

PUBLIC HEALTH DEPARTMENT [641]
Adopted and Filed

Pursuant to the authority of Iowa Code section 136C.3, the Department of Public Health hereby gives Notice of Intended Action to amend 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," Chapter 42, "Minimum Certification Standards for Diagnostic Radiographers, Nuclear Medicine Technologists, and Radiation Therapists," Chapter 45, "Radiation Safety Requirements for Industrial Radiographic Operations," and Chapter 46, "Minimum Requirements for Tanning Facilities," Iowa Administrative Code.

The following itemize the proposed changes.

Items 1, 11, 18, 21, 23, and 57 amend the rules to reflect current federal regulations.

Items 2 and 24 amend definitions to meet Nuclear Regulatory Commission (NRC) compatibility requirements.

Item 3 adds requirements for electronic records as new technology.

Items 4 and 10 correct the agency address.

Item 5 increases fees to cover the cost of the inspections.

Items 6 and 7 increase fees to cover the cost of administering the service.

Item 8 removes an incorrect reference.

Item 9 adds new language for highway route controlled quantities to correspond to the addition added in Item 2. It also increases a fee to cover the cost of monitoring the shipments.

Item 12 changes language to meet NRC compatibility requirements for decommissioning.

Items 13 and 15 increase fees required for financial assurance for decommissioning to meet NRC compatibility requirements.

Items 14 and 16 adopt new language for decommissioning to meet NRC compatibility requirements.

Item 17 adds new language for transportation of radioactive material to clarify language and to meet NRC compatibility requirements.

Items 19 and 20 add new language for security and control of certain licensed material to meet NRC compatibility requirements.

Item 22 clarifies the requirements for operators of different types of X-ray equipment.

Item 25 corrects a reference that is rescinded in another item.

Items 26, 27, 28, 29, and 30 correct language for medical use of radioactive material to meet NRC compatibility requirements.

Item 31 clarifies the term "physically present."

Item 32 rescinds subrule 41.2(65) and replaces it with updated language to meet NRC compatibility requirements for a radiation safety officer.

Item 33 rescinds subrule 41.2(66). The content of the rescinded subrule is incorporated into subrule 41.2(75) in Item 42.

Item 34 rescinds subrule 41.2(67) and replaces it with updated language to meet NRC compatibility requirements for training of authorized users for uptake, dilution, and excretion studies.

Item 35 amends language to meet NRC compatibility requirements for training of authorized users for imaging and localization studies.

Item 36 rescinds subrule 41.2(69) and replaces it with updated language to meet NRC compatibility requirements for training of authorized users of certain unsealed by-product material.

Item 37 rescinds subrule 41.2(70) and replaces it with updated language to meet NRC compatibility requirements for training of authorized users of manual brachytherapy sources.

Item 38 rescinds subrule 41.2(71) and replaces it with updated language to meet NRC compatibility requirements for training of authorized users for ophthalmic use of strontium-90.

Item 39 rescinds subrule 41.2(72) and replaces it with updated language to meet NRC compatibility requirements for training of authorized users of sealed sources for diagnosis.

Item 40 rescinds subrule 41.2(73) and replaces it with updated language to meet NRC compatibility requirements for training of authorized users of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Item 41 rescinds subrule 41.2(74) and replaces it with updated language to meet NRC compatibility requirements for training of authorized medical physicists.

Item 42 amends language to meet NRC compatibility requirements for experienced radiation safety officers, authorized medical physicists, authorized nuclear pharmacists, authorized users and teletherapy or medical physicists.

Item 43 corrects language by adding a reference.

Item 44 amends language to meet NRC compatibility requirements for authorized nuclear pharmacists.

Item 45 adopts new language to meet NRC compatibility requirements for training for authorized users for oral administration of sodium iodide I-131 in certain quantities.

Items 46, 47, and 48 remove certain mammography continuing education requirements for interpreting physicians because the FDA no longer requires the training.

Items 49 and 50 add requirements for physicians in mammography to be licensed physicians in Iowa. This change is to meet FDA and Iowa Board of Medical Examiners requirements.

Item 51 amends definitions by correcting a reference, removing a subject that does not apply and removing definitions that are defined in previous chapters.

Item 52 adds a word to correct a phrase.

Item 53 adds language to require additional training for limited radiographers opting to perform pediatric radiography. This training is not included in the basic training of limited radiographers. The additional training provides competency in pediatric radiography to improve imaging.

Item 54 clarifies dual imaging devices and adopts new language to require training for individuals operating certain dual imaging devices. This change is made in order to address new technology in imaging.

Item 55 corrects a misspelled word.

Item 56 adopts a new requirement for radiologist assistant to have a delegation agreement, similar to licensed physicians, on file at a facility.

Item 58 adds language to meet NRC compatibility requirements.

Item 59 removes language that does not apply to the subrule.

Item 60 removes all references to ethnic groups and leaves only references to skin and eye color. It removes any offensive language to certain groups.

Notice of Intended Action regarding these amendments was published in the Iowa Administrative Bulletin on February 1, 2006, as **ARC 4842B**. A public hearing was held on February 28, 2006. No one attended the hearing. Five sets of written comments were received and reviewed, and changes were incorporated as appropriate. The changes made from the Notice of Intended Action are as follows:

In Item 2, the definition of "radiopharmaceutical" was removed because this definition was in conflict with the term, "radioactive drug."

In items 28, 30, 34, 35, 36, 37, 40, 42, 44, and 45, the term, "by-product material," was replaced with, "radioactive material." This allows the use of accelerator-produced material and NARM by licensees and allows the agency to regulate the additional material.

In Item 54, the phrase, "SPECT/PET/CT," was replaced with, "SPECT/CT or PET/CT." The phrase, "specialty examination for PET/CT," was replaced with, "speciality examination for CT." The phrase, "radiologic technology" unit was replaced with, "CT" in the second sentence and "SPECT/CT or PET/CT," unit in the third sentence. The last phrase, 4) Restrict performance of CT procedures to the SPECT/CT or PET/CT unit was deleted. These changes were based on written comments.

The State Board of Health adopted these amendments on March 8, 2006.

These amendments will become effective May 3, 2006.

These amendments are intended to implement Iowa Code chapters 136C and 136D.

The following amendments are adopted.

ITEM 1. Amend subrule **38.1(2)** as follows:

38.1(2) All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 4, 2005~~ May 3, 2006.

ITEM 2. Amend rule **641—38.2(136C)** as follows:

Amend the following definitions:

“Authorized medical physicist” means an individual who meets the requirements of 641—subrule 41.2(74) and 641—subrule 41.2(77); or before May 3, 2006, meets the requirements in 10 CFR 35.961(a) or (b) and 10 CFR 35.59; and or is identified as an authorized medical physicist or teletherapy physicist on a specific medical license issued by this agency, the NRC, or an agreement state, a medical use permit issued by the NRC master material licensee, a permit issued by an NRC or agreement state broad scope medical use licensee, a permit issued by an NRC or agreement state broad scope medical use licensee, or a permit issued by an NRC master material license broad scope medical use permittee.

“Type A quantity” means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material, or A_2 , for normal form radioactive material as defined in 10 CFR 71.4.

“Type B quantity” means a quantity of radioactive material greater than a Type A quantity as defined in 10 CFR 71.4.

Rescind the definitions for "A₁" and "A₂."

Add the following **new** definitions in alphabetical order as follows:

"Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

"Consignment" means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

"Highway route controlled quantity" means a quantity within a single package which exceeds:

1. 3,000 times the A₁ value of the radionuclides as specified in 49 CFR 173.435 for special form Class 7 (radioactive) material;
2. 3,000 times the A₂ value of the radionuclides as specified in 49 CFR 1783.435 for normal form Class 7 (radioactive) material; or
3. 1,000 TBq (27,000 Ci), whichever is least.

"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.

“Radionuclide” means a radioactive element or a radioactive isotope.

"Site area emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by off-site response organizations to protect persons off-site.

“X-radiation” means penetrating electromagnetic radiation with energy greater than 0.1 kV produced by bombarding a metallic target with fast electrons in a high vacuum.

ITEM 3. Amend subrule **38.4(1)** as follows:

38.4(1) Records.

a. _____ Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these rules.

b. Electronic records.

(1) A record or signature shall not be denied legal effect or enforceability solely because it is in electronic form.

(2) A contract shall not be denied legal effect or enforceability solely because an electronic record was used in its formation.

(3) If a rule requires a record to be in writing, an electronic record shall satisfy the rule.

(4) If a rule requires a signature, an electronic signature shall satisfy the rule.

ITEM 4. Amend subrule **38.7(1)** as follows:

38.7(1) All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the agency at its office located at the Iowa Department of Public Health, Bureau of Radiological Health, ~~401 SW 7th Street, Suite D, Des Moines, Iowa 50309-4614~~ Lucas State Office Building, 5th Floor, Des Moines, Iowa 50319.

ITEM 5. Amend subrule **38.8(1)**, paragraph "b," subparagraph (1), as follows:

(1) Mammography unit inspections fees:

- ~~\$850~~ \$900 for the first unit and, if the facility has additional units at the address of the first unit, a fee of ~~\$300~~ \$325 for each additional unit; or
- ~~\$850~~ \$900 per portable unit for each site where the unit is off-loaded and used and where the processing and patient films are stored; or
- Dollar amount to be determined and justified by the department on a case-by-case basis for facilities which do not meet the above criteria; or
- ~~\$400~~ \$450 for the second facility follow-up visit to review or determine the corrective action taken to address noncompliances; ~~;~~ or
- ~~\$850~~ \$900 for each stereotactic breast biopsy unit.

ITEM 6. Amend subrule **38.8(1)**, paragraph "**d**," as follows:

d. Each person engaged in providing health physics services in mammography in Iowa, who meets the requirements of 641—paragraph 41.6(3)“c” and is deemed qualified by this agency, must submit a ~~\$35~~ \$40 annual listing fee to this agency.

ITEM 7. Amend subrule **38.8(3)**, paragraph "**a**," as follows:

a. A nonrefundable fee of ~~\$125~~ \$150 shall be submitted with each application for taking an industrial radiography examination to become certified by the agency.

ITEM 8. Amend subrule **38.8(8)**, paragraph "**a**," as follows:

a. Radiation machines. Any out-of-state person who wishes to bring an X-ray machine or linear accelerators into the state to perform work or services shall pay a reciprocity fee of \$100 for each source of radiation ~~pursuant to 38.8(7)~~.

ITEM 9. Amend subrule **38.8(11)** as follows:

Amend the introductory paragraph:

~~38.8(11) Radioactive waste material transport fee schedule, effective July 1, 2002.~~

Amend paragraph "**a**," subparagraphs (1) to (13), as follows:

(1) ~~\$1800~~ per highway cask for each truck shipment of spent nuclear fuel, high-level radioactive waste ~~or~~ transuranic waste, or highway route controlled quantity of radioactive materials or any material shipped in accordance with 641—subrule 40.54(5) traversing the state or any portion thereof. Single cask truck shipments are subject to a surcharge of \$20 per mile for every mile over 250 miles traveled.

(2) ~~\$1300~~ for the first cask and ~~\$125~~ for each additional cask for each rail shipment of spent nuclear fuel, high-level radioactive waste ~~or~~ transuranic waste, or highway route controlled quantity of radioactive materials or any material shipped in accordance with 641—subrule 40.54(5) traversing the state or any portion thereof.

(3) ~~\$125~~ \$175 for each shipment by truck or by rail paid by the shipper for low-level radioactive waste shipped in or across Iowa. The department may accept an annual shipment fee as negotiated with a shipper or accept payment per shipment. This fee applies to waste shipped to a site authorized by a government agency to receive low-level radioactive waste or shipped to a storage site to be held for future disposal.

ITEM 10. Amend subrule **38.8(11)**, paragraph "**b**," as follows:

b. All fees must be received by the department prior to shipment. Fees must be in the form of a check or money order made payable to the Iowa Department of Public Health and sent to the Iowa Bureau of Radiological Health, ~~401 SW 7th Street, Suite D~~ Lucas State Office Building, 5th Floor, Des Moines, Iowa ~~50309-4611~~ 50319. Other

methods of fee payment may be considered by the department on a case-by-case basis upon request of the shipper. A request for an alternative method of payment must be made to the department prior to shipment.

ITEM 11. 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 4, 2005~~ May 3, 2006.

ITEM 12. Amend subrule **39.4(26)**, paragraph "b," as follows:

b. (1) Each holder of or applicant for a specific license authorizing possession and use of ~~radioactive material~~ sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in 39.4(26)"d" (or when a combination of isotopes is involved if R, as defined in 39.4(26)"a," divided by 10^{12} is greater than 1) shall submit a decommissioning funding plan as described in 39.4(26)"e."

(2) Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in 39.4(26)"d" shall either:

(1) 1. Submit a decommissioning funding plan as described in 39.4(26)"e"; or
(2) 2. Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 39.4(26)"d" using one of the methods described in 39.4(26)"f." For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of 39.4(26)"f" must be submitted before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit, As as part of the certification, a ~~copy~~ signed original of the financial instrument obtained to satisfy the requirements of 39.4(26)"f." is submitted to the agency.

ITEM 13. Amend subrule **39.4(26)**, paragraph "c," subparagraph (2), as follows:

(2) Each holder of a specific license issued before July 1, 1993, and of a type described in 39.4(26)"a," shall submit, on or before ~~July 1, 1993~~ January 1, 2007, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to ~~\$750,000~~ \$1,125,000 in accordance with the criteria set forth in this subrule. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

ITEM 14. Amend subrule **39.4(26)**, paragraph "c," by adopting new subparagraphs (4) and (5) as follows:

(4) Any licensee who submitted an application before July 1, 2003, for renewal of license shall provide financial assurance for decommissioning in accordance with 39.4(26)"a" and "b."

(5) Waste collectors and waste processors must provide financial assurance in an amount based on a decommissioning funding plan as described in 39.4(26)"e." The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license, and the cost of disposal of the

maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of 641—Chapters 39 and 40.

ITEM 15. Amend subrule **39.4(26)**, paragraph "d," as follows:

d. Table of required amounts of financial assurance for decommissioning by quantity of material.

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix F of 641—Chapter 40 in unsealed form. (For a combination of isotopes, if R, as defined in 39.4(26)“a,” divided by 10^4 is greater than 1, but R divided by 10^5 is less than or equal to 1.) ~~750,000~~
1,125,000

Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix F of 641—Chapter 40 in unsealed form. (For a combination of isotopes, if R, as defined in 39.4(26)“a,” divided by 10^3 is greater than 1, but R divided by 10^4 is less than or equal to 1.) ~~150,000~~
225,000

Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of Appendix F or 641—Chapter 40 in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 39.4(26)“a,” divided by 10^{10} is greater than 1, but R divided by 10^{12} is less than or equal to 1.)
~~75,000~~ 113,000

Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan.

ITEM 16. Amend subrule **39.4(26)**, paragraph "e," as follows:

e. Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from 39.4(26)“f,” including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at intervals not to exceed three years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate and a signed original of the financial instrument obtained to satisfy the requirements of 39.4(26)“f.”

ITEM 17. Amend rule **641—39.5(136C)** as follows:

641—39.5(136C) Transportation of radioactive material. All persons who transport radioactive material or deliver radioactive material to a carrier for transport must comply with the applicable provisions contained in 10 CFR Part 71 and 49 CFR Parts 170 through 189. The regulations in 10 CFR Part 71 apply to any licensee authorized by specific or general license to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage, or transports that material on public highways. No provision of 10 CFR Part 71 authorizes possession of licensed material.

ITEM 18. Amend subrule **40.1(5)** as follows:

40.1(5) All references to Code of Federal Regulations (CFR) in this chapter are those in effect on or before ~~May 4, 2005~~ May 3, 2006.

ITEM 19. Adopt new rule **641—40.54(136C)** as follows:

641—40.54(136C) Security and control of licensed radioactive material in quantities of concern.

40.54(1) The following increased controls apply to licensees that, at any given time, possess radioactive sources greater than or equal to the quantities of concern of radioactive material defined in Appendix G.

40.54(2) In order to ensure the safe handling, use, and control of licensed material in use and in storage, each licensee shall control access at all times to radioactive material quantities of concern and devices containing such radioactive material (devices), and limit access to such radioactive material and devices to only approved individuals who require access to perform their duties.

a. The licensee shall allow only trustworthy and reliable individuals, approved in writing by the licensee, to have unescorted access to radioactive material quantities of concern and devices. The licensee shall approve for unescorted access only those individuals with job duties that require access to such radioactive material and devices. Personnel who require access to such radioactive material and devices to perform a job duty, but who are not approved by the licensee for unescorted access, must be escorted by an approved individual.

b. For individuals employed by the licensee for three years or less, and for nonlicensee personnel, such as physicians, physicists, housekeeping personnel, and security personnel under contract, trustworthiness and reliability shall be determined, at a minimum, by verifying employment history, education, and personal references. The licensee shall also, to the extent possible, obtain independent information to corroborate that information provided by the employee (i.e., seek references not supplied by the individual). For individuals employed by the licensee for longer than three years, trustworthiness and reliability shall be determined, at a minimum, by a review of the employees' employment history with the licensee.

c. Service providers shall be escorted unless determined to be trustworthy and reliable by an NRC-required background investigation as an employee of a manufacturing and distribution (M&D) licensee. Written verification attesting to or certifying the person's trustworthiness and reliability shall be obtained from the manufacturing and distribution licensee providing the service.

d. The licensee shall document the basis for concluding that there is reasonable assurance that an individual granted unescorted access is trustworthy and reliable, and does not constitute an unreasonable risk for unauthorized use of radioactive material quantities of concern. The licensee shall maintain a list of persons approved by the licensee for unescorted access to such radioactive material and devices.

40.54(3) In order to ensure the safe handling, use, and control of licensed material in use and in storage, each licensee shall have a documented program to monitor and immediately detect, assess, and respond to unauthorized access to radioactive material quantities of concern and devices. Enhanced monitoring shall be provided during periods of source delivery or shipment, when the delivery or shipment exceeds 100 times the Appendix G values.

a. The licensee shall respond immediately to any actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices. The response shall include requesting assistance from a local law enforcement agency (LLEA).

b. The licensee shall have a prearranged plan with the LLEA for assistance in response to an actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices which is consistent in scope and timing with realistic potential vulnerability of the sources containing such radioactive material. The prearranged plan shall be updated when changes to the facility design or operation affect the potential vulnerability of the sources. Prearranged LLEA coordination is not required for temporary job sites.

c. The licensee shall have a dependable means to transmit information between and among the various components used to detect and identify an unauthorized intrusion, to inform the assessor, and to summon the appropriate responder.

d. After initiating an appropriate response to any actual or attempted theft, sabotage, or diversion of radioactive material or of the devices, the licensee shall, as promptly as possible, notify the bureau of radiological health at (515)281-3478 during normal working hours of 7:30 a.m. to 4:30 p.m., Monday through Friday. After hours and on holidays, the licensee shall call (515)323-4360 and request the homeland security and emergency management duty officer.

e. The licensee shall maintain documentation describing each instance of unauthorized access and any necessary corrective actions to prevent future instances of unauthorized access.

40.54(4) In order to ensure the safe handling, use, and control of licensed material in transportation for domestic highway and rail shipments by a carrier other than the licensee for quantities that equal or exceed those in Appendix G but are less than 100 times Appendix G quantities, per consignment, the licensee shall:

a. Use carriers that:

- (1) Use package tracking systems;
- (2) Implement methods to ensure trustworthiness and reliability of drivers;
- (3) Maintain either constant control or surveillance during transit;
- (4) Have the capability for immediate communication to summon appropriate response or assistance;

b. Verify and document that the carrier employs the measures listed in paragraph "a";

c. Contact the recipient to coordinate the expected arrival time of the shipment;

d. Confirm receipt of the shipment; and

e. Initiate an investigation to determine the location of the licensed material if the shipment does not arrive on or about the expected arrival time. When, through the course of the investigation, it is determined that the shipment has become lost, stolen, or missing, the licensee shall immediately notify the bureau of radiological health at (515)281-3478 during normal working hours of 7:30 a.m. to 4:30 p.m., Monday through Friday. After hours and on holidays, the licensee shall call (515)323-4360 and request the homeland security and emergency management duty officer. If, after 24 hours of investigating, the location of the material still cannot be determined, the radioactive material shall be deemed missing and the licensee shall immediately notify the bureau of radiological health.

40.54(5) For domestic highway and rail shipments, prior to shipping licensed radioactive material that exceeds 100 times the quantities in Appendix G per consignment, the licensee shall:

a. Notify the NRC (Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555) in writing, at least 90 days prior to the anticipated date of shipment. The NRC will issue the Order to implement the Additional Security Measures (ASMs) for the transportation of Radioactive Material Quantities of Concern (RAM QC). The licensee shall not ship the material until the ASMs for the transportation of RAM QC are implemented or the licensee is notified otherwise, in writing, by the NRC.

b. Once the licensee has implemented the ASMs for the transportation of RAM QC, the notification requirements of 40.54(5)"a" shall not apply to future shipments of licensed radioactive material that exceed 100 times the Appendix G quantities. The licensee shall implement the ASMs for the transportation of RAM QC.

40.54(6) If a licensee employs an M&D licensee to take possession of the licensed radioactive material and ships it under the M&D licensee's M&D license, the requirements of 40.54(4) and 40.54(5) above shall not apply.

40.54(7) If the licensee is to receive radioactive material greater than or equal to the Appendix G quantities, per consignment, the licensee shall coordinate with the originating licensee to:

a. Establish an expected time of delivery; and

b. Confirm receipt of transferred radioactive material. If the material is not received at the expected time of delivery, notify the originating licensee and assist in any investigation.

40.54(8) In order to ensure the safe handling, use, and control of licensed material in use and in storage, each licensee that possesses mobile or portable devices containing radioactive material in quantities greater than or equal to Appendix G values shall:

a. For portable devices, have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.

b. For mobile devices:

(1) That are only moved outside of the facility (e.g., on a trailer), have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.

(2) That are only moved inside a facility, have a physical control that forms a tangible barrier to secure the material from unauthorized movement or removal when the device is not under direct control and constant surveillance by the licensee.

c. For devices in or on a vehicle or trailer, have a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee.

40.54(9) The licensee shall retain documentation required by the increased controls for three years after the increased controls are no longer effective.

a. The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years after an individual's employment ends.

b. Each time the licensee revises the list of approved persons required by 40.54(2)"d," or the documented program required by 40.54(3), the licensee shall retain the previous documentation for three years after the revision.

c. The licensee shall retain documentation on each radioactive material carrier for three years after the licensee discontinues use of that particular carrier.

d. The licensee shall retain documentation on shipment coordination, notifications, and investigations for three years after the shipment or investigation is completed.

e. After the license is terminated or amended to reduce possession limits below the quantities of concern, the licensee shall retain all documentation required by these increased controls for three years.

40.54(10) Detailed information generated by the licensee that describes the physical protection of radioactive material quantities of concern is sensitive information and shall be protected from unauthorized disclosure.

a. The licensee shall control access to its physical protection information to those persons who have an established need to know the information and are considered to be trustworthy and reliable.

b. The licensee shall develop, maintain, and implement policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, its physical protection information for radioactive material covered by these requirements. The policies and procedures shall include the following:

(1) General performance requirement that each person who produces, receives, or acquires the licensee's sensitive information protect the information from unauthorized disclosure;

(2) Protection of sensitive information during use, storage, and transit;

(3) Preparation, identification or marking, and transmission;

(4) Access controls;

(5) Destruction of documents;

(6) Use of automatic data processing systems; and

(7) Removal from the licensee's sensitive information category.

ITEM 20. Adopt **new 641—Chapter 40**, Appendix G, as follows:

APPENDIX G
RADIONUCLIDES OF CONCERN

Radionuclide	Quantity of Concern ¹ (TBq)	Quantity of Concern ² (Ci)
Am-241	0.6	16
Am-241/Be	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14
Co-60	0.3	8.1

Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pm-147	400	11,000
Pu-238	0.6	16
Pu-239/Be	0.6	16
Ra-226	0.4	11
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations of radioactive materials listed above ³	See Footnote Below ⁴	

¹ The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity equals or exceeds the quantity of concern.

² The primary values used for compliance with this Order are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

³ Radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

⁴ If several radionuclides are aggregated, the sum of the ratios of the activity of each source, i of radionuclide, n , $A_{(i,n)}$, to the quantity of concern for radionuclide n , $Q_{(n)}$, listed for that radionuclide equals or exceeds one. [(aggregated source activity for radionuclide A) ÷ (quantity of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) ÷ (quantity of concern for radionuclide B)] + etc..... ≥ 1

Use the following method to determine which sources of radioactive material require increased controls (ICs):

- Include any single source equal to or greater than the quantity of concern in Appendix G.
- Include multiple collocated sources of the same radionuclide when the combined quantity equals or exceeds the quantity of concern.
- For combinations of radionuclides, include multiple collocated sources of different radionuclides when the aggregate quantities satisfy the following unity rule: [(amount of radionuclide A) ÷ (quantity of concern of

$$\text{radionuclide A)]} + [(\text{amount of radionuclide B}) \div (\text{quantity of concern of radionuclide B})] + \text{etc....} \geq 1$$

Guidance for Aggregation of Sources

NRC supports the use of the IAEA's source categorization methodology as defined in TECDOC-1344, "Categorization of Radioactive Sources," (July 2003) (see http://www-pub.iaea.org/MTCD/publications/PDF/te_1344_web.pdf) and as endorsed by the agency's Code of Conduct for the Safety and Security of Radioactive Sources, January 2004 (see <http://www-pub.iaea.org/MTCD/publications/PDF/Code-2004.pdf>). The Code defines a three-tiered source categorization scheme. Category 1 corresponds to the largest source strength (equal to or greater than 100 times the quantity of concern values listed in the table in Appendix G.) and Category 3 corresponds to the smallest (equal to or exceeding one-tenth the quantity of concern values listed in the table in Appendix G.). Increased controls apply to sources that are equal to or greater than the quantity of concern values listed in the table in Appendix G, plus aggregations of smaller sources that are equal to or greater than the quantities in the table in Appendix G. Aggregation only applies to sources that are collocated.

Licensees that possess sources in total quantities that equal or exceed the table in Appendix G quantities are required to implement increased controls. Where there are many small (less than the quantity of concern values) collocated sources whose total aggregate activity equals or exceeds the table in Appendix G values, licensees are to implement increased controls.

Some source handling or storage activities may cover several buildings or several locations within specific buildings. The question then becomes: When are sources considered collocated for purposes of aggregation? For purposes of the additional controls, sources are considered collocated if breaching a single barrier (e.g., a locked door at the entrance to a storage room) would allow access to the sources. Sources behind an outer barrier should be aggregated separately from those behind an inner barrier (e.g., a locked source safe inside the locked storage room). However, if both barriers are simultaneously open, then all sources within these two barriers are considered to be collocated. This logic should be continued for other barriers within or behind the inner barrier.

The following example illustrates the point: A lockable room has sources stored in it. Inside the lockable room, there are two shielded safes with additional sources in them. Inventories are as follows:

The room has the following sources outside the safes: Cf-252, 0.12 TBq (3.2 Ci); Co-60, 0.18 TBq (4.9 Ci), and Pu-238, 0.3 TBq (8.1 Ci). Application of the unity rule yields: $(0.12 \div 0.2) + (0.18 \div 0.3) + (0.3 \div 0.6) = 0.6 + 0.6 + 0.5 = 1.5$. Therefore, the sources would require increased controls.

Shielded safe #1 has a 1.9 TBq (51 Ci) Cs-137 source and a 0.8 TBq (22 Ci) Am-241 source. In this case, the sources would require increased controls, regardless of location, because they each exceed the quantities in the table in Appendix G.

Shielded safe #2 has two Ir-192 sources, each having an activity of 0.3 TBq (8.1 Ci). In this case, the sources would not require increased controls while locked in the safe. The combined activity does not exceed the threshold quantity 0.8 TBq (22 Ci).

Because certain barriers may cease to exist during source handling operations (e.g., a storage location may be unlocked during periods of active source usage), licensees should, to the extent practicable, consider two modes of source usage — “operations” (active source usage) and “shutdown” (source storage mode). Whichever mode results in the greatest inventory (considering barrier status) would require increased controls for each location.

ITEM 21. Amend subrule **41.1(1)**, paragraph "**b**," as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 4, 2005~~ May 3, 2006.

ITEM 22. Amend subrule **41.1(3)**, paragraph "**a**," subparagraph (2), as follows:

(2) Individuals who will be operating the X-ray systems shall be adequately instructed in safe operating procedures and be competent in the safe use of the equipment. In addition:

1. Operators in medical facilities shall meet the requirements of in accordance with 641—Chapter 42 as applicable. The individual’s permit to practice shall be posted in the immediate vicinity of the general work area and visible to the public.

2. Operators in dental facilities shall meet the requirements of the Iowa dental examiners board.

ITEM 23. Amend subrule **41.2(1)**, paragraph "**b**," as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 5, 2004~~ May 3, 2006.

ITEM 24. Amend subrule **41.2(2)** as follows

Amend the following definitions:

“Authorized nuclear pharmacist” means a pharmacist who ~~has~~ :

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

~~a. Is practicing nuclear pharmacy as authorized by a current Iowa radioactive materials license; or~~

b. Is identified as an authorized nuclear pharmacist on:

1. A specific license issued by the agency, NRC or agreement state that authorizes medical use or the practice of nuclear pharmacy;

2. A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

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

4. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or
 - c. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or
 - d. Is designated as an authorized nuclear pharmacist in accordance with 641—39.4(29)“j”(2)“3.”

“Authorized user” means a physician, dentist, or podiatrist who has met the appropriate requirements of 41.2(67)“a,” 41.2(68)“a,” 41.2(69)“a,” 41.2(70)“a,” 41.2(71), 41.2(72)“a,” ~~or~~ 41.2(73)“a,” 41.2(81)“a,” or 41.2(82)“a,” or before May 3, 2006, meets the requirements in 10 CFR 35.910(a), 35.920(a), 35.930(c), 35.940(a), 35.950(a), or 35.960(a) and 10 CFR 35.59; ~~and~~ or who is identified on:

1. A current Iowa, NRC, or agreement state license that authorizes the medical use of radioactive material;
2. A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;
3. A permit issued by an NRC, agreement state, or Iowa-specific licensee of broad scope that is authorized to permit medical use of radioactive material; or
4. A permit issued by an NRC master material license broad scope permittee that is authorized to permit medical use of radioactive material.

“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,” ~~41.2(66) or and 41.2(77) and~~, 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.

ITEM 25. Amend subrule **41.2(10)**, paragraph “c,” as follows:

- 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(66)~~ 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 26. Amend subrule **41.2(11)**, paragraph “a,” introductory paragraph and subparagraph (1), as follows:

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

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

ITEM 27. Amend subrule **41.2(11)**, paragraph “b,” subparagraphs (1) and (2), as follows:

(1) Follow the instructions of the supervising authorized user for the medical uses of by-product material;

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

ITEM 28. Amend subrule **41.2(11)**, paragraph "c," introductory paragraph and subparagraph (2), as follows:

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

(2) Require the supervised individual to follow the instructions ~~given pursuant to 41.2(11)"e" and to comply with~~ of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter and license conditions; and

ITEM 29. Amend subrule **41.2(27)**, paragraph "a," as follows:

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

ITEM 30. Amend subrule **41.2(31)**, introductory paragraph and paragraph "b," as follows:

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

b. Prepared by:

(1) ~~An~~ An authorized nuclear pharmacist,

(2) ~~A~~ A physician who is an authorized user and who meets the requirements specified in ~~41.2(67), 41.2(68) or 41.2(69)~~ and has work experience in eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; or before May 3, 2006, who meets the requirements of 10 CFR part 35.920; or

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

ITEM 31. Amend subrule **41.2(53)**, paragraph "f," subparagraph (3), as follows:

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

ITEM 32. Rescind subrule 41.2(65) and adopt the following new subrule in lieu thereof:

41.2(65) Training for radiation safety officer. Except as provided in 41.2(66), the licensee shall require an individual fulfilling the responsibilities of the 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, NRC, or an agreement state and who meets the requirements in 41.2(65)"d" and "e." (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.) 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 either 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) or 41.2(69); 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 a structured educational program consisting of both:

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

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiation biology; and

5. Radiation dosimetry; and

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

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 has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as a 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 license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities; and

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. Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee is seeking approval. This training requirement may be satisfied by completing training that is supervised by a 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.

ITEM 33. Rescind and reserve subrule 41.2(66).

ITEM 34. Rescind subrule 41.2(67) and adopt the following **new** subrule in lieu thereof:

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 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 that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's 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, which include the topics listed 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, before May 3, 2006, meets the requirements in 10 CFR 35.910, 35.920, or 35.930, or meets equivalent 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), or 41.2(69), or before May 3, 2006, the requirements in 10 CFR 35.910, 35.920, or 35.930, or equivalent 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 before May 3, 2006, 10 CFR 35.910, 35.920, or 35.930, or equivalent 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 independently as an authorized user for the medical uses authorized in 41.2(31).

ITEM 35. Amend subrule **41.2(68)** as follows:

41.2(68) Training for imaging and localization studies. Except as provided in 41.2(76), the licensee shall require the authorized user of ~~a radiopharmaceutical, generator, or reagent kit~~ unsealed radioactive material specified in 41.2(33) to be a physician who:

~~a. Is certified in:~~

~~(1) Nuclear medicine by the American Board of Nuclear Medicine;~~

~~(2) Diagnostic radiology by the American Board of Radiology;~~

~~(3) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or~~

~~(4) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine;~~
~~or~~

~~(5) Nuclear medicine by the Royal College of Physicians and Surgeons of
Canada; or~~

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 that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's 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 uptake, dilution, and excretion studies that include the topics listed 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 before May 3, 2006, meets the requirements in 10 CFR 35.920, or equivalent agreement state requirements; or

~~b. Has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience, and 500 hours of supervised clinical experience.~~

~~(1) To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:~~

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:

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

~~(2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:~~
2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(68) or 41.2(68)"c"(1)"2", seventh bulleted paragraph, and 41.2(69), or before May 3, 2006, meets the requirements in 10 CFR 35.920, or equivalent agreement state requirements, involving:

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

~~2. Calibrating dose calibrators and diagnostic instruments~~ 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 the misadministration of radioactive material~~ a medical event involving the use of unsealed radioactive material;

~~5. Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and~~

~~6. Administering dosages of radioactive drugs to patients or human research subjects; and~~

~~7. Eluting technetium-99m from generator systems, assaying appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for molybdenum-99 and alumina contamination~~ radionuclidic purity, and processing the eluate with reagent kits to prepare technetium-99m-labeled radiopharmaceuticals labeled radioactive drugs; and

~~(3) To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:~~

~~1. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;~~

~~2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;~~

~~3. Administering dosages to patients or human research subjects and using syringe radiation shields;~~

~~4. Collaborating with the authorized user in the interpretation of radionuclide test results; and~~

~~5. Patient or human research subject follow-up; or~~

~~c. Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 41.2(68)"b";~~

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(68) or 41.2(69) and 41.2(68)"c"(1)"2", seventh bulleted paragraph, or, before May 3, 2006, meets the requirements in 10 CFR 35.920, or equivalent 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 independently as an authorized user for the medical uses authorized under 41.2(31) and 41.2(33).

~~d. Be identified on a current agreement state or NRC license as an authorized user for those uses listed in 41.2(33).~~

ITEM 36. Rescind subrule 41.2(69) and adopt the following **new** subrule in lieu thereof:

41.2(69) Training for use of unsealed by-product 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 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", the seventh bulleted paragraph, and 41.2(69)"b"(2). (The names of specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's 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", the 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 before May 3, 2006, meets the requirements in 10 CFR 35.930, or equivalent agreement state requirements. A supervising authorized user, who meets the requirements in 41.2(69)"b," or before May 3, 2006, meets the requirements in 10 CFR 35.930(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 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 photon energy less than 150 keV for which a written directive is required; or
 - 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 independently as an authorized user for the medical uses authorized under 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69), or before May 3, 2006, meets the requirements in 10 CFR 35.930, or equivalent agreement state requirements. The preceptor authorized user who meets the requirements in 41.2(69)"b," or before May 3, 2006, meets the requirements in 10 CFR 35.930(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.

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).

ITEM 37. Rescind subrule 41.2(70) and adopt the following **new** subrule in lieu thereof :

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 in 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 specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's 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 meet the requirements in 41.2(70), or before May 3, 2006, meets the requirements in 10 CFR 35.940, or equivalent agreement state requirements at a medical institution, 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 before May 3, 2006, meets the requirements in 10 CFR 35.940, or equivalent 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 before May 3, 2006, meets the requirements in 10 CFR 35.940, or equivalent 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 independently as an authorized user of manual brachytherapy sources for the medical uses in 41.2(43).

ITEM 38. Rescind subrule 41.2(71) and adopt the following **new** subrule in lieu thereof:

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 before May 3, 2006, meets the requirements in 10 CFR 35.940 or 35.941, or equivalent 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) or 41.2(71), or, before May 3, 2006, meets the requirements in 10 CFR 35.940 or 35.941, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(71)"a" and "b" and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

ITEM 39. Rescind subrule 41.2(72) and adopt the following **new** subrule in lieu thereof:

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 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 "c" and whose certification has been recognized by the agency, NRC, or an agreement state. (The names of specialty board that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.); or

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

ITEM 40. Rescind subrule 41.2(73) and adopt the following **new** subrule in lieu thereof:

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 use authorized in 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 specialty board that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's 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 before May 3, 2006, meets the requirements in 10 CFR 35.960, or equivalent agreement state requirements at a medical institution, involving:

- Reviewing full calibration measurements and periodic spotchecks;
- 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, before May 3, 2006, meets the requirements in 10 CFR 35.960, or equivalent 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 independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(73), or before May 3, 2006, 10 CFR 35.960, or equivalent agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; 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.

ITEM 41. Rescind subrule 41.2(74) and adopt the following new subrule in lieu thereof:

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 specialty board that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's 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 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) or 41.2(73); 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," and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 41.2(74), or before May 3, 2006, the requirements in 10 CFR 35.961, or equivalent 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.

ITEM 42. Amend subrule **41.2(75)** as follows:

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(73)~~41.2(65), 41.2(74), or 41.2(78).

(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 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).

b.(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of ~~byproduct~~ radioactive material on a license issued by this 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, 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), ~~or~~ 41.2(73), 41.2(81), 41.2(82), or 41.2(89).

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive 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, 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).

ITEM 43. Amend subrule **41.2(77)** as follows:

41.2(77) Recentness of training. The training and experience specified in 41.2(65) to 41.2(79) and 41.2(81), 41.2(82), 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.

ITEM 44. Amend subrule **41.2(78)** as follows:

41.2(78) Training for an authorized nuclear pharmacist. Except as provided in 41.2(79), 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 specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.)and whose certification has been recognized by the NRC or agreement state; ~~or~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

(3) Provide evidence of having acquired at least 4,000 hours of combined training and experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

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

or

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

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

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

5. Radiation biology; and

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

1. to 5. No change.

c. Has obtained written ~~certification~~ 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) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

ITEM 45. Adopt **new** subrules **41.2(81)**, **41.2(82)**, and **41.2(89)** 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 specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's 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 before May 3, 2006, meets the requirements in 10 CFR 35.930, 35.932, or 35.934, or meets equivalent 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," or 41.2(82), or before May 3, 2005, meets the requirements in 10 CFR 35.930, 35.932, or 35.934, or equivalent 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 independently as an authorized user for medical uses authorized under 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69), 41.2(81), or 41.2(82), or before May 3, 2006, meets the requirements in 10 CFR 35.930, 35.932, or 35.934, or equivalent agreement state requirements. A preceptor 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.

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 specialty board that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's 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 before May 3, 2006, meets the requirements in 10 CFR 35.930 or 35.934, or meets equivalent 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," or 41.2(82), or before May 3, 2006, meets the requirements in 10 CFR 35.930 or 35.934, or equivalent 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 independently as an authorized user for medical uses authorized in 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69) or 41.2(82), or before May 3, 2006, meets the requirements in 10 CFR 35.930 or 35.934, or equivalent agreement state requirements. A preceptor authorized user who meets the requirements in 41.1(69)"b" must also have experience in oral administration of greater than 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131.

41.2(89) Training for the parenteral administration of unsealed by-product material requiring a written directive. 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. Is an authorized user under 41.2(69), or before May 3, 2006, meets the requirements in 10 CFR 35.930, for uses listed in 41.2(89), or meets equivalent agreement state requirements; or
- b. Is an authorized user under 41.2(70) or 41.2(73), or before May 3, 2006, meets the requirements in 10 CFR 35.940 or 35.960, or meets equivalent agreement state requirements, and who meets the requirements in 41.2(89)"d;" or
- c. 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), or before May 3, 2006, meets the requirements in 10 CFR 35.940 or 35.960 and who meets the requirements in 41.2(89)"d";
- d.(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. 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) or 41.2(89), or before May 3, 2006, meets the requirements in 10 CFR 35.930, or equivalent 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. A supervising authorized user who meets the requirements in 41.2(69) or before May 3, 2006, meets the requirements in 10 CFR 35.930 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. 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 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 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; and
- (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(89)"b" or "c," and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed by-product material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69) or 41.2(89), or before May 3, 2006, meets the requirements in 10 CFR 35.930, or equivalent agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69), or before May 3, 2006, meets the requirements in 10 CFR 35.930, 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.

ITEM 46. Amend subrule **41.6(3)**, paragraph "a," subparagraph (2), the second numbered paragraph "2," as follows:

2. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)"a"(1) were completed, the interpreting physician shall have taught or completed at least 15 category I continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA

inspection or the last day of the calendar quarter immediately preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period. ~~This training shall include at least six category I continuing medical education credits in each mammographic modality used by the interpreting physician in the interpreting physician's practice; and~~

ITEM 47. Amend subrule **41.6(3)**, paragraph "b," subparagraph (3), as follows:

Rescind numbered paragraph "3" as follows:

~~3. At least 6 of the continuing education units required in this subrule shall be related to each mammographic modality used by the technologist.~~

Renumber numbered paragraphs "4" and "5" as "3" and "4."

Amend renumbered paragraph "3" as follows:

3. Requalification. ~~Radiologic technologists~~ A radiologic technologist who ~~fail~~ fails to meet the continuing education requirements of 41.6(3)"b"(3)"1" shall obtain a sufficient number of continuing education units in mammography to bring ~~their~~ the total up to at least 15 in the previous three years, ~~at least 6 of which shall be related to each modality used by the technologist in mammography.~~ The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

ITEM 48. Amend subrule **41.6(3)**, paragraph "c," subparagraph (3), the numbered paragraph "1," as follows:

1. Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)"c"(1) or (2) were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. ~~This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during the physicist's surveys or oversight of quality assurance programs.~~ Units earned through teaching a specific course can be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.

ITEM 49. Amend subrule **41.7(3)**, paragraph "b," subparagraph (1), by renumbering paragraph "1" to "3" as "2" to "4" and adopting **new** numbered paragraph "1" as follows:

1. Be licensed to practice medicine in Iowa;

ITEM 50. Amend subrule **41.7(3)**, paragraph "d," subparagraph (1), by adopting **new** numbered paragraph 1. as follows and renumbering the remaining paragraphs:

1. Be licensed to practice medicine in Iowa;

ITEM 51. Amend subrule **42.1(2)**, definitions, as follows:

Amend the following definitions:

"Diagnostic radiographer" means an individual, other than a licensed practitioner or podiatric or dental assistant with radiography qualification, who applies X-radiation to the human body for diagnostic purposes while under the supervision of a licensed

practitioner or registered nurse ~~registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152 under 641—41.1(3)"a"(7).~~ The types are as follows:

1. "General diagnostic radiographer" applies X-radiation to any part of the human body.

2. "Limited diagnostic radiographer" applies X-radiation to ~~not more than three of only~~ the following body parts: chest, extremities (upper and lower), spine, or sinus. This individual is restricted to performing radiography in that area of the facility specifically designed for X-ray. This individual may not perform pediatric radiography (children under three years of age) without additional training in pediatric radiography taken as a part of the basic limited training or a specifically approved training program (see 42.2(6)).

3. "Limited in-hospital radiographer" applies X-radiation as permitted in 42.3(1)"c."

"Special category course" means those programs still related to health care but indirectly related to diagnostic radiography, nuclear medicine technology, or radiation therapy. Such programs are: ~~venipuncture~~, CPR, educator's programs, management programs, personal improvement, for example.

Rescind the definitions of "radionuclide," "radiopharmaceutical," and "X-radiation."

ITEM 52. Amend subrule **42.2(3)**, paragraph "**b**," subparagraph (**5**), as follows:

(5) No continuing education credit is approved for passing a certification examination, hands-on practice, or mandatory abuse reporting, ultrasound or MRI courses that are less than 50 percent directly related to radiography.

ITEM 53. Amend subrule **42.2(6)** by adopting new paragraph "**c**" as follows:

c. Additional training for limited radiographers wishing to perform pediatric radiography. Training requires a general radiographer to submit to the agency a training program that includes the additional anatomy and physiology, positioning, radiation protection, technique, and film critique necessary for pediatrics. The training must include both chest and extremities but no spinal radiography. The program must include didactic instruction plus film critique time. Upon completion of training, the general radiographer must submit a letter of competency to the agency. No additional testing will be required.

ITEM 54. Amend subrule **42.2(7)**, paragraph "**a**" as follows:

42.2(7) Requirements for operators of dual imaging devices.

a. When a unit is operated as a stand-alone nuclear medicine imaging device, the operator must have a permit to practice as a nuclear medicine technologist and meet the requirements of 641—42.4(136C). When the unit is operated as a radiologic technology stand-alone CT imaging device, the operator must have a permit to practice as a general diagnostic radiographer and meet the requirements of 641—42.3(136C). When a unit is operated in dual mode as a SPECT/CT or PET/CT device, the operator must have a permit to practice as a nuclear medicine technologist.

b. In order to operate a SPECT/CT or PET/CT unit as a stand-alone CT unit, the individual must:

- (1) Be certified as a nuclear medicine technologist;
- (2) Complete a training program approved by the agency; and

(3) Successfully complete the ARRT specialty examination for CT.

ITEM 55. Amend subrule **42.6(1)**, paragraph "c," as follows:

c. Satisfactorily complete an advanced academic program approved by this agency. Approved training shall include appropriate coursework, training, and experience in performing procedures, including but not limited to fluoroscopy, ~~modified~~ barium swallow, needle localization, needle aspiration, thoracentesis, arthrography, ~~myelography~~ mylegraphy, venography, angiography, and biopsy.

ITEM 56. Amend subrule **42.6(1)** by adopting new paragraph "f" as follows:

f. Have a delegation agreement on file at the place of employment that:

(1) Outlines all procedures the radiologist assistant will be allowed to perform at the place of employment; and

(2) Is signed by all supervising physicians.

ITEM 57. Amend subrule **45.1(1)**, paragraph "b," as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 4, 2005~~ May 3, 2006.

ITEM 58. Amend subrule **45.1(10)**, paragraph "a," subparagraph (1), numbered paragraph "1," as follows:

1. The subjects outlined in Appendix A, presented in a 40-hour course approved by the agency, another agreement state, or the U.S. Nuclear Regulatory Commission;

ITEM 59. Amend subrule **45.6(6)**, paragraph "a," as follows:

a. Each source of radiation, ~~except accelerators~~, shall be provided with a storage or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

ITEM 60. Amend **641—Chapter 46, Appendix 2**, as follows:

Appendix 2

SUN-REACTIVE SKIN TYPES USED IN CLINICAL PRACTICE

SKIN TYPE	SKIN REACTIONS TO SOLAR RADIATION(a) EXAMPLES	EXAMPLES
I	Always burns easily and severely (painful burn). Tans little or none and peels.	(b) People most often with fair skin, blue eyes, freckles. Unexposed skin is white.
II	Usually burns easily and severely (painful burn). Tans minimally or lightly, also peels.	(b) People most often with fair skin; red or blonde hair; blue, hazel or even brown eyes. Unexposed skin is white.
III	Burns moderately and tans about average.	Normal average Caucasoid. Unexposed skin is white.
IV	Burns minimally, tans easily, and above average with each exposure. Exhibits IPD (immediate	People with white or light brown skin, dark skin, dark brown hair, dark eyes (e.g., Mediterraneans, Orientals,

	pigment darkening) reaction.	Hispanics, etc.). Unexposed skin is brown.
V	Rarely burns, tans easily and substantially. Always exhibits IPD reaction.	Brown-skinned person (e.g., Amerindians, East Indians, Hispanics, etc.). Unexposed skin is brown.
VI	Never burns and tans profusely; exhibits IPD reaction.	Blacks (e.g., African and American Blacks, Australian and South Indian Aborigines); unexposed Unexposed skin is black.

(a) Based in the first 45-60 minutes (=2-3 minimum erythema dose) exposure of the summer sun (early June) at sea level.

(b) ~~They may be of Celtic background (Irish or Scottish); others may even have dark hair or brown eyes~~

Mary Mincer Hansen, RN, PhD., Director
Department of Public Health

Date