ARC 5059C

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Rule making related to radiation machines and radioactive materials

The Public Health Department hereby amends Chapter 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," Chapter 38, "General Provisions for Radiation Machines and Radioactive Materials," Chapter 39, "Registration of Radiation Machine Facilities, Licensure of Radioactive Materials and Transportation of Radioactive Materials," Chapter 40, "Standards for Protection Against Radiation," Chapter 41, "Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials," and Chapter 45, "Radiation Safety Requirements for Industrial Radiographic Operations," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code chapter 136C.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 136C.

Purpose and Summary

These amendments reflect current federal regulations, amend rules to correct errors discovered by staff, and amend rules to meet U.S. Nuclear Regulatory Commission (USNRC) compatibility requirements pursuant to the stipulations of the state of Iowa's status as a USNRC agreement state. Additional amendments clarify rules related to new technology for dosimetry processes that have become available and radiation machines used on humans for security purposes at correctional facilities and jails.

Iowa rules must maintain compatibility as defined by the USNRC. Most of these amendments require the wording to be the same as or substantially the same as that published in the CFR by the USNRC. The dosimetry and machine-related rules are two areas that have been prohibited in the current rules and have been allowed through a variance process for the last couple of years.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on January 15, 2020, as **ARC 4856C**. No public comments were received. The USNRC provided five comments requesting minor changes to Items 2, 48, and 55. In response to the USNRC comments, the following changes were made from the Notice:

In Item 2: The phrase "in accordance with rule 641—37.7(136C)" was added to the new sentence in paragraph 37.23(2)"b."

In Item 48: The phrase "for three years" has been stricken, and the following phrase was added in its place: "until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit."

In Item 53: The phrase "oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide (I-131) for" was added to the first sentence in subparagraph 41.2(81)"c"(3), and the phrase "oral administration of greater than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide (I-131) for" was added to the first sentence in subparagraph 41.2(82)"c"(3).

In Item 55: The word "with" was stricken and the word "within" was added in its place in subparagraph 41.2(87)"h"(2).

In Item 56: In 41.2(89)"b"(3)"2," a citation to subrule 41.2(59) was corrected to instead cite subrule 41.2(69) and the words "NRC or" were added so that the language now reads as follows: "or equivalent NRC or agreement state requirements."

Adoption of Rule Making

This rule making was adopted by the State Board of Health on May 13, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 22, 2020.

The following rule-making actions are adopted:

ITEM 1. Amend subrule 37.1(4) as follows:

37.1(4) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 16, 2018~~ July 22, 2020.

ITEM 2. Amend paragraph **37.23(2)"b"** as follows:

b. Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Each licensee shall provide oath or affirmation certifications to the agency in accordance with rule 641—37.7(136C). The fingerprints of the named reviewing official must be taken by a law enforcement agency, federal or state agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a state to take fingerprints. Every ten years, the licensee shall recertify that the reviewing official is deemed trustworthy and reliable in accordance with 37.25(3).

ITEM 3. Amend subrule 37.27(3) as follows:

37.27(3) *Procedures for processing of fingerprint checks.*

a. For the purpose of complying with these rules, licensees shall use an appropriate method listed in 10 CFR 37.7 to submit to the U.S. Nuclear Regulatory Commission, Director, Division of ~~Facilities and Security~~ Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop ~~TWB-05-B32M~~ T-8B20, Rockville, Maryland 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category

1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by ~~writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling (630)829-9565, or by email to FORMS.Resource@nrc.gov~~ emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at ~~www.nrc.gov/site-help/e-submittals.html~~ www.nrc.gov/security/chp.html.

b. Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the ~~Security Branch, Division of Facilities and Security at 1-301-492-3531~~ Division of Physical and Cyber Security Policy by emailing Crimhist.Resource@nrc.gov.) Combined payment for multiple applications is acceptable. The Nuclear Regulatory Commission publishes the amount of the fingerprint check application fee on the NRC's public website. (To find the current fee amount, go to the ~~Electronic Submittals page at www.nrc.gov/site-help/e-submittals.html and see the link for the Criminal History Program under Electronic Submission Systems.)~~ Licensee Criminal History Records Checks & Firearms Background Check information page at www.nrc.gov/security/chp.html and see the link for "How do I determine how much to pay for the request?")

c. The Nuclear Regulatory Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

ITEM 4. Amend subrule 37.43(4) as follows:

37.43(4) *Protection of information.*

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

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

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

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

(2) If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in 37.25(1).

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

(1) The categories of individuals listed in rule 641—37.29(136C); or

(2) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in 37.25(1), has been provided by the security service provider.

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

f. Licensees shall maintain a list of persons currently approved for access to the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access, or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person

from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to obtain the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access.

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

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

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

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

ITEM 5. Amend rule 641—37.77(136C) as follows:

641—37.77(136C) Advance notification of shipment of category 1 quantities of radioactive material.

37.77(1) As specified in 37.77(1)*"a"* and *"b,"* each licensee shall provide advance notification to the NRC and the governor of a state, or the governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the state, before the transport, or delivery to a carrier for transport, of the licensed material outside the confines of the licensee's facility or other place of use or storage.

a. Procedures for submitting advance notification.

(1) The notification must be made to the NRC and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the NRC's website at scp.nrc.gov/special/designee.pdf. A list of the contact information is also available upon request from the Director, Division of ~~Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs,~~ Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Notifications to the NRC must be to the NRC's Director, ~~Division of Security Policy,~~ Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The notification to the NRC may be made by email to RAMQC_SHIPMENTS@nrc.gov or by fax to (301)816-5151.

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

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

b. Information to be furnished in advance notification of shipment. Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

(2) The license numbers of the shipper and receiver;

(3) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(4) The point of origin of the shipment and the estimated time and date that shipment will commence;

(5) The estimated time and date that the shipment is expected to enter each state along the route;

(6) The estimated time and date of arrival of the shipment at the destination; and

(7) A point of contact, with a telephone number, for current shipment information.

c. Revision notice.

(1) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the state or the governor's designee and to the NRC's Director ~~of Nuclear Security~~, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(2) A licensee shall promptly notify the governor of the state or the governor's designee of any changes to the information provided in accordance with 37.77(1)*"b"* and 37.77(1)*"c"*(1). The licensee shall also immediately notify the NRC's Director, ~~Division of Security Policy,~~ Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, of any such changes.

d. Cancellation notice. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the governor of each state or to the governor's designee previously notified and to the NRC's Director, ~~Division of Security Policy,~~ Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled.

e. Records. The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for three years.

f. Protection of information. State officials, state employees, and other individuals, whether or not licensees of the commission or an agreement state, who receive schedule information of the kind specified in 37.77(1)*"b"* shall protect that information against unauthorized disclosure as specified in 37.43(4).

ITEM 6. Amend subrule 38.1(2) as follows:

38.1(2) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 16, 2018~~ July 22, 2020.

ITEM 7. Adopt the following **new** definitions of "FDA" and "Sealed Source and Device Registry" in rule **641—38.2(136C)**:

"FDA" means the Food and Drug Administration.

"Sealed Source and Device Registry" or *"SSDR"* means the national registry that contains all the registration certificates, generated by both the NRC and the agreement states, that summarizes the radiation safety information for the sealed sources and devices and describes the licensing and use conditions approved for the product.

ITEM 8. Amend rule **641—38.2(136C)**, definitions of "Agreement state," "Decay-in-storage," "Preceptor" and "Reportable medical event," as follows:

"Agreement state" means any state with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under Subsection 274b of the Atomic Energy Act of 1954 as amended (73 Stat. 689). The state of Iowa is an agreement state as of January 1, 1986.

"Decay-in-storage" means the holding of radioactive material having half-lives of less than or equal to 120 days~~, except Cobalt-57,~~ until it decays to background levels. Before disposal in ordinary trash, the material must have been held for a minimum of ten half-lives and its radioactivity is indistinguishable from background as indicated by a survey meter set on its most sensitive scale with no interposing shielding.

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

"Reportable medical event" means the medical event~~, except for an event that results from patient intervention, in which the administration of by-product material or radiation from by-product material results in~~:

~~*a.* A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and~~

~~1. The total dose delivered differs from the prescribed dose by 20 percent or more;~~

~~2. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or~~

~~3. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.~~

~~*b.* A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:~~

~~1. An administration of the wrong radioactive drug containing by-product material;~~

~~2. An administration of a radioactive drug containing by-product material by the wrong route of administration;~~

~~3. An administration of a dose or dosage to the wrong individual or human research subject;~~

~~4. An administration of a dose or dosage delivered by the wrong mode of treatment; or~~

~~5. A leaking sealed source.~~

~~*c.* A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).~~

~~*d.* An event resulting from intervention of a patient or human research subject in which administration of by-product material or radiation from by-product material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.~~

a. In which, except for an event that results from patient intervention:

(1) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in:

1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and

- The total dose delivered differs from the prescribed dose by 20 percent or more;
- The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
- The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

2. A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

- An administration of the wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;
- An administration of a radioactive drug containing byproduct material by the wrong route of administration;
- An administration of a dose or dosage to the wrong individual or human research subject;
- An administration of a dose or dosage delivered by the wrong mode of treatment; or
- A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

- 50 rem (0.5 Sv) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and
- 50 percent or more the expected dose from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration;

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

1. The total source strength administered differing by 20 percent or more from the total source strength documented in the postimplantation portion of the written directive;

2. The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the postimplantation portion of the written directive; or

3. An administration that includes any of the following:

- The wrong radionuclide;
- The wrong individual or human research subject;
- Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the postimplantation portion of the written directive; or
- A leaking sealed source resulting in a dose that exceeds 50 rem (0.5 Sv) to an organ or tissue.

b. Resulting from intervention of a patient or human research subject in which administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

ITEM 9. Rescind the definition of "Teletherapy" in rule **641—38.2(136C)**.

ITEM 10. Amend rule 641—38.6(136C) as follows:

641—38.6(136C) Prohibited uses. A hand-held fluoroscopic screen shall not be used with X-ray equipment unless it has been accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health. A shoe-fitting fluoroscopic device shall not be used. Radiation from radiation-emitting machines or radioactive materials shall not be used on humans for nonmedical purposes except as approved by the agency for security-related purposes.

ITEM 11. Amend subrule 38.8(2) as follows:

38.8(2) *Radioactive material fee schedule.* Fees associated with the possession and use of radioactive materials in Iowa shall not exceed those specified in 10 CFR 170.31 and 10 CFR 171.16. The following fee schedule shall apply.

	Program Code	Category	Type	New License Fee	Inspection Priority	Annual Fee
(3.L.)	01100	AAB	Academic Type A Broad	$5,400	1	$14,600
(8.A.)	03710	CD	Civil Defense	$2,500	5	$2,000
(3.E.)	03510	I1	Irradiators, Self-Shielding <10,000 Curies	$3,200	5	$2,600
(3.O.)	03320	IR1	Industrial Radiography – Temporary Job Sites	$3,100	1	$8,000
(3.P.)	03120	FG	Measuring Systems – Fixed Gauge	$3,400	5	$2,000
(3.P.)	03121	PG	Measuring Systems – Portable Gauge	$3,400	5	$2,000
(3.P.)	02410	IVL	*In-Vitro* Testing Laboratory	$3,400	5	$2,000
(7.C.)	02230	HDR	High Dose Rate Afterloader	$5,500	1	$5,100
(7.C.)	02120	M1	Medical – Diagnostic & Therapy	$5,500	3	$4,000
(7.C.)	02121	M2	Medical – Diagnostic Only	$5,500	4	$3,600
(7.C.)	02240	MET	Medical – Diagnostic, Therapeutic, Emerging Technologies	$5,500	2	$4,500
(3.S.)	03210	PET	Accelerator-Produced RAM	$7,500	1	$5,375
(3.C.)	02500	NP	Nuclear Pharmacy	$5,100	1	$7,700
(7.C.)	02231	NV1	Nuclear Medical Van	$4,140	2	$4,000

	Program Code	Category	Type	New License Fee	Inspection Priority	Annual Fee
(7.C.)	22160	PMM	Pacemaker – Byproduct and/or SNM	$2,600	~~T~~ R	Note 5
(3.M.)	03620	RD2	Research & Development – Other	$4,375	3	$4,000
(2.C.)	11300	SM1	Source Material, Other, >150 Kilograms	$2,600	3	$4,000
(1.D.)	22120	SNM2	SNM Plutonium – Neutron Source	$2,600	5	$3,750
(3.P.)	03221	CAL	Calibration and W/L Tests	$2,275	5	$3,900
(3.P.)	03122	XRF	X-Ray Fluorescent Analyzer	$2,275	~~7~~ 5	$1,860
(3.P.)	02400	VMT	Veterinary Medicine – Therapy	$3,250	3	$3,900
(3.B.)	03214	MD	Manufacturing/Distribution	$3,500	3	$3,980

NOTES:

1. Reciprocity fee is $1,800 annually (180 days).
2. Inspection priorities are based on NRC inspection manual chapter 2800. Priority ~~"T"~~ "R" is a ~~telephonic~~ remote contact and is not considered an inspection.
3. License amendment fee for all categories is $600.
4. Annual fees are due no later than September 1 of each year. A 10 percent late charge will be assessed per month for late payments. Licensees with more than two authorized locations of use will be charged an additional 10 percent of the annual fee per location.
5. Separate annual fees will not be assessed for pacemaker licenses issued to medical institutions that also hold nuclear medicine licenses with the agency.
6. General license registration fee is $700 annually on registration anniversary.

ITEM 12. Amend subrule 38.8(12) as follows:

38.8(12) *Fee waiver.* Any fee may be waived in exchange for services (low-level waste disposal, radiation detection instrument calibration, instrument repair, sample analysis, etc.) provided to the agency. The waiver may only occur as a result of a 28E agreement or memorandum of understanding between the parties.

ITEM 13. Amend subrule 38.9(1) as follows:

38.9(1) *Scope.*

a. This rule prescribes the procedure in cases initiated by the staff, or upon a request by any person, to impose requirements by order, or to modify, suspend, or revoke a license, registration, or certificate or to take other action as may be proper against any person subject to the jurisdiction of the agency. The term "regulated entity" as used in this rule refers to any facility, person, partnership, corporation or other organization which is regulated by the agency by virtue of these rules, the Iowa Code, licensing documents, registrations, certificates, or other official regulatory promulgation. "Authorization" means license, registration, certificate, permit, or any other document issued or received by the agency that authorizes specific activities related to the possession and use of radioactive materials or radiation-producing machines in Iowa.

b. This rule also prescribes the procedures in cases initiated by the staff to impose civil penalties pursuant to Iowa Code section 136C.4~~, to impose serious misdemeanor penalties pursuant to Iowa Code section 136B.5 or to impose simple misdemeanor penalties pursuant to Iowa Code section 136D.8~~.

ITEM 14. Amend subrule 39.1(3) as follows:

39.1(3) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 16, 2018~~ July 22, 2020.

ITEM 15. Amend paragraph **39.3(2)"a"** as follows:

a. Apply for registration of such facility with the agency prior to the operation of a radiation machine facility. In order to register equipment, the person must have a storage area located in Iowa where records of equipment maintenance and quality assurance, personnel monitoring, and personnel certification must be kept for review during an inspection. The records may be stored on a ~~van~~ vehicle, if appropriate. An Iowa mailing address is not required. Application for registration shall be completed on forms furnished by the agency, shall contain all information required by the agency as indicated on the forms and accompanying instructions, and shall include the appropriate fee from 641—38.8(136C).

ITEM 16. Amend subparagraph **39.4(21)"e"(3)** as follows:

(3)

1. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 39.4(21)*"e"*(1) shall file Agency Form "Registration Certificate—Use of Depleted Uranium Under General License" with the agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish on the Agency Form "Registration Certificate—Use of Depleted Uranium Under a General License" the following information and such other information as may be required by that form:

- Name and address of the general licensee;
- A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 39.4(21)*"e"*(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and
- Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 39.4(21)*"e"*(3)"1."

2. The general licensee possessing or using depleted uranium under the general license established by 39.4(21)*"e"*(1) shall report in writing to the agency any changes in information furnished by the general licensee in Agency Form "Registration Certificate—Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

ITEM 17. Amend subparagraph **39.4(22)"d"(3)** as follows:

(3) Any person who acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license in 39.4(22)*"d"*(1):

1. to 12. No change.

13. Shall register as follows:

- Shall register devices as approved in the Sealed Source and Device Registry. Each address for a location of use, as described in 39.4(22)*"d"*(3)"13," represents a separate general licensee and requires a separate registration and fee;
- If in possession of devices meeting the criteria of 39.4(22)*"d"*(3)"13," shall register these devices annually with the agency and shall pay the fee required in 641—paragraph 38.8(2)*"c."* Registration must be done by verifying, correcting, and adding to the information provided in a request for registration received from the agency. The registration information must be submitted 30 days from the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of 39.4(22)*"d"*(3)"13" is subject to the bankruptcy notification requirement of 39.4(32)*"e"*;
- In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the agency:

—Name and mailing address of the general licensee;

—Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label);

—Name, title, and telephone number of the responsible person designated as a representative of the general licensee;

—Address or location at which the device(s) is both used and stored. For portable devices, the address of the primary place of storage;

—Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and check of label information.;

—Certification by the responsible representative of the general licensee that the licensee is aware of the requirements of the general license.

- Persons generally licensed by this agency under 39.4(22)*"d"*(3)"13" or an agreement state are not subject to registration requirements of 39.4(22)*"d"*(3)"13" if the devices are used in areas subject to this agency's jurisdiction for a period of less than 180 days in any calendar year. The agency will not request registration information from such licensees;

14. and 15. No change.

ITEM 18. Amend subparagraph **39.4(29)"j"(1)** as follows:

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing ~~by-product~~ byproduct material for use by persons authorized pursuant to 641—41.2(136C) will be approved if:

1. to 3. No change.

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

- A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted.
- A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

ITEM 19. Amend subparagraph **39.4(29)"j"(2)** as follows:

(2) A licensee as described by 39.4(29)*"j"*(1)"2":

1. to 4. No change.

5. Shall provide to the agency a copy of each individual's:

- Certification by a specialty board whose certification process has been recognized by the NRC or an agreement state as specified in 641—paragraph 41.2(78)*"a"* ~~with the written attestation signed by a preceptor as required by 641—paragraph 41.2(78)*"c"*~~; or
- NRC or agreement state license; or
- NRC master materials licensee permit; or
- Permit issued by a licensee or NRC master materials permittee of broad scope or authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or
- Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and
- State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to 39.4(29)*"j"*(2)"2," first and third bulleted paragraphs, the individual to work as an authorized nuclear pharmacist.

ITEM 20. Renumber subparagraphs **39.4(29)"j"(3)** and **(4)** as **39.4(29)"j"(4)** and **(5)**.

ITEM 21. Adopt the following **new** subparagraph **39.4(29)"j"(3)**:

(3) A licensee shall satisfy the labeling requirements in 39.4(29)*"j."*

ITEM 22. Amend paragraph **39.4(32)"e"** as follows:

e. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination,

respectively, in accordance with 641—subrule 41.2(34). The licensee shall record the results of each test and retain each record for three years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in 641—paragraph 41.2(34)*"a"* at the time of generator elution, in accordance with 641—paragraph 41.2(34)*"e."*

ITEM 23. Amend subrule 40.1(5) as follows:

40.1(5) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 16, 2018~~ July 22, 2020.

ITEM 24. Amend subrule 40.16(1) as follows:

40.16(1) If the licensee or registrant is required to monitor pursuant to both ~~40.19(1)~~ 40.37(1) and ~~40.19(2)~~ 40.37(2), the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to ~~40.19(1)~~ 40.37(1), or only pursuant to ~~40.19(2)~~ 40.37(2), then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to 40.16(2), 40.16(3) and 40.16(4). The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

ITEM 25. Amend subrule 40.37(3) as follows:

40.37(3) Location of individual monitoring devices. Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with 641—40.37(136C) wear individual monitoring devices in accordance with the dosimetry vendor specifications and processed in accordance with NVLAP-approved calculation methods. Additional requirements are as follows:

~~*a.* An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded portion of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device shall be near the midline of the body, under the apron;~~

~~*b.*~~ *a.* An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman shall be located at the waist under any protective apron being worn by the woman;

~~*c.*~~ *b.* An individual monitoring device used for monitoring the eye dose equivalent, to demonstrate compliance with 641—40.15(136C) shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye;

~~*d.*~~ *c.* An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with 641—40.15(136C), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

ITEM 26. Amend paragraph **41.2(1)"b"** as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 16, 2018~~ July 22, 2020.

ITEM 27. Adopt the following **new** definitions of "Associate radiation safety officer," "Ophthalmic physicist," "Stereotactic radiosurgery" and "Teletherapy" in subrule **41.2(2)**:

"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.

"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.

"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.

ITEM 28. Amend subrule **41.2(2)**, definition of "Radiation safety officer," as follows:

"Radiation safety officer" means an individual who, in addition to the definition in 641—38.2(136C)~~, meets the requirements of 41.2(77) and 41.2(65)*"a,"* or 41.2(65)*"c"*(1), or before May 3, 2006, meets the requirements in 10 CFR 35.900(a) and 10 CFR 35.59; or is identified as a radiation safety officer on a specific medical use license issued by Iowa, the NRC, or agreement state or a medical use permit issued by an NRC master material licensee.~~:

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.

ITEM 29. Rescind the definition of "Teletherapy physicist" in subrule **41.2(2)**.

ITEM 30. Amend subrules 41.2(4) and 41.2(5) as follows:

41.2(4) *License amendments.*

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

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

~~*b.*~~ (2) Before permitting anyone~~, except a visiting authorized user or visiting authorized nuclear pharmacist described in 41.2(12),~~ 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);

~~*c.*~~ (3) Before changing a radiation safety officer~~, teletherapy physicist or authorized medical physicist~~;

(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;

~~*d.*~~ (5) Before receiving ~~radioactive~~ byproduct material in excess of the amount authorized on the license;

~~*e.*~~ (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.

~~*f.* Before changing statements, representations, and procedures which are incorporated into 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 provide to the agency a copy of the board certification, the NRC or agreement state license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as a visiting authorized user or a visiting authorized nuclear pharmacist.~~

~~*b.* A licensee shall notify the agency by letter no later than 30 days after:~~

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

~~(2) The licensee's mailing address changes.~~

~~*c.* The licensee shall mail the documents required in this subrule to the Iowa Department of Public Health, Des Moines, Iowa.~~

~~*d.* 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)*"b"*;~~

~~(2) The provisions of 41.2(4)*"e"* regarding additions to or changes in the areas of use only at the addresses specified in the license;~~

~~(3) The provision of 41.2(5)*"a"*;~~

~~(4) The provisions of 41.2(5)*"b"*(1) for authorized user or an authorized nuclear pharmacist.~~

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).

ITEM 31. Amend paragraphs **41.2(10)"b"** and **"c"** as follows:

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 authorized user or~~ 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).

ITEM 32. Amend subrule 41.2(12) as follows:

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 ~~an agency, agreement state, licensing state or U.S. Nuclear Regulatory Commission~~ 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 ~~as an authorized user~~ 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 ~~agency (~~ NRC or agreement state~~, licensing state or U.S. Nuclear Regulatory Commission)~~ 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.

ITEM 33. Amend subrule 41.2(14) as follows:

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

a. When a ~~misadministration or~~ 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 ~~misadministration or~~ 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 ~~misadministration or~~ 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 ~~misadministration or~~ 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 ~~misadministration or~~ reportable medical event, a written report to the patient or the human research subject and the referring physician by sending either:

1. and 2. No change.

c. Rescinded IAB 4/4/01, effective 5/9/01.

d. Each licensee shall retain a record of ~~each misadministration for ten years and~~ 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. and *f.* No change.

ITEM 34. Amend paragraph **41.2(17)"e"** as follows:

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) to (4) No change.

ITEM 35. Amend subrule 41.2(20) as follows:

41.2(20) *Authorization for calibration and reference sources.*

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

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

~~*b.*~~ (2) Any ~~radioactive~~ 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);

~~*c.*~~ (3) Any ~~radioactive~~ 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

~~*d.*~~ (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.

ITEM 36. Rescind and reserve subrule **41.2(32)**.

ITEM 37. Amend subrule 41.2(34) as follows:

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 ~~preparing:~~ 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."*

~~(1) Technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract; or~~

~~(2) Rubidium-82 radiopharmaceuticals from strontium-82/rubidium-82 generators shall measure the strontium-82 and strontium-85 concentration before the first patient use of the day.~~

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."*

~~*c.*~~ *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.

~~*d.*~~ *e.* A licensee shall report ~~immediately to the agency each occurrence of molybdenum-99 concentration exceeding the limits specified in 41.2(34)*"a"*(1) and strontium-82 or strontium-85 concentration exceeding the limits specified in 41.2(34)*"a"*(2).~~ 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."*

ITEM 38. Rescind and reserve subrule **41.2(36)**.

ITEM 39. Amend subrule 41.2(37), introductory paragraph, as follows:

41.2(37) *Use of unsealed ~~by-product~~ byproduct material for which a written directive is required.* A licensee may use any unsealed ~~by-product~~ 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:

ITEM 40. Amend subrule 41.2(38) as follows:

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 ~~keep~~ maintain a record of ~~individuals receiving instruction required by 41.2(38)"a,"~~ 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.

ITEM 41. Amend subrule 41.2(39), catchwords, as follows:

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

ITEM 42. Rescind and reserve subrule **41.2(40)**.

ITEM 43. Amend subrule 41.2(41) as follows:

41.2(41) *Use of sealed sources for diagnosis.* ~~A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.~~

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.

ITEM 44. Rescind and reserve subrule **41.2(42)**.

ITEM 45. Amend subrules 41.2(43) to 41.2(45) as follows:

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

a. As approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

b. In research to deliver therapeutic doses for medical use 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 ~~implant therapy~~ 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 ~~individuals receiving instruction required by 41.2(44)*"a,"*~~ 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 ~~implant therapy~~ manual brachytherapy a licensee shall:

(1) to (6) No change.

b. No change.

ITEM 46. Rescind and reserve subrule **41.2(48)**.

ITEM 47. Amend subrule 41.2(49) as follows:

41.2(49) *Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.* ~~A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses as approved in the Sealed Source and Device Registry or in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15) are met.~~

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.

ITEM 48. Amend subrule 41.2(52) as follows:

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

a. to *c.* No change.

d. A licensee shall ~~provide~~:

(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)~~ 1. The procedures identified in 41.2(52)*"a"*(4); and

~~(2)~~ 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)*"d,"*~~ 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)*"a"*(4) and~~ 41.2(52)*"d"*(2) shall be retained ~~for three years~~ until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

ITEM 49. Amend subrule 41.2(53), catchwords, as follows:

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

ITEM 50. Rescind and reserve subrule **41.2(54)**.

ITEM 51. Amend subrules 41.2(64) to 41.2(75) as follows:

41.2(64) ~~*Five-year inspection*~~ *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 ~~teletherapy~~ each source replacement ~~or at intervals not to exceed five years, whichever comes first,~~ to ~~ensure~~ 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 ~~agency,~~ NRC or an agreement state~~, or the U.S. Nuclear Regulatory Commission~~.

c. A licensee shall maintain a record of the full inspection and servicing for the duration of the ~~license~~ 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 ~~this agency,~~ the NRC~~,~~ or an agreement state and who meets the requirements in 41.2(65)*"d."* ~~and *"e."* (~~The names of the ~~specialty boards~~ board certifications that have been recognized by the ~~agency,~~ NRC~~,~~ or an agreement state ~~must be~~ 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 ~~agency,~~ 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 ~~completed~~:

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

~~(1)~~ 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. Radiation biology; and~~

~~5. Radiation dosimetry; and~~

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

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

~~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 instruments used to measure radionuclides;~~

~~3. Securing and controlling radioactive material;~~

~~4. Using administrative controls to avoid mistakes in the administration of radioactive material;~~

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

~~6. Using emergency procedures to control radioactive material; and~~

~~7. Disposing of radioactive material; or~~

- 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 ~~agency,~~ NRC~~,~~ or an agreement state under ~~41.2(74) and~~ 41.2(74)*"a,"* has experience in radiation safety ~~for~~ aspects of similar types of use of ~~radioactive~~ 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 ~~who~~ meets the requirements in 41.2(65)*"d"* ~~and *"e"*~~; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on ~~the licensee's~~ an NRC or agreement state license ~~and~~, 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 ~~radioactive~~ byproduct material for which the licensee seeks the approval of the individual ~~has~~ as the radiation safety officer ~~responsibilities~~ or associate radiation safety officer and meets the requirements in 41.2(65)*"d"*; ~~and~~ 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 obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in 41.2(65)*"e"* and 41.2(65)*"a"*(1)"1" and "2" or 41.2(65)*"a"*(2)"1" and "2" or 41.2(65)*"b"*(1) or 41.2(65)*"c"*(1), and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and~~

~~*e.*~~ *d.* Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee ~~is seeking~~ 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) *Training for experienced radiation safety officer.* Rescinded IAB 3/29/06, effective 5/3/06.

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 ~~radioactive~~ 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 ~~agency,~~ NRC~~,~~ or an agreement state ~~and who meets the requirements in 41.2(67)*"c."* (~~. The names of ~~specialty boards~~ board certifications that have been recognized by the ~~agency,~~ NRC~~,~~ or agreement state ~~must be~~ 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~~, signed by 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,~~ that the individual has satisfactorily completed the requirements in ~~41.2(67)*"a"*(1) or~~ 41.2(67)*"c"*(1) and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user ~~for the medical uses authorized in~~ 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 ~~radioactive~~ 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 ~~agency,~~ NRC~~,~~ or an agreement state ~~and who meets the requirements in 41.2(68)*"c."* (~~. The names of ~~specialty boards~~ board certifications that have been recognized by the ~~agency,~~ NRC~~,~~ or agreement state ~~must be~~ 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~~, and 41.2(69)~~; 41.2(75); or equivalent NRC or agreement state requirements~~, involving:~~. 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~~, signed by 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; 41.2(75); or equivalent NRC or agreement state requirements~~, that the individual has satisfactorily completed the requirements in ~~41.2(68)*"a"*(1) or~~ 41.2(68)*"c"*(1) and ~~has achieved a level of competency sufficient to function~~ 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 ~~by-product~~ 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 ~~radioactive~~ 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 ~~agency,~~ NRC~~,~~ or an agreement state and who meets the requirements in 41.2(69)*"b"*(1)"2," seventh bulleted paragraph~~, and 41.2(69)*"b"*(2)~~. ~~(~~The names of the ~~specialty boards~~ board certificates that have been recognized by the ~~agency,~~ NRC~~,~~ or agreement state ~~must be~~ are posted on the NRC's Medical Uses Licensee 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 ~~involving~~ 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 ~~either~~ any ~~beta emitter or a photon-emitting radionuclide with a~~ 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; ~~or~~ and

~~– Parenteral administration of any other radionuclide 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)*"a"*(1) and 41.2(69)*"b"*(1)"2," seventh bulleted paragraph, or~~ 41.2(69)*"b"*(1)~~,~~ and ~~has achieved a level of competency sufficient to function~~ 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 written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements. The preceptor authorized user who meets the requirements in 41.2(69)*"b"* must 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 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 ~~agency,~~ NRC~~,~~ or an agreement state~~, and who meets the requirements in 41.2(70)"b"(3)~~. (The names of the ~~specialty boards~~ board certifications that have been recognized by the ~~agency,~~ 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 ~~institution~~ 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~~, signed by a preceptor authorized user who meets the requirements in 41.2(70) or 41.2(75) or equivalent NRC or agreement state requirements,~~ that the individual has satisfactorily completed the requirements in ~~41.2(70)*"a"*(1) or~~ 41.2(70)*"b"*(1) and (2)~~,~~ and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user of 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 ~~has achieved a level of competency sufficient to function~~ 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 ~~for use in~~ 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)*"b"* and~~ 41.2(72)*"c"* and *"d"* and whose certification has been recognized by the ~~agency,~~ NRC~~,~~ or an agreement state. ~~(~~The names of the ~~specialty boards~~ board certificates that have been recognized by the ~~agency,~~ 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

~~*b.*~~ *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

~~c.~~ *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 ~~agency,~~ NRC~~,~~ or an agreement state~~,~~ and who meets the requirements in ~~41.2(73)*"b"*(3) and~~ 41.2(73)*"c."* ~~(~~The names of ~~the specialty boards~~ board certification that have been recognized by the ~~agency,~~ NRC~~,~~ or agreement state ~~must be~~ 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 ~~institution~~ 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)*"a"*(1) or~~ 41.2(73)*"b"*(1) and (2)~~,~~ and 41.2(73)*"c,"* and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The ~~written~~ attestation must be ~~signed by a~~ 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; ~~and~~ 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)*"b"*(2) and~~ 41.2(74)*"c."* ~~(~~The names of the ~~specialty boards~~ board certifications that have been recognized by the ~~agency,~~ NRC~~,~~ or agreement state ~~must be~~ 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 ~~agency,~~ 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)*"a"*(1) and (2) and 41.2(74)*"c"* or~~ 41.2(74)*"b"*(1) and ~~41.2(74)*"c,"*~~ *"c"* and ~~has achieved a level of competency sufficient to function~~ 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~~; and~~.

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 as a radiation safety officer, teletherapy or medical physicist, or nuclear pharmacist on an agency, NRC or agreement state license or a permit issued by an NRC or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope before January 1, 2003, does not need to comply with the training requirements of 41.2(65), 41.2(74), or 41.2(78).~~ 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) ~~An individual identified as a radiation safety officer, an authorized medical physicist, or an authorized nuclear pharmacist on the agency, NRC, or agreement state license or permit issued by the agency, NRC, or agreement state broad scope licensee or issued by master material license permit or issued by a master material license permittee of broad scope between January 1, 2003, and May 3, 2006, need not comply with the training requirements of 41.2(65), 41.2(74), or 41.2(78).~~ 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 ~~radioactive~~ byproduct material on a license issued by ~~the agency,~~ 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 ~~January 1, 2003~~ 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 ~~radioactive~~ byproduct material issued by ~~the agency,~~ 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 ~~between January 1, 2003, and May 3, 2006~~ 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.

ITEM 52. Amend subrules 41.2(77) and 41.2(78) as follows:

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 ~~as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements of 41.2(78)*"b."* (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's web page.)~~ 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) to (4) No change.

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

(1) No change.

(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 ~~by-product~~ 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)*"a"*(1), (2), and (3), or 41.2(78)*"b"*(1)~~ 41.2(78)*"b"* and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

ITEM 53. Amend subrules 41.2(81) and 41.2(82) as follows:

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 ~~agency,~~ NRC~~,~~ or an agreement state ~~and who meets the requirements in 41.2(81)*"c"*(3)~~. ~~(~~The names of the ~~specialty boards~~ board certifications that have been recognized by the ~~agency,~~ NRC~~,~~ or agreement state ~~must be~~ 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 ~~has achieved a level of competency sufficient to function~~ 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 ~~written~~ attestation must be ~~signed by a~~ 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~~. A preceptor authorized user who meets the requirements in 41.2(69)*"b"* must also have~~ 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 ~~agency,~~ NRC~~,~~ or agreement state~~, and who meets the requirements in 41.2(82)*"c"*(3)~~. (The names of the ~~specialty boards~~ board certifications that have been recognized by the ~~agency,~~ 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 ~~has achieved a level of competency sufficient to function~~ 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 ~~written~~ attestation must be ~~signed by a~~ 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~~. A preceptor authorized user who meets the requirements in 41.2(69)*"b"* must also have~~ 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).

ITEM 54. Amend subrule 41.2(85) as follows:

41.2(85) ~~*Decay of strontium-90*~~ *Strontium-90 sources for ophthalmic treatment.*

~~*a.* Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 41.2(84).~~

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.

~~*b.*~~ *c.* A licensee shall retain a record of the activity of each strontium-90 source ~~in accordance with 41.2(84).~~ 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.

ITEM 55. Amend subrule 41.2(87) as follows:

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 ~~by-product~~ byproduct material or any therapeutic dose of radiation from ~~by-product~~ 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 ~~either~~ sodium iodide ~~I-125 or~~ I-131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide ~~I-125 or~~ 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 ~~radioisotope~~ radionuclide, treatment site, dose per fraction, number of fractions and total dose; ~~or~~

(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

~~(6)~~ (7) For all other brachytherapy, including low-, medium-, and pulsed-dose-rate remote afterloaders:

1. Prior to implantation: treatment site, the ~~radioisotope~~ radionuclide, ~~number of sources, and source strengths~~ and dose; and

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

~~(7)~~ (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. ~~Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.~~ 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.

~~*g.*~~ *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 ~~by-product~~ 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 ~~with~~ within 48 hours of the oral revision.

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

ITEM 56. Amend subrule 41.2(89) as follows:

41.2(89) *Training for the parenteral administration of unsealed ~~by-product~~ 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:

~~*a.*~~ (1) Is an authorized user under 41.2(69) for parenteral administration ~~of either any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required~~ uses listed in 41.2(69)*"b"*(1)"2," seventh bulleted paragraph, or equivalent NRC or agreement state requirements; or

~~*b.*~~ (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)*"d"*~~ 41.2(89)*"b"*; or

~~*c.*~~ (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)*"d"*~~ 41.2(89)*"b"*; or

~~*d.*~~ *b.* The physician:

(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations~~, for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required~~ 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 ~~for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required~~ 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 ~~of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required~~ 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 ~~radioactive~~ byproduct material;

5. Using procedures to contain spilled ~~radioactive~~ 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 ~~for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required~~ 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 ~~*"c,"*~~ (2), and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed ~~by-product~~ byproduct material requiring a written directive. The ~~written~~ attestation must be ~~signed by a~~ 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 ~~of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required.~~ 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).

ITEM 57. Amend **641—Chapter 45**, title, as follows:

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL

RADIOGRAPHIC OPERATIONS, PARTICLE ACCELERATORS FOR NONHUMAN USE, ANALYTICAL X-RAY EQUIPMENT, AND WELL-LOGGING

ITEM 58. Amend paragraph **45.1(1)"b"** as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 16, 2018~~ July 22, 2020.

ITEM 59. Amend subrule 45.1(18) as follows:

45.1(18) ~~*Notification of incidents*~~ *Notifications.*

a. The agency shall be notified of thefts or losses of sources of radiation, overexposures, and excessive levels in accordance with 641—40.95(136C) and 641—40.97(136C).

b. Each licensee or registrant shall submit a written report within 30 days to the agency whenever one of the following events occurs:

(1) The source assembly cannot be returned to the fully shielded position and properly secured;

(2) The source assembly becomes disconnected from the drive cable;

(3) The failure of any component (critical to safe operation of the radiographic exposure device) to properly perform its intended function; or

(4) An indicator on a radiation-producing machine fails to show that radiation is being produced or an exposure switch fails to terminate production of radiation when turned to the off position.

c. The licensee or registrant shall include the following information in each report submitted in accordance with 45.1(18)*"b"*:

(1) A description of the equipment problem;

(2) Cause of each incident, if known;

(3) Manufacturer and model number of equipment involved in the incident;

(4) Location, time, and date of the incident;

(5) Actions taken to establish normal operations;

(6) Corrective actions taken or planned to prevent recurrence; and

(7) Names of personnel involved in the incident.

d. Any licensee conducting radiographic operations or storing radioactive material at any location not listed on the license for a period in excess of 180 days in a calendar year shall notify the agency prior to exceeding the 180 days.

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