Fields of Opportunities

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DEPARTMENT OF PUBLIC HEALTH
STEPHEN C. GLEASON, D.O., DIRECTOR

August 23, 2002

Josephine Piccone, Deputy Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Ms. Piccone:

Enclosed is a copy of the proposed revision to the Iowa Radiation Machines and Radioactive Materials Rules. The proposed rules will be available for public comment on October 2, 2002 with a request for comments by October 22, 2002. We request NRC's comments by October 22, 2002. Radioactive materials proposed revisions are identified by item number and underlined/strikeout text. The corresponding NRC reference is in bold italics.

We believe adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) procedure SA-200.

If you have any questions, please feel free to contact me at 515/725-0306 or Donald Flater at 515/281-3478 or email dflater@idph.state.ia.us or Fax 515/725-0318.

Sincerely,

Charlene Craig
Bureau of Radiological Health
515-725-0306; email: ccraig@idph.state.ia.us

STP-006 Template
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**From:** "Craig, Charlene" <CCRAIG@health.state.ia.us>
**To:** "'jll2@nrc.gov'" <jll2@nrc.gov>
**Date:** 8/23/02 12:35PM
**Subject:** Merry Christmas!!!!

Merry Christmas!!!!
<<nrc rule amendments-coded.doc>> <<NRC rule letter.doc>> charlene craig
515/725-0306

PUBLIC HEALTH DEPARTMENT [641]
Notice of Intended Action

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"; and Chapter 45, "Radiation Safety Requirements for Industrial Radiographic Operations", Iowa Administrative Code.

The following itemize the proposed changes.

Items 1, 3, 9, 21, and 72 amend the rules to reflect current federal regulations.

Item 2 amends the definition of "airborne radioactivity area" to include all airborne radioactive material; "monitoring" clarifies wording; "prescribed dosage" changes wording from quantity to activity; "prescribed dose" adds wording to include brachytherapy afterloaders; "public dose" changes wording from radiation possessed to radiation released; "reportable medical event" adds more descriptive wording and adds exposure from a leaking sealed source or intervention by the patient; "shallow dose equivalent" adds exposure to the whole body and deletes the average; "written directive" deletes wording that is detailed in another rule. Item 2 also adds definitions for "authorized medical physicist" and respirators in order to meet NRC compatibility requirements.

Item 4 adds wording to include registration as well as certificates, both of which the agency currently issues.

Items 5, 30, and 54 expand the wording for clarity and to meet NRC compatibility requirements.

Items 6 and 23 rescind the current rules and replace them with wording in order to meet NRC compatibility requirements.

Item 7 changes the requirement to include transfer of devices, adds an effective date for labeling, and adds two new devices for labeling requirements in order to meet NRC compatibility requirements.

Item 8 rescinds the current rules and replaces it with wording in order to meet NRC compatibility requirements. The wording adds requirements for reports and records.

Item 10 amends the definition of "Class" and "declared pregnant woman" to meet NRC compatibility requirements.

Item 11 adds exposure limits for the skin of the whole body. This is a NRC compatibility requirement.

Item 12 clarifies from what part of the body the exposures must be taken. This is a NRC compatibility requirement.

Item 13 changes wording to include areas not regulated before and may cause facilities to reevaluate public access areas. This is a NRC compatibility requirement.

Items 14 and 43 adopt new wording to include exposure limits to patient visitors. This is a NRC compatibility requirement.

Item 15 requires prompt processing of dosimetry. This is a NRC compatibility requirement.

Item 16 adds decontamination to the licensee requirements. This is a NRC compatibility requirement.

Items 17, 18, and 19 add wording to include respirators to meet NRC compatibility requirements.

Item 20 adds new wording to protect employees from discrimination when they are involved in certain activities. NRC recommended this rule because there is no protection currently.

Item 22 expands the definition of "authorized nuclear pharmacist" and "authorized user" to meet NRC compatibility requirements. It includes more ways to meet the definition. It also includes a new definition for "authorized medical physicist" which was not included before. The definition of "radiation safety officer" was added to this chapter because it is expanded from the definition in Chapter 38. This is a NRC compatibility requirement.

Item 24 expands the requirements to include items required by other personnel. This is a NRC compatibility requirement.

Item 25 adds wording to clearly delineate who has authority for control of radioactive material. It also adds wording for mobile services that is now in regulatory guides. This is a NRC compatibility requirement.

Items 26 and 28 add reportable events to the record requirements. This is a NRC compatibility requirement.

Item 27 shortens the time frame for reporting reportable medical events. This is a NRC compatibility requirement.

Item 29 rescinds requirements that did not fit into this subrule. They are added in subrule 41.2(87). Any changes are a NRC compatibility requirement.

Item 31 adds wording to require items already commonly submitted. This is a NRC compatibility requirement.

Item 32 allows elimination of certain surveys. This is a NRC compatibility requirement.

Item 33 corrects wording that was in error.

Items 34, 35, and 36 add wording to include common sources of material. This is a NRC compatibility requirement.

Item 37 adds a new category of patients to be discussed in training. This is a NRC compatibility requirement.

Items 38, 43 and 45 add a substitute for the radiation safety officer. This is a NRC compatibility requirement.

Item 39 changes the requirement to allow a semi-private room if both individuals are being treated. This is a NRC compatibility requirement.

Items 40 and 41 require sealed sources to meet certain requirements. This is a NRC compatibility requirement.

Item 42 adds a new paragraph to require accountability for sources. This is a NRC compatibility requirement.

Item 44 requires emergency equipment be present. This is a NRC compatibility requirement.

Item 46 is amended to include remote afterloaders. This is a NRC compatibility requirement.

Items 47, 48, 49, 50, 52, 53, 55, and 64 are amended to include remote afterloaders and gamma stereotactic radiosurgery units. This is a NRC compatibility requirement.

Item 51 is amended to require nationally recognized protocols for calibration. This is a NRC compatibility requirement.

Items 54, 56, 58, 59, 60, 61, 62, 63, 65, and 68 rescind the current wording and adopt new wording in order to meet NRC compatibility requirements.

Items 57, 66, and 69 change the date for individuals meeting the requirements of these rules.

Item 67 adds an omitted reference.

Item 70 adds new rules in order to meet NRC compatibility requirements. It also includes rules for written directives moved in Item 29.

Item 71 rescinds a requirement omitted in previous rule changes.

Items 73 and 74 add requirements for approved processing services of monitoring devices and clarify wording in order to meet NRC compatibility requirements.

Items 75, 76, 77, 79, 80, 81, 82, and 83 amend or add requirements for well-logging in order to be compatible with NRC requirements.

Item 78 amends recordkeeping times, methods, intervals, and reports in order to be compatible with NRC requirements.

These rules are subject to waiver pursuant to the Department's exemption provision contained at 641—38.3(136C). For this reason, the Department has not provided a specific provision for waiver of these particular rules.

Any interested person may make written suggestions or comments on these proposed amendments prior to the close of business on October 22, 2002. Such written materials should be directed to Donald A. Flater, Chief, Bureau of Radiological Health, Department of Public Health, 401 SW 7th Street, Suite D, Des Moines, Iowa 50309-4611; fax (515)725-0318; or E-mail: dflater@idph.state.ia.us.

A public hearing will be held on October 22, 2002, at 8:30 a.m. in the Conference Room, Department of Public Health, 401 SW 7th Street, Suite D, Des Moines, Iowa, at which time persons may present their views orally or in writing. At the hearing, persons will be asked to give their names and addresses for the record and to confine their remarks to the subject of the amendments.

Any person who plans to attend the public hearing and has special requirements such as those related to hearing or mobility impairments should contact the Department to advise of specific needs.

These amendments are intended to implement Iowa Code chapter 136C.

The following amendments are proposed.

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 8, 2002~~ January 1, 2003.

***20.1003*** ITEM 2. Amend rule **641—38.2(136)** as follows:

Amend the following definitions:

"Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive material (composed wholly or partly of licensed material) exists in concentrations (1) in excess of the derived air concentrations (DACs) specified in Appendix A of 641—Chapter 40; or (2) to such a degree that an individual present in the

area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

"Monitoring (radiation monitoring, radiation protection monitoring)" means the measurement of radiation levels, radioactive material concentrations, surface area ~~activities~~ concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. ~~For purposes of these rules, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.~~

*35.2* "Prescribed dosage" means the ~~quantity~~ specified activity or range of activity of ~~radiopharmaceutical activity~~ unsealed radioactive material as documented:

*35.2* "Prescribed dose" means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

2. For teletherapy, particle accelerators and X-ray systems, the total dose and dose per fraction as documented in the written directive; or

3. For manual brachytherapy, either the total source strength and exposure time or the total doses, as documented in the written directive.

4. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

"Public dose" means the dose received by a member of the public from exposure to ~~sources of radiation possessed~~ radiation or to radioactive material released by a licensee, registrant, or other person, or to any other source of radiation under the control of a licensee, registrant, or other person. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered sources of radiation and released in accordance with 41.2(27) or from voluntary participation in medical research programs.

"Reportable medical event" means the ~~administration of radioactive material for diagnostic medical use that results in the patient's or human research subject's receiving~~ medical event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in:

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

1. ~~Greater or less than 20 percent of a prescribed dose~~ The total dose delivered differs from the proscribed dose by 20 percent or more;

2. ~~A dose intended for another individual; or~~ The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

3. ~~A dose that was not prescribed by an authorized user.~~ The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

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

1. An administration of a wrong radioactive drug containing byproduct material;

2. An administration of a radioactive drug containing byproduct material by the wrong route of administration;

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

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

5. A leaking sealed source.

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

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

"Shallow dose equivalent" ($H_s$), which applies to the external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm$^2$) ~~averaged over an area of 1 square centimeters.~~

"Written directive" means an order in writing for a specific patient or human research subject, dated and signed by an authorized user or individual qualified by training and experience to conduct particle accelerator or X-ray therapy, prior to the administration of a radiopharmaceutical or radiation, ~~except as specified in paragraph "6" of this definition, containing the following information:~~

~~1. For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;~~

~~2. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;~~

~~3. For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;~~

~~4. For teletherapy, particle accelerator or X-ray: the total dose, dose per fraction, treatment site, and overall treatment period;~~

~~5. For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or~~

~~6. For all other brachytherapy:~~

~~a. Prior to implantation: the radioisotope, number of sources, and source strengths; and~~

~~b. After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose)~~ as specified in 41.2(87).

Add the following **new** definitions:

"Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

"Assigned protection factor (APF)" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled

concentration can be estimated by dividing the ambient airborne concentration by the APF.

"Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SRAs) and self-contained breathing apparatus (SCBA) units.

*35.2* "Authorized medical physicist" means an individual who meets the requirements of 641—41.2(74) and 641—41.2(77), 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 a NRC or Agreement State broad scope medical use licensee, or a permit issued by a NRC master material license broad scope medical use permittee.

"Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason.

"Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

"Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

"Filtering facepiece (dust mask)" means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

"Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

"Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

"Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

"Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

"Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

"Negative pressure respirator (tight fitting)" means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

"Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

"Powered air-purifying respirator (PAPR)" means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

"Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

"Qualitative fit test (QLFT)" means a pass-fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

"Quantitative fit test (QNFT)" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

"Self-contained breathing apparatus (SCBA)" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

"Supplied-air respirator (SRA) or airline respirator" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

"Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

*35.2* "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in the written directive.

"User seal check (fit check)" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

ITEM 3. 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 8, 2002~~ January 1, 2003.

*30.31* ITEM 4. Amend subrule **39.4(20)**, paragraph **"a"** as follows:

a. General licenses provided in this chapter are effective without the filing of applications with the agency or the issuance of licensing documents to the particular persons, although the filing of a certificate or registration application with the agency may be required by the particular general license. The general license is subject to all other applicable portions of these rules and any limitations of the general license.

*31.1* ITEM 5. Amend subrule **39.4(22), introductory** paragraph, as follows:

39.4(22) General licenses—radioactive material other than source material. This subrule establishes general licenses for the possession and use of radioactive material and a general license for ownership of radioactive material. (Note: Different general licenses are issued in this subrule, each of which has its own specific conditions and requirements.)

*31.5* ITEM 6. Rescind subrule **39.4(22)"d"** and adopt **new** subrule **39.4(22)"d"** as follows:

d. Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.

(1) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and federal, state or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of 39.4(22)"d"(2), (3), and (4), radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in 39.4(22)"d"(1) applies only to radioactive material contained in devices which have been manufacturer or initially transferred and labeled in accordance with the specifications contained in a specific license by this agency issued under 39.4(29)"d"; or an equivalent specific license issued by the NRC or an Agreement State or a licensing state, which authorized distribution of the devices. The devices must have been received from one of the specific licensees described in 39.4(22)"d"(2) or through a transfer made under 39.4(22)"d"(3).

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

1. Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels; and,

2. Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six month intervals or at such other intervals as are specified in the label; however:

- Devices containing only krypton need not be tested for leakage of radioactive material; and
- Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

3. Shall assure that the test required by 39.4(22)"d"(3) and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

- In accordance with the instructions provided by the labels; or
- By a person holding a specific license pursuant to 641—39.4, the NRC, an Agreement State or a licensing state to perform such activities;

4. Shall maintain records showing compliance with the requirements of 39.4(22)"d"(3). The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

- Each record of a test for leakage or radioactive material required by 39.4(22)"d"(3) must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of;
- Each record of a test of the on-off mechanism and indicator required by 39.4(22)"d"(3) must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of;
- Each record that is required by 39.4(22)"d"(3) must be retained for three years from the date of the recorded event or until the device is transferred or disposed of;

5. Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific

license to repair such devices that was issued by this agency, NRC, an Agreement State or licensing state. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by this agency. A report containing a brief description of the event and the remedial action taken, and in the case of detection of 0.005 microcurie(185 Bq) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the agency within 30 days. Under these circumstances, the criteria set out in 641—40.29 "Radiological criteria for unrestricted use," may be applicable, as determined by the agency on a case-by-case basis;

6. Shall not abandon the device containing radioactive material;

7. Shall not export the device containing radioactive material except in accordance with CFR 10 Part 110;

8. Shall transfer or dispose the device containing radioactive material only by export as provided by 39.4(22)"d"(3)"7," by transfer to another general licensee as authorized in 39.4(22)"d"(3)"9," to a person authorized to receive the device by a specific license issued by the agency, the NRC, an Agreement State or a licensing state whose specific license authorizes the person to receive the device or which authorizes waste collection, or as otherwise approved under 39.4(22)"d"(3):

- Shall furnish a report to this agency within 30 days after the transfer of a device to a specific licensee or export. The report must contain the identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number; the name, address and license number of the person receiving the device (license number not applicable if exported); and the date of the transfer;
- Shall obtain write agency approval before transferring the device to any other specific licensee not specifically identified in 39.4(22)"d";

9. Shall transfer the device to another general licensee only if:

- The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of these rules, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to this agency the manufacturer's (or initial transferor's) name; the model number and the serial number of the device transferred; the transferee's name and mailing address for the location of use; and the name, title, and phone number of the responsible individual identified by the transferee in accordance with 39.4(22)"d"(3)"12" to have knowledge of and authority to take actions to ensure compliance with the appropriate rules and requirements; or
- The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee;

10. Shall comply with the provisions of 641—40.95 and 40.96, but shall be exempt from the other requirements of Chapter 40;

11. Shall respond to written requests from this agency to provide information relating to the general license within 30 calendar days of the date of the request, or other item specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the agency and providing written justification as to why it cannot comply;

12. Shall appoint an individual responsible for having knowledge of the appropriate rules and requirements and the authority for taking required actions to comply with appropriate rules and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate rules and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;

13. Registration.

- Shall register devices containing at least 10 mCi (370 MBq) or cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37 MBq) of cobalt-60, 1 mCi (37MBq) of americium-241, .01 mCi (.37 MBq) of radium-226, or any other transuranic (i.e., element with atomic number greater than uranium (92)), or 1000 times the activity indicated in Appendix B of Chapter 39 (excluding hydrogen-3), based on the activity indicated on the label. Each address for a location of use, as described in 39.4(22)"d"(3)"13" represents a separate general licensee and requires a separate registration and fee;
- If in possession of a device meeting the criteria of 39.4(22)"d"(3)"13" shall register these devices annually with the agency and shall pay the fee required in 38.8(2)"c." Registration must be done by verifying, correcting, and adding to the information provided in a request for registration received from the agency. The registration information must be submitted 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria or 39.4(22)"d"(3)"13" is subject to the bankruptcy notification requirement of 39.4(32)"e;"
- In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the agency:

Name and mailing address of the general licensee;

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

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

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

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

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

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

14. Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the agency within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage;

15. May not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The

testing required by 39.4(22)"d" need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(4) The general license in 39.4(22)"d"(1) does not authorize the manufacture or import of devices containing radioactive material.

*32.51* ITEM 7. Amend subrule **39.4(29)**, paragraph **"d,"** subparagraphs **(1)** and **(3)**, in part, as follows:

(1) An application for a specific license to manufacture or ~~distribute~~ initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 39.4(22)"d" or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state will be approved if:

1. The applicant satisfies the general requirements of 39.4(25);

2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

- The device can be safely operated by persons not having training in radiological protection,
- Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of ~~1 calendar quarter~~ one year a dose in excess of 10 percent of the annual limits specified in 641—40.15(136C); and

3. Each device bears a durable, legible, clearly visible label or labels approved by the agency, NRC, or agreement state or licensing state, which contains in a clearly identified and separate statement:

- Instructions and precautions necessary to ensure safe installation, operation, and servicing of the device. Documents such as operating and service manuals may be identified in the label and used to provide this information;
- The requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and
- The information called for in one of the following statements, as appropriate, in the same or substantially similar form:

> The receipt, possession, use and transfer of this device, Model _____, Serial No. _____, (devices licensed prior to January 19, 1975, may bear labels authorized by the rules in effect on January 1, 1975)(the model, serial number, and name of the manufacturer or ~~distributor~~ initial transferor may be omitted from the label provided the information is elsewhere specified in labeling affixed to the device) are subject to a general license or the equivalent and the chapter of the U.S. Nuclear Regulatory

Commission or a state with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION—RADIOACTIVE MATERIAL

_____

Name of manufacturer or distributor

~~The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent, and the regulations of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.~~

~~CAUTION—RADIOACTIVE MATERIAL~~

~~_____~~

~~Name of manufacturer or distributor~~

4. Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in subrule 40.60(1), and the name of the manufacturer or initial distributor; and,

5. Each device meeting the criteria of 39.4(22)"d"(3)"13" bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in subrule 40.60(1).

(3) In the event the applicant desires that the general licensee under 39.4(22)"d," or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a ~~calendar quarter~~ dose in excess of 10 percent of the annual limits specified in 641—40.15(136C).

*32.52* ITEM 8. Rescind subparagraph **39.4(29)"d"(4)** in its entirety and adopt **new** subparagraphs **(4)**, **(5)**, and **(6)** as follows:

(4) Information to be provided before transfer.

1. If a device containing radioactive material is to be transferred for use under the general license contained in 39.4(22)"d", each person that is licensed under 39.4(22)"d" shall provide the information specified to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In

the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

- A copy of the general license contained in 39.4(22), or if 39.4(22)"d"(3)"2," "3," or "4" or 39.4(22)"d"(3)"13" do not apply to the particular device, those paragraphs may be omitted;
- A copy of 39.4(20), 39.4(52), 40.95, and 40.96;
- A list of the services that can only be performed by a specific licensee;
- Information on acceptable disposal options including estimated costs or disposal; and
- An indication that it is the policy of the U.S. Regulatory Commission and this agency to issue high civil penalties for improper disposal.

2. If radioactive material is to be transferred in a device for use under an equivalent general license of an agreement state, each person that is licensed under 39.4(29)"d" shall provide the information specified in this paragraph to each person to whom a device is to be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

- A copy of the agreement state's rules equivalent to 39.4(29)"d". If a copy of the U.S. Regulatory Commission's regulations is provided to a prospective general licensee in lieu of the agreement state's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the agreement state; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;
- A list of the services that can only be performed by a specific licensee;
- Information on acceptable disposal options including estimated costs of disposal; and
- The name or title, address, and phone number of the contact at the agreement state regulatory agency from which additional information may be obtained.

3. An alternative approach to informing customers may be proposed by the licensee for approval by the agency.

4. Each device that is transferred after February 19, 2002, must meet the labeling requirements in 39.4(29)"d".

5. If a notification of bankruptcy has been made or the license is to be terminated, each person licensed under 39.4(29)"d" shall provide, upon request, to the NRC and to any appropriate agreement state, records of final disposition.

(5) Transfer reports and records. Each person licensed under 39.4(29)"d" to initially transfer devices to generally licensed persons shall comply with the requirements of this subparagraph.

1. The person shall report all transfers of devices to persons for use under the general license in 39.4(29)"d" and all receipts of devices from persons licensed under 39.4(29)"d" to the NRC, this agency, or another agreement state. The report must be submitted on a quarterly basis in a clear and legible report containing all of the data required in this subrule. The required information for transfers to general licensees includes:

- The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

- The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate rules and requirements;
- The date of transfer;
- The type, model number, and serial number of the device transferred; and
- The quantity and type of radioactive material contained in the device.

2. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

3. For devices received from general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

4. If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update the required information, the report must identify the general licensee, the device, and the changes to information on the device label.

5. The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

6. The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

7. If no transfers have been made to or from persons generally licensed under 39.4(29)"d" during the reporting period, the report must so indicate.

(6) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by 39.4(29)"d". Records required in 39.4(29)"d" must be maintained for three years following the date of the recorded event.

ITEM 9. 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 9, 2001~~ January 1, 2003.

***20.1003*** ITEM 10. Amend subrule **40.2(2)** definitions as follows:

"Class (or lung class or inhalation class)" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. ~~For purposes of these rules, "lung class" and "inhalation class" are equivalent terms.~~

"Declared pregnant woman" means a woman who has voluntarily informed her ~~employer~~ licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

***20.1201*** ITEM 11. Amend subrule **40.15(1)**, paragraph **"b"** as follows:

b. The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are:

(1) A lens dose equivalent of 15 rem (0.15 Sv), and

(2) A shallow dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

*20.1201* ITEM 12. Amend subrule **40.15(3),** paragraph **one**, as follows:

40.15(3) The assigned deep dose equivalent ~~and shallow-dose equivalent shall~~ must be for the portion of the body receiving the highest exposure ~~determined as follows:~~ The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure.

*20.1301* ITEM 13. Amend subrule **40.26(2)** as follows:

40.26(2) If the licensee or registrant permits members of the public to have access to ~~restricted~~ controlled areas, the limits for members of the public continue to apply to those individuals.

*20.1301* ITEM 14. Adopt **new** subrule **40.26(6)** as follows:

40.26(6) Notwithstanding the requirements of 40.26(1)"a," a licensee may permit visitors to an individual who cannot be released under 41.2(27), to received a radiation dose greater than 0.1 rem (1 mSv) if:

a. The radiation dose received does not exceed 0.5 rem (5 mSv); and

b. The authorized user, as defined in 41.2(2) has determined before the visit that is if appropriate.

*34.47* ITEM 15. Add **new** subrule **40.36(5)** as follows:

40.36(5) After replacement, each personnel dosimeter must be sent for processing as soon as possible.

*20.1701* ITEM 16. Amend rule **641—40.48(136C)** as follows:

641—40.48(136C) Use of process or other engineering controls. The licensee shall use, to the extent practical, process or other engineering controls, such as containment, decontamination, or ventilation, to control the concentrations of radioactive material in air.

*20.1702* ITEM 17. Amend rule **641—40.49(136C)** as follows:

641—40.49(136C) Use of other controls.

a. When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

~~40.49(1)~~ (1) Control of access; ~~or~~

~~40.49(2)~~ (2) Limitation of exposure times; ~~or~~

~~40.49(3)~~ (3) Use of respiratory protection equipment; or

~~40.49(4)~~ (4) Other controls.

b. If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

*20.1703* ITEM 18. Amend subrule **40.50(1)** as follows:

40.50(1) If the licensee ~~uses~~ assigns or permits the use of respiratory protection requirement to limit intakes pursuant to 40.49(136C):

a. ~~Except as provided in 40.50(1), the~~ The licensee shall use only respiratory protection equipment that is tested and certified ~~or had certification extended~~ by the

National Institute for Occupational Safety and Health~~ and the Mine Safety and Health Administration.~~ (NIOSH) except as otherwise noted in this part.

b. If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health ~~and the Mine Safety and Health Administration has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration,~~ or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

c. The licensee or registrant shall implement and maintain a respiratory protection program that includes:

(1) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; ~~and~~

(2) Surveys and bioassays, as appropriate, to evaluate actual intakes; ~~and~~

(3) Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use; ~~and~~

(4) Written procedures regarding ~~selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and record keeping; and~~ monitoring, including air sampling and bioassays; supervision and training of respirator user; fit testing; respirator selection; breathing air quality; inventory and control; storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment; record keeping; and limitations on periods of respirator use and relief from respirator use;

(5) Determination by a physician ~~prior to initial fitting of respirators, and either every 12 months thereafter, or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment.~~ that the individual user is medically fit to use respiratory protection equipment; before the initial fitting of a face sealing respirator; before the first field use of non-face sealing respirators; and either every 12 months thereafter, or periodically at a frequency determined by a physician; and,

(6) Fit testing, with fit factor equal to or greater than 10 times the APF for negative pressure devices, and a fit factor equal to or greater than 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

~~d. The licensee shall issue a written policy statement on respirator usage covering;~~

~~(1) The use of process or other engineering controls, instead of respirators; and~~

~~(2) The routine, nonroutine, and emergency use of respirators; and~~

~~(3) The length of periods of respirator use and relief from respirator use.~~

~~e.~~d. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

e. The licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

~~f. The licensee or registrant shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.~~

f. Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

g. Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "commodity Specification for Air," 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E)). Grade D quality air criteria include:

(1) Oxygen content (v/v) of 19.5-23.5%;

(2) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

(3) Carbon monoxide (CO) content of 10 ppm or less;

(4) Carbon dioxide content of 1000 ppm or less; and

(5) Lack of noticeable odor.

h. The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face, facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

i. In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

***20.1704*** ITEM 19. Amend subrule **40.50(4)** as follows:

40.50(4) Further restrictions.

a. The licensee shall notify the agency in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either 40.50(1) or 40.50(2).

b. The agency may impose restrictions in addition to those listed in these rules in order to ~~limit individual exposures.~~:

(1) Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

(2) Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

ITEM 20. Adopt **new** rule **641—40.117(136C)** as follows:

641—40.117(136C) Employee Protection

40.117(1) Discrimination by a licensee or registrant, an applicant for a license or registration, or a contractor or subcontractor of a licensee or applicant against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirements imposed under the Atomic Energy Act or the Energy Reorganization Act.

a. The protected activities include but are not limited to:

(1) Providing the Agency or his or her employer information about alleged violations of either of the statutes named in this rule or possible violations of requirements imposed under either of those statutes:

(2) Refusing to engage in any practice made unlawful under either of the statutes named in this rule or under these requirements if the employee has identified the alleged illegality to the employer;

(3) Requesting the Agency to institute action against his or her employer for the administration or enforcement of these requirements:

(4) Testifying in any Agency proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (proposed provision) of either of the statutes named in this rule.

(5) Assisting or participating in, or is about to assist or participate in, these activities.

b. These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

c. This rule has no application to any employee alleging discrimination prohibited by this rule who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

40.117(2) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in 40.117(1)"a" may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administration proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

40.117(3) A violation of 40.117(1) or (4) by a licensee or registrant, an applicant for a license or registration, or a contractor or subcontractor of a licensee or applicant may be grounds for:

a. Denial, revocation, or suspension of the license or registration.

b. Imposition of a civil penalty on the licensee, registrant, or applicant.

c. Other enforcement action.

40.117(4) Actions taken by an employer or others, which adversely affect an employee, may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by non-prohibited considerations.

40.117(5) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in 40.117(1)"a" including, but not limited to, providing information to the Agency or to his or her employer on potential violations or other matters within the Agency's regulatory responsibilities.

ITEM 21. Amend subrule **41.2(1)** as follows:

41.2(1) Purpose and scope.

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

b. All references to any Code of federal Regulations (CFR) in this chapter are those in effect as of ~~July 1, 1998~~ January 1, 2003.

*35.2* ITEM 22. Amend subrule **41.2(2)** as follows:

Amend the following definitions:

"Authorized nuclear pharmacist" means a pharmacist who has met the appropriate requirements of 41.2(78) and 41.2(77) and who:

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 U.S. Regulatory Commission or Agreement State that authorizes medical use or the practice of pharmacy;

(2) A permit issued by a U.S. Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(3) A permit issued by the U.S. Regulatory Commission or Agreement State broad scope medical use licensee that authorizes more than the practice of nuclear pharmacy; or

(4) A permit issued by a U.S. Regulatory Commission master material license broad scope medical use permittee that authorizes 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 39.4(29)"j"(2) numbered paragraph 3.

"Authorized user" means a physician, dentist, or podiatrist who has met the appropriate requirements of 41.2(67), 41.2(68), 41.2(70), 41.2(71), 41.2(72), or 41.2(73) and who: ~~uses radioactive materials as authorized by a current medical use Iowa radioactive materials license~~.

a. Is identified on a current Iowa, U.S. Regulatory Commission, or agreement state license that authorizes the medical use of radioactive material;

b. A permit issued by a U.S. Regulatory Commission master material licensee that is authorized to permit the medical use of radioactive material;

c. A permit issued by a Commission, agreement state, or Iowa specific licensee of broad scope that is authorized to permit medical use of radioactive material; or

d. A permit issued by a U.S. Regulatory Commission master material license broad scope permittee that is authorized to permit medical use of radioactive material.

Adopt **new** definitions as follows:

"Authorized medical physicist" means an individual who:

a. Meets the requirements of 41.2(74) and 41.2(77); or

b. Is identified as an authorized medical physicist or teletherapy physicist on:

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

(2) A medical use permit issued by a NRC master material licensee;

(3) A permit issued by a U.S. Regulatory Commission or agreement state broad scope medical use licensee; or

(4) A permit issued by a U.S. Regulatory Commission master material license broad scope medical use permittee.

"Radiation safety officer" means an individual who, in addition to the definition in subrule 38.1(2), meets the requirements of 41.2(65), (66), and (77) and is identified as a Radiation safety officer on a specific medical use license issued by Iowa, the U.S. Regulatory Commission, or agreement state or medical use permit issued by a U.S. Regulatory Commission master material licensee..

***35.24*** ITEM 23. Rescind subrule **41.2(10)** and adopt **new** subrule **41.2(10)** as follows:

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

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

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

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

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

b. A licensee's management shall appoint a Radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Office, shall ensure that the radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

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 (66) to function as a temporary Radiation safety officer to perform the functions of Radiation safety officer, as provided in 41.2(10)"g," if the licensee takes the actions required in 41.2(10)"b," "e," "g," and "h" and notifies this agency in accordance with 41.2(5).

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

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

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

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

(1) Identify radiation safety problems;

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

(3) Verify implementation of corrective actions, and

(4) Stop unsafe operations.

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

*35.27* ITEM 24. Amend subrule **41.2(11)**, paragraph "**a**," subparagraph **(1)** as follows:

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

*35.80* ITEM 25. Amend subrule **41.2(13)**, paragraph "**b**" and adopt **new** paragraph "**e**" as follows:

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

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

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

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

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

*35.3045* ITEM 26. Amend subrule **41.2(14)**, title and paragraph "**a**" as follows:

41.2(14) Records and reports of misadministrations~~,~~ and reportable events~~, and written directives~~.

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

***35.3045*** ITEM 27. Amend subrule **41.2(14)**, paragraph "**b**," subparagraph **(1)**, the first sentence as follows:

(1) The licensee shall submit a written report to the agency within 15 days after discovery of the misadministration ~~and 30 days after discovery of a~~ or reportable medical event.

***35.3045*** ITEM 28. Amend subrule **41.2(14)**, paragraph "**b**," subparagraph **(2)** as follows:

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

ITEM 29. Rescind subrule **41.2(14)**, paragraph "**f**."

***35.61*** ITEM 30. Amend subrule **41.2(18)**, paragraph "**c**" as follows:

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

***35.3067*** ITEM 31. Amend subrule **41.2(21)**, paragraph "**e**," subparagraph **(2)** as follows:

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

***35.70*** ITEM 32. Amend subrule **41.2(26)** by adopting **new** paragraph "**i**"as follows:

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

***35.92*** ITEM 33. Amend subrule **41.2(30)**, paragraph "**a**" as follows:

a. A licensee may hold radioactive material with half-lives of less than ~~65~~ 120 days, except for Cobalt-57 for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of 641—subrule 40.70(1) if the licensee:

***35.100*** ITEM 34. Amend subrule **41.2(31), introductory** paragraph, and adopt **new** paragraphs "**c**" and "**d**" as follows:

41.2(31) Use of radiopharmaceuticals for uptake, dilution, or excretion studies. ~~The~~ Except for quantities that require a written directive under 641—41.2(87), a licensee may use for uptake, dilution, excretion and imaging studies any unsealed by-product material prepared for medical use that is either:

c. Obtained from and prepared by a NRC or Agreement state licensee for use in research in accordance with Radioactive Drug Research committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA, or

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

***35.200*** ITEM 35. Amend subrule **41.2(33), introductory** paragraph and paragraph "**a**," and adopt **new** paragraphs "**c**" and "**d**" as follows

41.2(33) Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies. ~~The~~ Except for the quantities that require written directive under 641—41.2(87), a licensee may use for imaging and localization studies any unsealed by-product material prepared for medical use that is either:

a. Obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29)"j" or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements: ~~or~~

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

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

***35.300*** ITEM 36. Rescind subrule **41.2(37)** and adopt **new** subrule **41.2(37)** as follows:

41.2(37) Use of radiopharmaceutial for therapeutic use or unsealed byproduct material for which a written directive is required. Material must be:

a. Obtained from a manufacturer or preparer licensed by a NRC, or agreement state to manufacture and prepare byproduct material for medical use; or

b. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements of 41.2(68) or (69), or an individual under the supervision of either as specified in 41.2(11); or

c. Obtained from and prepared by a NRC, or agreement state licensee for use in research in accordance with the Investigation New Drug (IND) protocol accepted by FDA; or

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

***35.310*** ITEM 37. Amend subrule **41.2(38)**, paragraph "**a**" as follows:

a. A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subject undergoing radiopharmaceutical therapy and hospitalized for compliance with 41.2(27). Refresher training shall be provided at intervals not to exceed one year.

*35.310* ITEM 38. Amend subrule **41.2(38)**, paragraph "**b**," subparagraph **(5)** as follows:

(5) Notification of the Radiation safety officer, Radiation safety officer designee, or authorized user in case of the patient's or human research subject's death or medical emergency; and

*35.315* ITEM 39.Amend subrule **41.2(39)**, paragraph "**a**," subparagraph **(1)** as follows:

(1) Provide a private room with a private sanitary facility or a room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be be released under 41.2(27);

*35.500* ITEM 40. Rescind subrule **41.2(41)** and adopt **new** subrule **41.2(41)** as follows:

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

*35.400* ITEM 41. Rescind subrule **41.2(43)** and adopt **new** subrule **41.2(43)** as follows:

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

a. As approved in the Sealed Source and Device Registry; or

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

35.406 ITEM 42. Amend subrule **41.2(46)** by adopting **new** paragraph "**e**" as follows:

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

*35.410* ITEM 43. Amend subrule **41.2(44)**, paragraph "**b**," subparagraphs **(4)** and **(5)** as follows:

(4) Procedures for visitor control, to include routine visitation of hospitalized individuals in accordance with 641—40.26 and visitation authorized in accordance with 641—40.26;

(5) Procedures for notification of the Radiation safety officer, Radiation safety officer designee, or authorized user if the patient or human research subject dies or has a medical emergency; and

*35.415* ITEM 44. Amend subrule **41.2(45)**, paragraph "**a**," by adopting **new** subparagraph **(6)** as follows:

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

*35.415* ITEM 45. Amend subrule **41.2(45)**, paragraph "**b**" as follows:

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

*35.604* ITEM 46. Amend subrule **41.2(47)**, paragraph "**a**" as follows:

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

*35.600* ITEM 47. Rescind subrule **41.2(49)** and adopt **new** subrule **41.2(49)** as follows:

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

*35.605* ITEM 48. Rescind subrule **41.2(50)** and adopt **new** subrule **41.2(50)** as follows:

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

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

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

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

*35.2605* d. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader teletherapy units, and gamma stereotactic radiosurgery units for three years. The record must include the date, description of the service, and the name of the individual who performed the work.

*35.610* ITEM 49. Rescind subrule **41.2(52)** and adopt **new** subrule **41.2(52)** as follows:

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

a. A licensee shall:

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

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

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

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

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

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

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

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

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

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

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

d. A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, appropriate to the individual's assigned duties, in:

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

(2) The operating procedures for the unit.

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

f. A licensee shall retain a record of individuals receiving instruction required by 41.2(52)"d," a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years. A copy of the procedures required in 41.2(52)"a"(4) and "d"(2) shall be retained for three years.

***35.615*** ITEM 50. Amend subrule **41.2(53), introductory** paragraph, rescind paragraph "**c**," and adopt **new** paragraphs "**c**," "**d**," "**e**," "**f**," and "**g**" as follows:

41.2(53) ~~Doors, interlocks, and warning systems.~~ Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery unit.

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

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

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

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

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

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

2. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator in the event of an emergency involving the unit to be immediately available during continuation of all patient treatments involving the unit.

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

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

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

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist be physically present throughout all patient treatments involving the unit.

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

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

***35.630*** ITEM 51. Amend subrule **41.2(57)**, paragraph "**a**" as follows:

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

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

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

~~intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.~~ The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for ~~calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source~~ sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, if applicable, and sources of the same radionuclide as the source used at the licensee's facility.

*35.632* ITEM 52. Rescind subrule **41.2(58)** and adopt new subrule **41.2(58)** as follows:

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

a. Teletherapy units.

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

1. Before the first medical use of the unit; and
2. Before medical use under the following conditions:

- Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output of the last full calibration corrected mathematically for radioactive decay;
- Following replacement of the source or following reinstallation of the teletherapy unit in a new location;
- Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

1. At intervals not exceeding 1 year.

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

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

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

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

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

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

(7) A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the unit and the source, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the authorized medial physicist.

*35.633* b. Remote afterloader units.

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

1. Before the first medical use of the unit;
2. Before medical use under the following conditions:

- Following replacement of the source or following reinstallation of the unit in a new location outside the facility;
- Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

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

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

1. The output within $\pm$ 5 percent;
2. Source positioning accuracy to within $\pm$ 1 millimeter;
3. Source retraction with backup battery upon power failure;
4. Length of the source transfer tubes;
5. Timer accuracy and linearity over the typical range of use;
6. Length of the applicators; and
7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

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

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

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

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

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

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

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

*35.635* c. Gamma stereotactic radiosurgery units.

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

1. Before the first medical use of the unit;
2. Before medical use under the following conditions:

- Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
- Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
- Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

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

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

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

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

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

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

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

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

***35.642*** ITEM 53. Rescind subrule **41.2(59)** and adopt **new** subrule **41.2(59)** as follows:

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

a. Teletherapy units.

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

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

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

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

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

1. Electrical interlocks at each teletherapy room entrance;
2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
4. Viewing and intercom systems:
5. Treatment room doors from inside and outside the treatment room; and
6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

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

*35.2642* (6) A licensee shall retain a record of each spot-check required in 41.2(59)"a" for three years. The record must include:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
3. An assessment of timer linearity and constancy;
4. The calculated on-off error;
5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
6. The determined accuracy of each distance measuring and localization device;
7. The difference between the anticipated output and the measured output;
8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical source exposure indicator light, and the viewing and intercom system and doors; and
9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

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

*35.643*

b. Remote afterloader units.

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

1. Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;
2. Before each patient treatment with a low dose-rate remote afterloader unit: and
3. After each source installation.

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

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

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

1. Electrical interlocks at each remote afterloader unit room entrance;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;
4. Emergency response equipment;
5. Radiation monitors used to indicate the source position;
6. Timer accuracy;

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

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

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

(6) A licensee shall retain a record of each check required in 41.2(59)"b"(4) and a copy of the procedures required by 41.2(59)"b"(2). The record must include:

1. The date of the spot-check;

2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

3. An assessment of timer accuracy;

4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

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

***35.2643***

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

***35.645***

c. Gamma stereotactic radiosurgery units

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

1. Monthly;

2. Before the first use of the unit on a given day; and

3. After each source installation.

(2) A licensee shall:

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

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

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

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

2. Determine:

- The output for one typical set of operating conditions measured with the dosimetry system described in 41.2(57);
- The difference between the measurement made in the above and the anticipated output expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);
- Source output against computer calculation;

- Timer accuracy and linearity over the range of use;
- On-off error; and
- Trunnion centricity.

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

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

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

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

***35.2645***

(7) A licensee shall retain a record of each check required by 41.2(59)"c"(3) and (4) and a copy of the procedures required in 41.2(59)"c"(2). The record must include:

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

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

***35.652*** ITEM 54. Rescind subrule **41.2(60)**, paragraphs "**a**" and "**b**" and adopt <u>new</u> paragraphs "**a**" and "**b**" as follows:

41.2(60) Radiation surveys.

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

b. The licensee shall make the survey required in 41.2(60)"a" at installation of a new source, following repairs to the source shielding, the source driving unit, or other

electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the source.

*35.655* ITEM 55. Amend subrule **41.2(64)**, paragraphs "**a**" and "**c**" as follows:

a. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to ensure proper functioning of the source exposure mechanism.

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

*35.50* ITEM 56. Rescind subrule **41.2(65)** and adopt **new** as follows:

41.2(65) Training for Radiation safety officer. Except as provided in 41.2(66), 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 include all of the requirements in 41.2(65)"b" and whose certification has been recognized by this agency, the NRC, or an agreement state; or

b. Has completed a structured educational program consisting of both:

(1) 200 hours of didactic training in:

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 a NRC or agreement state license or permit issued by a NRC master material license that authorizes similar types of use of byproduct 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 and 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;
7. Disposing of radioactive material; and

(3) Has obtained written certification, signed by a preceptor Radiation safety officer, that the individual has satisfactorily complete the requirements of 41.2(65)"b" and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation safety officer for a medical use licensee; or

c. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the 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.

***35.901*** ITEM 57. Amend subrule **41.2(66)** as follows:

41.2(66) Training for experienced Radiation safety officer. An individual identified as a Radiation safety officer on an ~~agency,~~ agreement state, licensing state, or U.S. Nuclear Regulatory Commission license on ~~September 1, 1992~~ January 1, 2003, who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of 41.2(65).

***35.190*** ITEM 58. Rescind subrule **41.2(67)** and adopt **new** subrule **41.2(67)** as follows: 41.2(67) Training for uptake, dilution, and excretion studies. Except as provided in 41.2(76), the licensee shall require an authorized user of unsealed byproduct material for uses authorized under 41.2(31) to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(67)"b" and whose certification has been recognized by the NRC or an Agreement state; or

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

c. Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience shall include:

(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. Chemistry of byproduct material for medical use; and
5. Radiation biology; and

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

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Calibrating 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 humans research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material; and
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
6. Administering dosages of radioactive drugs to patients or human research subjects; and

(3) Written certification, signed by a preceptor authorized user who meets the requirements in 41.2(68) or 41.2(69), that the individual has satisfactorily completed requirements of 41.2(67)"b" and has achieved a level of competency sufficient to

function independently as an authorized user for the medical uses authorized under 41.2(31).

*35.290* ITEM 59. Rescind subrule **41.2(68)** and adopt <u>new</u> 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 an authorized user of unsealed byproduct material for medical uses as authorized under 41.2(33) to be a physician who:

a. Is certified by a medical specialty board whose certification includes all of the requirements in 41.2(68)"b" and whose certification has been recognized by this agency, the NRC or an agreement state; or

b. Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct 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 or radioactivity;
4. Chemistry of byproduct material for medical use;
5. Radiation biology; and

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

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Calibrating 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 control s to prevent a medical event involving the use of unsealed byproduct material;
5. Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
6. Administering dosages of radioactive drugs to patients or human research subjects; and
7. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare radioactive drugs; and

(4) Written certification, signed by a preceptor authorized user who meets the requirements in 41.2(68) or (69), that the individual has satisfactorily completed the requirements in 41.2(68) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in 41.2(31) and 41.2(33).

*35.390* ITEM 60. Rescind subrule **41.2(69)** and adopt <u>new</u> subrule **41.2(69)** as follows:

41.2(69) Training for therapeutic use of radiopharmaceuticals or use of unsealed byproduct material for which a written directive is required.

a. Except as provided in 41.2(66), (75), and (79), the licensee shall require the authorized user of unsealed byproduct material for authorized in 41.2(37) to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(69)"a"(2) and whose certification has been recognized by the NRC, or an agreement state; or

(2) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct 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 byproduct material for medical use; and radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements of 41.2(69)"a"(1) or (2). A supervising authorized user, who meets the requirements of 41.2(69)"a"(2) must have experience in administering dosages in the same dosage category or categories 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;
- Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of 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 byproduct material;
- Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;
- Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and
- 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:

(a) Oral administration of less than or equal to 33 millicuries (1.22 GBq) of sodium iodide I-131;

(b) Oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide I-131. Experience with at least three cases in this category also satisfies the requirements in (a) above;

(c) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; or

(d) Parenteral administration of any other radionuclide; and

3. Has obtained written certification that the individual has satisfactorily completed the requirements in 41.2(69)"a"(2)"1" and has achieved a level of competency sufficient

to function independently as an authorized user in the medical uses authorized 41.2(37). The written certification must be signed by a preceptor authorized user meeting the requirements in 41.2(69)"a"(1) or (2), or equivalent NRC or agreement state requirements. The preceptor authorized user who meets the requirements in 41.2(69)"a"(2), must have experience in administering dosages in the same dosage or categories (i.e., 41.2(69)"a"(2)"2" last bulleted paragraph) as the individual requesting authorized user status.

b. 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 GBq). Except as provided in 41.2(66), (75), and (79), the licensee shall require an authorized user for the oral administration of sodium iodide-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 GBq), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(69)"b"(3) and whose certification has been recognized by this agency, NRC, or agreement state; or

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

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

1. Radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; chemistry of byproduct material for medical use; and radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirement in 41.2(69)"a"(1) or (2) or 41.2(69)"b," or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)"a"(2), must have experience in administering dosages as specified in 41.2(69)"a"(2)"2" last bulleted paragraph (1). The work experience must involve:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Calibrating 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 byproduct material;
- Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;
- Administering dosages to patients or human research subjects, that includes at least 3 cases involving the administration of less than or equal to 33 millicuries (1.22 GBq); and

3. Written certification that the individual has satisfactorily completed the requirements in 41.2(69)"b"(3)"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 certification must be signed by a preceptor authorized user who meets the

requirements of 41.2(69), or equivalent agreement state requirements. A preceptor authorized user, who meets the requirement of 41.2(69)"a"(2), must have experience in administering specified in 41.2(69)"a"(2)"2," the first or second bulleted paragraph.

*35.490* ITEM 61. Rescind subrule **41.2(70)** and adopt <u>new</u> subrule **41.2(70)** as follows:

41.2(70) Training for therapeutic use of manual brachytherapy sources. Except as provided in 41.2(66), (75), and (79), the licensee shall require the authorized user using a manual brachytherapy source authorized in 41.2(43) to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(70)"b" and whose certification has been recognized by this agency, the NRC, or an agreement state; or

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

(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; and
4. Radiation biology; and

(2) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(70)"b" or equivalent NRC or agreement state requirements at a medical institution, involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Checking survey meters for proper operation;
3. Preparing, implanting, and removing brachytherapy sources;
4. Maintaining running inventories of material on hand;
5. Using administrative controls to prevent a medical even involving the use of byproduct material;
6. Using emergency procedures to control byproduct material; and

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

(4) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in 41.2(70) or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(70)"b" and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized in 41.2(43).

*35.491* ITEM 62. Rescind subrule **41.2(71)** and adopt <u>new</u> subrule **41.2(71)** as follows:

41.2(71) Training for ophthalmic use of strontium-90. Except as provided in 41.2(66), (75), and (79), the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy be a physician who:

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

b. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium ophthalmic radiotherapy.

(1) 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) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. The supervised 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 certification, signed by a preceptor authorized user who meets the requirements in 41.2(71) that the individual has satisfactorily completed the requirements of 41.2(71)"a" and "b" and has achieved a level of competency sufficient to function independently as a authorized user of strontium-90 for ophthalmic use.

ITEM 63. Rescind subrule **41.2(72)** and adopt **new** subrule **41.2(72)** as follows:

***35.590***

41.2(72) Training for use of sealed sources for diagnosis. Except as provided in 41.2(66), (75), and (79), the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized in 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 whose certification has been recognized by this agency, the NRC, or an agreement state; or

b. Has had 8 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;
(4) Radiation biology; and
(5) Training in the use of the device for the uses requested.

***35.690*** ITEM 64. Rescind subrule **41.2(73)** and adopt **new** **41.2(73)** follows:

41.2(73) Training for remote afterloader units, teletherapy, and gamma stereotactic radiosurgery units. Except as provided in 41.2(66), (75), and (77), the licensee shall require the authorized user of a sealed source specified in 41.2(49) to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(73)"b" and whose certification has been recognized by this agency, the NRC, or an agreement state; or

b. 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:

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

(2) 500 hours of work experience, under the supervision of an authorized user who meets the requirements of 41.2(73)"b" or equivalent agreement state requirements at a medical institution, involving:

1. Review of the full calibration measurements and periodic spot checks;
2. Preparing treatment plans and calculating treatment doses and times;
3. Using administrative controls to prevent a medical event involving the use of byproduct material;
4. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
5. Checking and using survey meters; and
6. Selecting the proper dose and how it is to be administered.

(3) Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements of 41.2(73) or equivalent agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education 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"(2); and

(4) Has obtained written certification that the individual has satisfactorily completed the requirements on 41.2(73)"b" 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 certification must be signed by a preceptor authorized user who meets the requirements of 41.2(73) for each type of therapeutic medical unit for which the individual is requesting authorized user status.

*35.51* ITEM 65. Rescind subrule **41.2(74)** and adopt **new** subrule **41.2(74)** as follows:

41.2(74) Training for teletherapy physicist or authorized medical physicist. Except as provided in 41.2(66), (75), and (77), the licensee shall require the authorized medical physicist to be an individual who:

a. Is certified by a specialty board whose certification process includes all of the training and experience required in 41.2(74)"b" and whose certification has been recognized by this agency, the NRC, or an agreement state for byproduct use only; or

b. Hold a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics; and

(1) Has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements of a teletherapy physicist or authorized medical physicist at a medical institution that includes the tasks listed in 41.2(21), 41.2(58), 41.2(59), 41.2(60), and 41.2(85), as applicable; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements of 41.2(74)"b"(1) 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 certification must be signed by a preceptor authorized medical physicist who meets the requirements of 41.2(74) for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

*35.57* ITEM 66. Amend subrule **41.2(75)** as follows:

41.2(75) Training for experienced authorized users and teletherapy or medical physicists. ~~Rescinded IAB 8/3/94, effective 9/7/94.~~

a. An individual identified as a teletherapy or medical physicist on a NRC or agreement state license or a permit issued by a 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).

b. Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material issued by this agency, the NRC, or agreement state, a permit issued by a NRC master material licensee, a permit issued by a NRC 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(68), (69), (70), (71), (72), or (73).

*35.59* ITEM 67. 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) 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 was completed.

*35.55* ITEM 68. Rescind subrule **41.2(78)** and adopt **new** 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" and whose certification has been recognized by the NRC or Agreement state; or

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

(1) Didactic 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 byproduct material for medical use; and
5. Radiation biology; and

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

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

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

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

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

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

c. Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual satisfactorily completed the requirements in 41.2(78)"b" and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

*35.57* ITEM 69. Rescind subrule **41.2(79)** and adopt **new** subrule **41.2(79)** as follows:

41.2(79) Training for experience nuclear pharmacists. An individual identified as a nuclear pharmacist on a NRC or Agreement state license or permit issued by a 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, need not comply with the training requirements of 41.2(78).

ITEM 70. Adopt **new** subrules **41.2(83), (84), (85), (86),** and **(87)** as follows:

*35.6*

41.2(83) Provisions for the protection of human research subject.

a. A licensee may conduct research involving human research subjects only if it uses the radioactive materials authorized on its specific license for the uses authorized on its license.

b. If the research is conducted, funded, supported, or regulated by another Federal agency that has implemented Federal Policy for the Protection of Human Subject (Federal Policy), the licensee shall, before conducting research:

1. Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

2. Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

c. If the research will not be conducted, funded, supported, or regulated by another federal agency that has the Federal Policy, the license shall, before conducting research, apply for and receive a specific amendment to its medical use license. The amendment request must include a written commitment that the licensee will, before research:

1. Obtain review and approval of the research from an "Institutional Review Board," as defined and described n Federal Policy; and

2. Obtain "informed consent," as defined and described in the Federal Policy, from the human research subjects.

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

*35.432*

41.2(84) Calibration measurements of brachytherapy sources.

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

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

(2) Determined source positioning accuracy within applicators; and

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

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

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

*35.2432*

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

(1) The date of the calibration;

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

(3) The source output or activity;

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

(5) The signature of the authorized medical physicist.

*35.433*

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

a. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 41.2(85).

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

*35.657 and 35.457*

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

a. The source-specific input parameters required by the dose calculation algorithm;

b. The accuracy of dose, dwell time, and treatment time calculations at representative points;

c. The accuracy of isodose plots and graphic displays;

d. The accuracy of the software used to determine sealed source positions from radiographic images; and

e. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

*35.40*

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

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

(1) For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(4) For teletherapy, particle accelerator or X-ray: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;

(5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

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

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

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

*35.41*

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

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

d. Each administration is in accordance with the written directive. Check both manual and computer-generated dose calculations. Verify that any computer-generated dose calculations are correctly transferred into the consoles of the medical units authorized by 641—chapter 41.

e. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken;

f. If because of the emergent nature of the patient's condition, a delay in order to provide a written directive jeopardizes the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

g. Retain a copy of the written directive in auditable form for three years after the date of administration.

ITEM 71. Amend subrule **41.3(6)** by rescinding paragraph "**e.**"

ITEM 72. Amend subrule **45.1(1)** as follows:

45.1(1) Purpose and scope.

a. The rules in this chapter establish radiation safety requirements for using sources of radiation for industrial radiography. The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements of 641—Chapters 38, 39, and 40. The rules in this chapter apply to all licensees or registrants who use sources of radiation for industrial radiography.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 8, 2002~~ January 1, 2003.

*34.47* ITEM 73. Amend subrule **45.1(12)**, paragraph **"b,"** subparagraphs **(1), (2), (4),** and **(8)** as follows:

(1) No licensee or registrant shall permit an individual to act as a radiographer, radiographer trainee, or radiographer trainer unless at all times during radiographic operations each individual wears, on the trunk of the body, a combination of direct-reading pocket dosimeter, an operating alarm ratemeter, and a film badge, an optically luminescent stimulated device (OSL device) or a thermoluminescent dosimeter (TLD) that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP). For permanent radiographic installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarm ratemeter is not required.

(2) Pocket dosimeters or electronic personal dosimeters shall meet the criteria in ANSI N322-1977 and shall have a range of zero to at least 200 ~~milliroentgens~~ millirems. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

(4) Pocket dosimeters or electronic personal dosimeters shall be read and exposures recorded at ~~least once daily,~~the beginning and at the end of each work shift, and before each recharging.

(8) If an individual monitoring device is lost or damaged, the worker shall cease work immediately until a replacement individual monitoring device is provided and the exposure is calculated for the time period from issuance to loss or damage of the individual monitoring device. The results of the calculated exposure and the time period for which the individual monitoring device was lost or damaged must be included in the records maintained in 45.1(12)"c."

*34.83* ITEM 74. Amend subrule **45.1(12),** paragraph **"c"** as follows:

c. Records of pocket dosimeter readings of personnel exposures and yearly operability checks required in 45.1(12)"d" shall be maintained for two years by the licensee or registrant for agency inspection. If the dosimeter readings were used to determine external radiation dose (i.e., no TLD or film badge exposure records exist), the records shall be maintained until the agency authorizes disposal. Records of estimates of exposures as a result of: off-scale personal direct reading dosimeters, or lost or damaged film badges, OSLs, or TLDs, shall be maintained until the agency terminates the license.

ITEM 75. Amend title to **641—45.6(136C)** as follows:

641—45.6(136C) Radiation safety requirements for well-logging, wireline service operations and subsurface tracer studies.

*39.2* ITEM 76. Amend subrule **45.6(3)** as follows:

Delete the definition of "mineral-logging."

Amend the following definitions:

"Logging supervisor" means the individual who uses ~~sources of radiation~~ licensed material or provides personal supervision ~~of the utilization of sources of radiation at the well site.~~ in the use of licensed material at a temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of these rules and the conditions of the license.

"Personal supervision" means guidance and instruction by the logging supervisor who is physically present at the temporary job site ~~and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance~~

~~given as required.~~ ,who is in personal contact with logging assistants, and who can give immediate assistance.

"Radioactive marker" means ~~radioactive~~ licensed material ~~placed subsurface or on a structure intended for subsurface use for the purpose of~~ used for depth determination or direction orientation. For purposes of this rule, this term includes radioactive collar markers and radioactive iron nails.

"Source holder" means a housing or assembly into which a ~~radioactive source~~ sealed source is placed ~~for the purpose of facilitating~~ to facilitate the handling and use of the source in well-logging operations.

"Subsurface tracer study" means the release of unsealed license material or a substance ~~tagged with radioactive~~ labeled with licensed material in a single well for the purpose of tracing the movement or position of the ~~tagged~~ material or substance in the well~~-bore~~ or adjacent formation.

"Temporary job site" means a ~~location~~ place where ~~radioactive~~ licensed materials are present for the purpose of performing ~~wireline service operations~~ well logging or subsurface tracer studies.

"Well~~-bore~~" means a drilled hole in which ~~wireline service operations or subsurface tracer studies are~~ may be performed. As used in this rule, "well" includes drilled holes for the purpose of oil, gas, mineral, groundwater, or geological exploration.

"Well-logging" means all operations involving the lowering and raising of measuring devices or tools which may contain ~~sources of radiation into well bores or cavities~~ licensed material or are used to detect licensed materials in wells for the purpose of obtaining information about the well or adjacent formations which may be used in oil, gas, mineral, groundwater, or geological exploration.

Adopt the following **new** definitions:

"Energy compensation source (ECS)" means a small sealed source, with an activity not exceeding 3.7 MBg (100 microcuries), used within a logging tool, or other tool components, to provide a reference standard to maintain the tool's calibration when in use.

"Fresh water aquifer" means a geologic formation that is capable of yielding fresh water to a well or spring.

"Safety review" means a periodic review provided by the licensee for its employees on radiation safety aspects of well logging. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.

"Surface casing" for protecting fresh water aquifers means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

"Tritium neutron generator target source" means a tritium source used within a neutron generator tube to produce neutrons for use in well logging applications.

***35.15*** ITEM 77. Rescind subrule **45.6(4)** and adopt **new** subrule **45.6(4)** as follows:

45.6(26) Agreement with well owner or operator.

a. A licensee may perform well-logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement must identify who will meet the following requirements:

(1) If a sealed source becomes lodged in the well, a reasonable effort will be made to recover it;

(2) A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture;

(3) The radiation monitoring required in 45.6(8) and 45.6(17) will be performed;

(4) If the environment, any equipment, or personnel are contaminated with licensed material, they must be decontaminated before release from the site or release for unrestricted use; and

(5) If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within 30 days:

1. Each irretrievable well-logging source must be immobilized and sealed in place with a cement plug;

2. A means to prevent inadvertent intrusion on the source, unless the source is not accessible to any subsequent drilling operations; and

3. A permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The size of the plaque must be at least 17 cm (7 inches) square and 3 mm [1/8-inch] thick. The plaque must contain:

- The word "Caution";
- The radiation symbol (the color requirement in 641—40.60 need not be met);
- The date the source was abandoned;
- The name of the well owner or well operator, as appropriate;
- The well name and well identification number(s) or other designation;
- An identification of the sealed source(s) by radionuclide and quantity;
- The depth of the source and depth to the top of the plug; and
- An appropriate warning, such as, "Do not re-enter this well."

b. The licensee shall retain a copy of the written agreement for three years after the completion of the well logging operation.

c. A licensee may apply, pursuant to 641—38.3, for agency approval, on a case-by-case basis, of proposed procedures to abandon an irretrievable well-logging source in a manner not otherwise authorized in 45.6(26)"a"(5).

d. A written agreement between the licensee and the well owner or operator is not required if the licensee and the well owner or operator are part of the same corporate structure or otherwise similarly affiliated. However, the licensee shall still otherwise meet the requirements in 45.6(26)"a"(1) through (5).

*39.35* ITEM 78. Amend subrule **45.6(9)** as follows:

a. ~~Requirements.~~ Testing and recordkeeping requirements. Each licensee using sealed sources of radioactive material shall have the sources tested for leakage periodically. Records of leak test results shall be kept in units of microcuries (Bq) and maintained for ~~inspection by the agency for six months after the next required leak test is performed or until transfer or disposal of the sealed source.~~ for three years after the leak test is performed.

b. Method of testing. Tests for leakage shall be performed only by persons specifically authorized to perform such test by ~~the agency, the U.S. Nuclear Regulatory Commission~~ the NRC, an agreement state, or a licensing state. The wipe of a sealed source must be performed using a leak test kit or method approved by NRC, an Agreement state, or a licensing state. ~~The test sample shall be taken from the surface of~~

~~the source, source holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate.~~ The wipe sample must be taken from the nearest assessable point to the sealed source where contamination might accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample.

c. Interval of testing.

(1) Each sealed source of radioactive material (except an energy compensation source (ECS)) shall be tested at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made six months prior to the transfer, the sealed source shall not be put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

(2) Each ECS that is not exempt from testing in accordance with 45.6(9)"c"(1) must be tested at intervals not to exceed three years. In the absence of a certificate from a transferor that a test has been made within the three years before the transfer, the ECS may not be used until tested.

d. Leaking or contaminated sources.

(1) If the test in 45.6(9)"c" reveals the presence of 0.005 microcurie (185 Bq) or more of ~~leakage or contamination~~ removeable radioactive material, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of ~~in accordance with these rules~~ by a NRC, agreement, or licensing state licensee that is authorized to perform these functions. The licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by a NRC, agreement, or licensing state licensee that is authorized to perform these functions.

(2) A report describing the equipment involved, the test results, any contamination which resulted from the leaking source, and the corrective action taken up to the time of the report shall be filed with the agency within five days of receiving the test results.

e. Exemptions. The following sources are exempted from the periodic leak test requirements of 45.6(9)"a" to "d";

(1) Hydrogen-3 (tritium) sources;

(2) Sources of radioactive material with a half-life of 30 days or less;

(3) Sealed sources of radioactive material in gaseous form;

(4) Sources of beta- or gamma-emitting radioactive material with an activity of 100 microcuries (3.7 MBq) or less; and

(5) Sources of alpha-emitting radioactive material with an activity of 10 microcuries (0.370 MBq) or less.

***35.417*** ITEM 79. Amend subrule **45.6(12)** as follows:

45.6(12) Design, performance, and certification criteria for sealed sources used in ~~downhole~~ well-logging operations.

a. ~~Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations shall be certified by the manufacturer, or other testing organization acceptable to the agency, to meet the following minimum criteria:~~ A licensee may use a sealed source for use in well-logging applications if:

(1) ~~Be of~~ The sealed source is double encapsulated construction;

(2) The sealed source ~~Contain radioactive material whose~~ contains chemical and physical forms are as insoluble and nondispersible as practical; and

(3) ~~Has been individually pressure tested to at least 24,656 pounds per square inch absolute (170 MN/m$^2$) without failure.~~ Meets the requirements of 45.6(12)"b," "c," and "d" of this rule.

~~b. For sealed sources, except those containing radioactive material in gaseous form, in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of 45.6(12)"a," the sealed source shall not be put into use until such determinations and testing have been performed.~~

~~c.~~b. ~~Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations, shall be certified by the manufacturer, or other testing organization acceptable to the agency, as meeting the sealed source performance requirements for oil well logging as contained in the American National Standard Institute (ANSI) N542-1977 or United States of America Standards Institute (USASI) N5.10-1968.~~ For a sealed source manufactured on or before July 14, 1989, a licensee may use the sealed source for use in well-logging applications if it meets the requirements of USASI N5.10-1968, "Classification of Sealed Radioactive Sources," or the requirements in 45.6(12)"c" or "d" of this rule.

c. For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source for well-logging applications if it meets the oil-well logging requirements of ANSI/HPS N43.6-1997, "Sealed Radioactive Sources—Classification."

d. ~~Certification documents shall be maintained for inspection by the agency for a period of two years after source disposal. If the source is abandoned downhole, the certification documents shall be maintained until the agency authorizes disposition.~~ For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source for use in well-logging applications if:

(1) The sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

1. Temperature. The test source must be held at –40 degrees C for 20 minutes, 600 degrees C for one hour, and then be subject to a thermal shock test with a temperature drop from 600 degrees C within 15 seconds.

2. Impact test. A 5 kg steel hammer, 2.5 cm in diameter, must be dropped from a height of 1 m onto the test source.

3. Vibration test. The test source must be subject to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes.

4. Puncture test. A one gram hammer and pin, 0.3 cm pin diameter, must be dropped from a height of 1 m onto the test source.

5. Pressure test. The test source must be subject to an external pressure of 1.695 x $10^7$ pascals (24,600 pounds per square inch absolute).

e. The requirements in 45.6(12)"a,", "b," "c," and "d" of this rule do not apply to sealed sources that contain licensed material in gaseous form.

f. The requirements of 45.6(12)"a,", "b," "c," and "d" of this rule do not apply to energy compensation sources (ECS). ECSs must be registered with the NRC, licensing state, or agreement state.

***39.65*** ITEM 80. Amend subrule **45.6(17),** paragraphs **"a"** and **"b,"** as follows:

a. No licensee or registrants shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears, at all times during the handling of licensed radioactive materials, either a film badge or a thermoluminescent dosimeter (TLD) that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP). Each film badge or TLD shall be assigned to and worn by only one individual. Film badges must be replaced at least monthly and TLDs replaced at least quarterly. After replacement, each film badge or TLD must be promptly processed.

b. Personnel monitoring records and bioassay results shall be maintained for inspection until the agency authorizes disposition.

*39.77* ITEM 81. Amend subrule **45.6(25),** paragraph **"c,"** subparagraph **(2),** as follows:

(2) Notify the agency be telephone, giving the circumstances of the loss, and request approval of the proposed abandonment procedures; or specify the implemented abandonment before receiving approval because the licensee believed there was an immediate threat to public health and safety; and

39.77 ITEM 82. Amend subrule **45.6(25),** paragraph **"c,"** subparagraph **(3),** as follows:

9. The immediate threat to public health and safety justification for implementing abandonment if prior approval was not obtained in accordance with 45.6(25)"c"(2).

~~9.~~10. Any other information, such as a warning statement, contained on the permanent identification plaque; and

~~10.~~11. The names of state agencies receiving a copy of this report.

Item 83. Adopt **new** subrules **45.6(27), (28), (29), (30),** and **(31),** as follows:

45.6(27) Radioactive markers. The licensee may use radioactive markers in wells only if the individual markers contain quantities of licensed material not exceeding the quantities specified in Chapter 39—Appendix B, Exempt Quantities. The use of markers is subject only to the requirements of 45.6(10).

*39.49* 45.6(28) Uranium sinker bars. The licensee may use uranium sinker bar in well-logging applications only if it is legibly impressed with the words "CAUTION—RADIOACTIVE-DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or Company name) IF FOUND."

*39.51* 45.6(29) Use of a sealed source in a well without a surface casing. The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved by the NRC or licensing or agreement state.

*39.53* 45.6(30) Energy compensation source. The licensee may use an energy compensation source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of licensed material not exceeding 100 microcuries (3.7 MBq).

a. For well-logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 45.6(9), (10), and (11).

b. For well-logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 45.6(4), (9), (10), (11), (25), and (29).

*39.55* 45.6(31) Tritium neutron generator target source.

a. Use of a tritium neutron generator target source, containing quantities not exceeding 30 curies (1110 MBq) and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of this rule except 45.6 (4), (12), and (25).

b. Use of a tritium neutron generator target source, containing quantities exceeding 30 curies (1110 MBq) or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of the rule except 45.6(12).