay corrections;
3. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units, as applicable; and
4. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units, as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(74) “b”(1) and “c” and is able to independently fulfill the radiation safety-related duties 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 41.2(74) or 41.2(75) 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.

c. Has training for the type 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 who is authorized for the type of use for which the individual is seeking authorization.

41.2(75) Training for experienced radiation safety officer, authorized medical physicist, nuclear pharmacist, authorized nuclear pharmacist, authorized users and teletherapy or medical physicists.

a. (1) An individual identified on an NRC or agreement state license, on a permit issued by the NRC or agreement state broad scope licensee, on a master material license permit, or by a master material license permittee of broad scope as a radiation safety officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before July 22, 2020, need not comply with the training requirements of 41.2(65), 41.2(74), or 41.2(78), respectively, except the radiation safety officers and authorized medical physicists identified in this paragraph must meet the training requirements in 41.2(65) “d” or 41.2(74) “c,” as appropriate, for any material or uses for which they were not authorized prior to this date.

(2) Any 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 on or before October 24, 2005, need not comply with the training requirements of 41.2(65) to be identified as a radiation safety officer or as an associate radiation safety officer on an NRC or an agreement state license or NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(3) Any 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, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in 41.2(74), for those materials and uses that these individuals performed on or before October 24, 2005.

b. (1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the NRC or agreement state, a permit issued by an NRC master material licensee, a permit issued by an NRC broad scope licensee, or a permit issued by an NRC master material license broad scope permittee before July 22, 2020, who perform only those medical uses for which they were authorized before that date need not comply with the training requirements of 41.2(67), 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), 41.2(73), 41.2(81), 41.2(82), or 41.2(89).

(2) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material issued by the NRC or agreement state, a permit issued by an NRC master material licensee, a permit issued by an NRC 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 on or before October 24, 2005, need not comply with the training requirements of 41.2(67), 41.2(68), 41.2(69),

41.2(70), 41.2(71), 41.2(72), 41.2(73), 41.2(81), 41.2(82), or 41.2(89) for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

1. For uses authorized under 41.2(31) or 41.2(33), or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or 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 41.2(37), a physician who was certified on or 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 41.2(43) or 41.2(49), a physician who was certified on or 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 41.2(41), a physician who was certified on or 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.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of 41.2(67), 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), 41.2(73), 41.2(81), 41.2(82), or 41.2(89) when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this rule.

c. Individuals who need not comply with training requirements as described in this subrule may serve as preceptors for, and supervisors of, applicants seeking authorization on an agency license for the same uses for which these individuals are authorized.

41.2(76) Reserved.

41.2(77) *Recentness of training.* The training and experience specified in 41.2(65) to 41.2(78) and 41.2(81), 41.2(82), 41.2(85), and 41.2(89) shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and continuing applicable experience since the required training and experience were completed.

41.2(78) *Training for an authorized nuclear pharmacist.* Except as provided in 41.2(75), the licensee shall require the 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 Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4,000 hours of combined training and experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomats of the specialty board that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

b. Has completed 700 hours in a structured education program consisting of both:

(1) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Supervised practical experience in a nuclear pharmacy involving:

1. Shipping, receiving, and performing related radiation surveys;

2. 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;

3. Calculating, assaying, and safely preparing dosages for patients or human research subjects;

4. Using administrative controls to avoid medical events in the administration of byproduct material; and

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

c. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual satisfactorily completed the requirements in 41.2(78) “*b*” and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

41.2(79) and 41.2(80) Reserved.

41.2(81) *Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels).* Except as provided in 41.2(75), the licensee shall 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 gigabecquerels) to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(81) “*c*”(1) and (2) and whose certification process has been recognized by the NRC or an agreement state. The names of the board certifications that have been recognized by the NRC or agreement state are posted on the NRC’s Medical Uses Licensee Toolkit web page; or

b. Is an authorized user under 41.2(69) “*a*” or “*b*” for uses in the oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 for which a written directive is required, or oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 or 41.2(82) or equivalent NRC or agreement state requirements; or

c. (1) Has 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:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69) “*a*” or “*b*,” 41.2(75), 41.2(81) or 41.2(82) or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69) “*b*” must also have experience

in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. 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 Gigabecquerels) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(81)“c”(1) and (2) and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide (I-131) for medical uses authorized under 41.2(37). The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(69), 41.2(75), 41.2(81) or 41.2(82) or equivalent NRC or agreement state requirements and has experience in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131; or
2. 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 41.2(69), 41.2(75), 41.2(81), 41.2(82), or equivalent NRC or agreement state requirements; has experience in administering dosages orally as specified in 41.2(69)“b”(1)“2,” seventh bulleted paragraph; 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 41.2(81)“c”(1) and (2).

41.2(82) Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels). Except as provided in 41.2(75), the licensee shall 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 gigabecquerels) to be a physician who:

- a. Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(82)“c”(1) and (2), and whose certification has been recognized by the NRC or agreement state. The names of the board certifications that have been recognized by the NRC or agreement state must be posted on the NRC’s Medical Uses Licensee Toolkit web page; or
- b. Is an authorized user under 41.2(69)“a” or “b” for oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 or meets equivalent NRC or agreement state requirements; or
- c. (1) Has 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:
 1. Radiation physics and instrumentation;
 2. Radiation protection;
 3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and
 5. Radiation biology; and
- (2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69)“a” or “b,” 41.2(75) or 41.2(82) or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)“b” must also have experience in oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131. The work experience must involve:
1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 3. Calculating, measuring, and safely preparing patient or human research subject dosages;
 4. Using administrative controls to prevent a medical event involving the use of radioactive material;
 5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 6. Administering dosages to patients or human research subjects that include at least three cases involving the oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131; and
- (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(82)“c”(1) and (2) and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide (I-131) for medical uses authorized in 41.2(37). The attestation must be obtained from either:
1. A preceptor authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(82) or equivalent NRC or agreement state requirements and has experience in oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131; or
 2. 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 41.2(69), 41.2(75), 41.2(82), or equivalent NRC or agreement state requirements; has experience in administering dosages orally with greater than 33 millicuries of sodium iodide I-131, as specified in 41.2(69)“b”(1)“2,” seventh bulleted paragraph; 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 41.2(82)“c”(1) and (2).
- 41.2(83) Provisions for the protection of human research subjects.**
- a. A licensee may conduct research involving human research subjects only if the licensee uses the radioactive materials authorized on its specific license for the uses authorized on its license.
 - b. If the research is conducted, funded, supported, or regulated by another federal agency that has implemented Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research:
 - (1) Obtain review and approval of the research from an “Institutional Review Board,” as defined and described in the Federal Policy; and
 - (2) Obtain “informed consent,” as defined and described in the Federal Policy, from the human research subjects.
 - c. If the research will not be conducted, funded, supported, or regulated by another federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:
 - (1) Obtain review and approval of the research from an “Institutional Review Board,” as defined and described in the Federal Policy; and

(2) Obtain “informed consent,” as defined and described in the Federal Policy, from the human research subjects.

d. Nothing in this subrule relieves a licensee from complying with the other requirements of these rules.

41.2(84) *Calibration measurements of brachytherapy sources.*

a. Before the first medical use of a brachytherapy source on or after January 1, 2003, a licensee shall have:

(1) Determined the source output or activity using a dosimetry system that meets the requirements of 41.2(57);

(2) Determined the source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of 41.2(84)“*a.*”

b. A licensee may use measurements that are provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine and that are made in accordance with 41.2(84)“*a*”(1) and (2).

c. A licensee shall mathematically correct the outputs or activities determined in 41.2(84)“*a*” for physical decay at intervals consistent with 1 percent physical decay.

d. A licensee shall retain a record of each calibration for three years after the last use of the source. The record must include:

(1) The date of the calibration;

(2) The manufacturer’s name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The signature of the authorized medical physicist.

41.2(85) *Strontium-90 sources for ophthalmic treatment.*

a. Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in 41.2(85)“*b*” are performed by either:

(1) An authorized medical physicist; or

(2) An individual who:

1. Is identified as an ophthalmic physicist on a specific medical use license issued by the NRC or an agreement state, permit issued by an NRC or agreement state broad scope medical use licensee, medical use permit issued by an NRC master material licensee, or permit issued by an NRC master material licensee broad scope medical use permittee; and

2. 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

3. Has successfully completed one 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

4. Has documented training in:

- The creation, modification, and completion of written directives;

- Procedures for administrations requiring a written directive; and

- Performing the calibration measurements of brachytherapy sources as detailed in 41.2(84).

b. The individuals who are identified in 41.2(85)“*a*” must:

(1) 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 41.2(84); 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 41.2(85)“*a*” 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.

c. A licensee shall retain a record of the activity of each strontium-90 source for the life of the source. The record must include:

- (1) The date and initial activity of the source under 41.2(84); and
- (2) For each decay calculation, the date and the source activity as determined under this subrule.

41.2(86) *Therapy-related computer systems.* The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance must include, as applicable, verification of:

- a. The source-specific input parameters required by the dose calculation algorithm;
- b. The accuracy of dose, dwell time, and treatment time calculations at representative points;
- c. The accuracy of isodose plots and graphic displays;
- d. The accuracy of the software used to determine sealed source positions from radiographic images; and
- e. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

41.2(87) *Written directives.* Each licensee or registrant shall meet the following objectives:

a. A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries, any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable.

(2) The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

b. Prior to administration, a written directive must contain the patient's or human research subject's name and the following information:

(1) For any administration of quantities greater than 30 microcuries of sodium iodide I-131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate setting per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;

(5) For high-dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions and total dose;

(6) For permanent implant brachytherapy:

1. Before implantation: the treatment site, the radionuclide, and the total source strength; and

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

(7) For all other brachytherapy, including low-, medium-, and pulsed-dose-rate remote afterloaders:

1. Prior to implantation: treatment site, the radionuclide, and dose; and

2. After implantation but prior to completion of the procedure: the radionuclide, treatment site, number of sources, total source strength and exposure time (or, equivalently, the total dose), and date;

(8) For therapeutic use of radiation machines, see 41.3(14).

c. Prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.

d. The final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives.

e. Each administration is in accordance with the written directive through checking both manual and computer-generated dose calculations and verifying that any computer-generated dose calculations are correctly transferred into the consoles of the medical units authorized by 641—Chapter 41.

f. Determine if a reportable medical event, as described in 641—38.2(136C), has occurred.

g. Determine, for a 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 postimplantation portion of the written directive, unless a written justification of patient unavailability is documented.

h. 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 byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(1) If, because of the patient's condition, a delay in order 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.

(2) 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.

i. A copy of the written directive in auditable form shall be retained for three years after the date of administration.

41.2(88) *Other medical uses of byproduct material or radiation from byproduct material.* A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in 641—41.2(136C) (e.g., Y-90 microspheres, liquid brachytherapy, intravascular brachytherapy) if:

a. The applicant or licensee has submitted the information required by the agency; and

b. The applicant or licensee has received written approval from the agency in a license or license amendment and uses the material in accordance with the regulations and specific conditions the agency considers necessary for the medical use of the material.

41.2(89) *Training for the parenteral administration of unsealed byproduct material requiring a written directive.*

a. Except as provided in 41.2(75), the licensee shall require an authorized user for the parenteral administration requiring a written directive to be a physician who:

(1) Is an authorized user under 41.2(69) for parenteral administration uses listed in 41.2(69) "b"(1)"2," seventh bulleted paragraph, or equivalent NRC or agreement state requirements; or

(2) Is an authorized user under 41.2(70) or 41.2(73) or equivalent NRC or agreement state requirements, and who meets the requirements in 41.2(89) "b"; or

(3) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state under 41.2(70) or 41.2(73) and who meets the requirements in 41.2(89) "b"; or

b. The physician:

(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in 41.2(69) "b"(1)"2," seventh bulleted paragraph. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(89) or equivalent NRC or agreement state requirements, in the parenteral administration listed in 41.2(69) "b"(1)"2," seventh bulleted paragraph. A supervising authorized user who meets the requirements in 41.2(69), 41.2(89), or equivalent NRC or agreement state requirements must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

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

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

5. Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

6. Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration as specified in 41.2(69)“b”(1)“2,” seventh bulleted paragraph; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(89)“b”(1) or (2), and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(89) or equivalent NRC or agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69), 41.2(89) or equivalent NRC or agreement state requirements must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

2. 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 41.2(69), 41.2(75), 41.2(89), or equivalent NRC or agreement state requirements; 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 41.2(89)“b”(1) and (2).

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