641—39.4 (136C) Requirements for licensing of radioactive materials.

39.4(1) *Additional requirements.*

a. In addition to the requirements of this chapter, all licensees are subject to the requirements of 641—Chapters 38, 40 and 41. Furthermore, licensees engaged in industrial/nonmedical radiographic operations are subject to the requirements of 641—Chapter 45; licensees using radionuclides in the healing arts are subject to the requirements of 641—41.2(136C) and 641—Chapter 42; and licensees engaged in land disposal of radioactive material are subject to the requirements of 641—Chapter 40.

b. An Iowa radioactive materials license requires that the person have a permanent storage area in Iowa where records are maintained pertaining to licensed activities, equipment maintenance and quality assurance, personnel monitoring, and personnel certification and where material can be stored. The records may be stored on a van, if appropriate. The storage area must be accessible during inspections. An Iowa mailing address is not required.

39.4(2) *Source material.*

a. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

b. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

c. Any person is exempt from the requirements for a license set forth in this chapter and from the rules in this chapter and 641—Chapter 40 to the extent that such person receives, possesses, uses, or transfers:

(1) Any quantities of thorium contained in:

1. Incandescent gas mantles,
2. Vacuum tubes,
3. Welding rods,
4. Electric lamps for illuminating purposes, provided that each lamp does not contain more than 50 milligrams of thorium,
5. Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting, provided that each lamp does not contain more than 2 grams of thorium,
6. Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or
7. Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium.

(2) Source material contained in the following products:

1. Glazed ceramic tableware manufactured before November 5, 2014, provided that the glaze contains not more than 20 percent by weight source material,
2. Glassware containing not more than 2 percent by weight source material or, for glassware manufactured before November 5, 2014, 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction,
3. Glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983, or
4. Piezoelectric ceramic containing not more than 2 percent by weight source material.

(3) Photographic film, negatives, and prints containing uranium or thorium.

(4) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by

weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part.

(5) Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

1. Reserved.

2. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM,"

3. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED," and

4. This exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

(6) Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

1. The shipping container is conspicuously and legibly impressed with the legend "CAUTION—RADIOACTIVE SHIELDING—URANIUM," and

2. The uranium metal is encased in mild steel or equally fire-resistant metal of minimum wall thickness of 1/8 inch (3.2 mm).

(7) Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than 10 percent by weight of thorium or uranium or, for lenses manufactured before November 5, 2014, 30 percent by weight of thorium; and that this exemption does not authorize either:

1. The shaping, grinding, or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror, or

2. The receipt, possession, use, or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

(8) Rescinded IAB 10/1/14, effective 11/5/14.

(9) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

1. The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and

2. The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

d. The exemptions in 39.4(2) do not authorize the manufacture of any of the products described.

e. The requirements specified in 39.4(2)*"c"*(5)"2" and "3" need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights are impressed with the legend, "CAUTION—RADIOACTIVE MATERIAL—URANIUM," as previously required by the rules.

f. No person may initially transfer for sale or distribution a product containing source material to persons exempt under these rules, or equivalent regulations of an agreement state or the Nuclear Regulatory Commission, unless authorized by a license issued under 10 CFR 40.52 to initially transfer such products for sale or distribution.

(1) Persons initially transferring for sale or distributing source material in products covered by the exemptions in these rules before November 5, 2014, without specific authorization may continue such distribution for one year beyond this date. Initial distribution may also be continued until the Nuclear Regulatory Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than one year beyond this date.

(2) Persons authorized to manufacture, process, or produce these materials or products containing source material by the agency, an agreement state, or the Nuclear Regulatory Commission, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under 10 CFR 40.52 for distribution only and are exempt from the requirements of 641—Chapter 40 and 39.4(25)*"a"* and *"b."*

39.4(3) *Radioactive material other than source material.*

a. Exempt concentrations.

(1) Except as provided in 39.4(3)*"a"*(2), any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Appendix A of this chapter.

(2) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 39.4(3)*"a"*(1) or equivalent regulations of the U.S. Nuclear Regulatory Commission, or any agreement state, except in accordance with a specific license issued pursuant to 10 CFR 32.11.

(3) An exemption is granted to persons who receive, possess, use, process, transfer, distribute, and dispose of materials containing or contaminated at concentrations less than 20 picocuries per gram of radium.

(4) This rule shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

(5) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license and from these rules to the extent that the manufacturer, processor, or producer transfers radioactive material contained in a product or material in concentrations not in excess of the requirements in Appendix A of this chapter and introduced into the product or material by a licensee holding a specific license issued by the U.S. Nuclear Regulatory Commission expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

b. Exempt quantities.

(1) Except as provided in 39.4(3)*"b"*(3), (4), and (5), any person is exempt from the requirements for a license and from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in Appendix B of this chapter.

(2) Any person who possesses radioactive material received or acquired under a general license is exempt from the requirements for a license set forth in this chapter to the extent that such person possesses, uses, transfers or owns such radioactive material.

(3) This paragraph (39.4(3)*"b"*) does not authorize for purposes of commercial distribution the production, packaging, repackaging or transfer of radioactive material or the incorporation of radioactive material into products intended for commercial distribution.

(4) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix B of this chapter, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 39.4(3) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR 32, which license states that the radioactive material may be transferred by the licensee to persons exempt under 39.4(3)*"b"* or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state, or licensing state. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing by-product material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(5) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in Appendix B of this chapter, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the rules in this chapter.

c. Exempt items.

(1) Certain items containing radioactive material. Except for persons who apply radioactive material to or persons who incorporate radioactive material into the following products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from the requirements for a license set forth in this chapter and from these rules to the extent that the person receives, possesses, uses, transfers, owns, or acquires the following products:

1. Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

- 25 millicuries (925 MBq) of tritium per timepiece;
- 5 millicuries (185 MBq) of tritium per hand;
- 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial);
- 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece;
- 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand;
- 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);
- One microcurie (37 kBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

2. The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

- For wrist watches, 0.1 millirad (1 μGy) per hour at 10 centimeters from any surface.
- For pocket watches, 0.1 millirad (1 μGy) per hour at 1 centimeter from any surface.
- For any other timepiece, 0.2 millirad (2 μGy) per hour at 10 centimeters from any surface.

3. Precision balances containing not more than 1 millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before December 17, 2007.

4. Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured before December 17, 2007.

5. Electron tubes, provided that each tube does not contain more than one of the following specified quantities of radioactive material:

- 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube;
- 1 microcurie (37 kBq) of cobalt-60;
- 5 microcuries (185 kBq) of nickel-63;
- 30 microcuries (1.11 MBq) of krypton-85;
- 5 microcuries (185 kBq) of cesium-137; and
- 30 microcuries (1.11 MBq) of promethium-147.

And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed 1 millirad (10 μGy) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber. For purposes of 39.4(3)*"c"*(1)"5," the term "electron tubes" includes spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes,

microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

6. Ionizing radiation measuring instruments, for purposes of internal calibration or standardization, containing one or more sources of radioactive material, provided that:

- Each source contains no more than one exempt quantity set forth in Appendix B of this chapter;
- Each device contains no more than ten exempt quantities. For purposes of this requirement, a device's source(s) may contain either one type of or different types of radionuclides, and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix B of this chapter, provided that the sum of such fractions shall not exceed unity; or
- For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under 39.4(3)*"c"*(1)"6."

7. Ionization chamber smoke detectors containing not more than 1 microcurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

Any person who desires to apply by-product material to, or to incorporate by-product material into, the products exempted in subparagraph 39.4(3)*"c"*(1), or who desires to initially transfer for sale or distribution such products containing by-product material, should apply for a specific license with the Nuclear Regulatory Commission pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to subparagraph 39.4(3)*"c"*(1).

(2) Self-luminous products containing radioactive material.

1. Tritium, krypton-85, or promethium-147. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the initial transfer of the product for use under these rules. Any person who desires to manufacture, process, produce or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use according to this paragraph shall apply for a license under 10 CFR 32.22 and for a certificate of registration in accordance with 10 CFR 32.210. The exemption in 39.4(3)*"c"*(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

2. Radium-226. Any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to the effective date of these rules.

(3) Gas and aerosol detectors containing radioactive material.

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the requirements for a license set forth in this chapter and from the requirements contained in 641—Chapters 38, 40, and 41 to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect health, safety or property and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR Part 32, which license authorizes the initial transfer of the product for use under this rule. This exemption also covers gas and aerosol detectors manufactured or distributed before November 20, 2007, in accordance with a specific license issued by a state under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

2. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use pursuant to 39.4(3)*"c"*(3)"1," shall apply for a license under 10 CFR 32.26 and for a certificate of registration in accordance with 10 CFR 32.210.

(4) 1. Static elimination devices which contain, as a sealed source or sources, by-product material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device.

2. Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, by-product material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

3. Such devices authorized before November 5, 2014, for use under the general license that was provided in 39.4(22)*"a"* and equivalent regulations of an agreement state or the Nuclear Regulatory Commission and manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the agency.

(5) Radioactive drug: capsules containing carbon-14 urea for "in vivo" diagnostic use for humans.

1. Except as provided in paragraphs *"b"* and *"c"* of this subrule, any person is exempt from the requirements for a license set forth in this chapter and in 641—41.2(136C) provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq 1μCi carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

2. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to 641—41.2(136C).

3. Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to 39.4(20) of this rule.

4. Nothing in this subrule relieves persons from complying with applicable FDA or other federal or state requirements governing receipt, administration, and use of drugs.

(6) Certain industrial devices. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material 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 an ionized atmosphere, any person is exempt from the requirements for a license set forth in this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.30, which license authorizes the initial transfer of the device for use under these rules. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing by-product material for use under these rules should apply for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 10 CFR 32.210.

39.4(4) to **39.4(19)** Reserved.

39.4(20) *Types of licenses.* There are two types of licenses for radioactive materials: general and specific.

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 licensee is subject to all other applicable portions of these rules and any limitations of the general license.

b. Specific licenses require the submission of an application to the agency and the issuance of a licensing document by the agency. The licensee is subject to all applicable portions of these rules as well as any limitations specified in the licensing document.

c. All licensees and registrants must submit the appropriate fee in 641—subrule 38.8(2).

39.4(21) *General licenses—source material.*

a. A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and federal, state and local government agencies to receive, possess, use and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

(1) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of November 5, 2014, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the agency takes final action on a pending application submitted on or before November 5, 2015, for a specific license for such material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2014, or until the agency takes final action on a pending application submitted on or before November 5, 2015, for a specific license for such material; and

(2) No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this paragraph unless it is accounted for under the limits of 39.4(21)*"a"*(1); or

(3) No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this paragraph; or

(4) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

b. Any person who receives, possesses, uses, or transfers source material in accordance with the general license issued in 39.4(21)*"a"*:

(1) Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the agency in a specific license.

(2) Shall not abandon such source material. Source material may be disposed of as follows:

1. A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, nondispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this paragraph is exempt from the requirements to obtain a license under this chapter to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under this chapter; or

2. In accordance with 641—40.70(136C).

(3) Is subject to the provisions in 641—38.4(136C), 641—38.9(136C), 39.4(21), 39.4(32)*"a"* through *"d"* and *"f,"*39.4(41), 39.4(51), 39.4(52), 641—40.95(136C), 641—40.96(136C), and 641—40.97(136C).

(4) Reserved.

(5) Shall not export such source material except in accordance with 10 CFR Part 110.

c. Any person who receives, possesses, uses, or transfers source material in accordance with 39.4(21)*"a"* shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the agency about such contamination and may consult with the agency as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 641—40.29(136C).

d. A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

e. Depleted uranium in industrial products and devices.

(1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 39.4(21)*"e"*(2), (3), (4), and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in 39.4(21)*"e"*(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 39.4(29)*"m"* or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an agreement state.

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

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

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

(4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 39.4(21)*"e"*(1):

1. Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

2. Shall not abandon such depleted uranium;

3. Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 39.4(41). In the case where the transferee receives the depleted uranium pursuant to the general license established by 39.4(21)*"e"*(1), the transferor shall furnish the transferee a copy of 641—Chapter 39 and a copy of Agency Form "Registration Certificate—Use of Depleted Uranium Under General License." In the case where the transferee receives the depleted uranium pursuant to a

general license contained in the U.S. Nuclear Regulatory Commission's or agreement state's regulation equivalent to 39.4(21)*"e"*(1), the transferor shall furnish the transferee a copy of 641—Chapter 39 and a copy of the Agency Form "Registration Certificate—Use of Depleted Uranium Under General License" accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or agreement state under requirements substantially the same as those in 641—Chapters 38, 39, 40, 41 and 45;

4. Within 30 days of any transfer, shall report in writing to the agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and

5. Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 39.4(21)*"e"*(1) is exempt from the requirements of 641—Chapter 40 with respect to the depleted uranium covered by that general license.

f. Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in 39.4(21)*"a"* is exempt from the provisions of 641—Chapter 40 to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of 641—40.29(136C) and 641—40.70(136C) to the extent necessary to meet the provisions of 39.4(21)*"b"*(2) and 39.4(21)*"c."* However, this exemption does not apply to any person who also holds a specific license issued under this chapter.

g. No person may initially transfer or distribute source material to persons generally licensed under 39.4(21)*"a"*(1) and (2), or equivalent regulations of the Nuclear Regulatory Commission or an agreement state, unless authorized by a specific license issued in accordance with 39.4(39) or equivalent provisions of the Nuclear Regulatory Commission or an agreement state. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by 39.4(21)*"a"* before November 5, 2014, without specific authorization may continue for one year beyond this date. Distribution may also be continued until the agency takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before November 5, 2015.

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.)

a. Rescinded IAB 10/1/14, effective 11/5/14.

b. and *c.* Reserved.

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 manufactured 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; or an equivalent specific license issued by a state with provisions comparable to 39.4(29)*"d,"* which authorizes 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 acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license in 39.4(22)*"d"*(1):

1. Shall ensure 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;

2. Shall ensure 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- or gamma-emitting material or both 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 ensure that the test required by 39.4(22)*"d"*(3) and other testing, installation, servicing, and removal from installation involving the radioactive material, 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(136C), 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, the 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(136C) 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 10 CFR Part 110;

8. Shall transfer or dispose of 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 device is exported); and the date of the transfer;
- Shall obtain written agency approval before transferring the device to any other specific licensee not specifically identified in 39.4(22)*"d"*; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval if the holder:

—Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

—Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by 39.4(22)*"d"*(3)"1") so that the device is labeled in compliance with 641—40.63(136C) of these rules; however the manufacturer, model number, and serial number must be retained;

—Obtains manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak-testing procedures); and

—Reports the transfer under 39.4(22)*"d"*(3)"8" of this chapter.

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 telephone 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(136C) and 641—40.96(136C), but shall be exempt from the other requirements of 641—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. Shall register as follows:

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

general licensee holding devices meeting the criteria of 39.4(22)*"d"*(3)"13" is subject to the bankruptcy notification requirement of 39.4(32)*"e"*;

- In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the agency:

—Name and mailing address of the general licensee;

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

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

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

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

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

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

14. 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; and

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.

(5) A general license to install devices generally licensed in 39.4(22)*"d."* Any person who holds a specific license issued by an agreement state authorizing the holder to manufacture, install, or service a device described in 39.4(22)*"d"* within such agreement state is hereby granted a general license to install and service such device in any non-agreement state and a general license to install and service such device in offshore waters, as defined in 641—45.1(136C), provided that:

1. The device has been manufactured, labeled, installed, and serviced in accordance with the applicable provision of the specific license issued to such person by the agreement state, and

2. Such person ensures that any labels required to be affixed to the device under regulations of the agreement state which licensed manufacture of the device bear a statement that removal of the label is prohibited.

e. Luminous safety devices for aircraft.

(1) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

1. Each device contains not more than 10 curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and

2. Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the agency or any agreement state to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 39.4(22)*"e"*(1) are exempt from the requirements of 641—Chapter 40 except that they shall comply with the provisions of 641—40.95(136C) and 40.96(136C).

(3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

(4) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

(5) This general license is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), and 641—39.5(136C).

f. Ownership of radioactive material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this chapter, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

g. Calibration and reference sources.

(1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of 39.4(22)*"g"*(4) and (5), americium-241 in the form of calibration or reference sources:

1. Any person who holds a specific license issued by the agency which authorizes the person to receive, possess, use, and transfer radioactive material; and

2. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes the person to receive, possess, use, and transfer special nuclear material.

(2) A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of 39.4(22)*"g"*(4) and (5) to any person who holds a specific license issued by the agency which authorizes the person to receive, possess, use, and transfer radioactive material.

(3) A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of 39.4(22)*"g"*(4) and (5) to any person who holds a specific license issued by the agency which authorizes the person to receive, possess, use, and transfer radioactive material.

(4) The general licenses in 39.4(22)*"g"*(1), (2), and (3) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the agency, any agreement state or licensing state pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70.

(5) The general licenses provided in 39.4(22)*"g"*(1), (2), and (3) are subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), 641—39.5(136C), and 641—Chapter 40. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

1. Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries (185 kBq) of americium-241, 5 microcuries (185 kBq) of plutonium, or 5 microcuries (185 kBq) of radium-226 in such sources;

2. Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

● The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS (AMERICIUM-241). (PLUTONIUM) (showing only the name of the appropriate material) DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or importer

OR

● The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of a licensing state. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or importer

3. Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to receive the source;

4. Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

5. Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

h. Reserved.

i. General license for use of radioactive material for certain in vitro clinical or laboratory testing. The New Drug Provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 39.4(22)*"i"*(2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

1. Carbon-14, in units not exceeding 10 microcuries (370 kBq) each.
2. Cobalt-57, in units not exceeding 10 microcuries (370 kBq) each.
3. Hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.
4. Iodine-125, in units not exceeding 10 microcuries (370 kBq) each.
5. Mock iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (1.85 Bq) of americium-241 each.
6. Iodine-131, in units not exceeding 10 microcuries (370 kBq) each.
7. Iron-59, in units not exceeding 20 microcuries (740 kBq) each.
8. Selenium-75, in units not exceeding 10 microcuries (370 kBq) each.

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 39.4(22)*"i"*(1) until the person has filed an Agency Form "Certificate—In Vitro Testing with Radioactive Material Under General License" with the agency and received from the agency a validated copy of the form with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish the following information on the form and such other information as may be required by the form:

1. Name and address of the physician, veterinarian, clinical laboratory or hospital;
2. The location of use; and
3. A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in 39.4(22)*"i"*(1) and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 39.4(22)*"i"*(1) shall comply with the following:

1. The general licensee shall not possess at any one time, pursuant to the general license in 39.4(22)*"i"*(1), at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, or cobalt-57 in excess of 200 microcuries (7.4 MBq).
2. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
3. The general licensee shall use the radioactive material only for the uses authorized by 39.4(22)*"i"*(1).
4. The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the agency, the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
5. The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in 39.4(22)*"i"*(1)"8" as required by 641—subrule 40.70(1).

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 39.4(22)*"i"*(1):

1. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 39.4(29)*"h"* or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any agreement state or licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or mock iodine-125 to persons generally licensed under 39.4(22)*"i"* or its equivalent, and
2. Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

● This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____

Name of manufacturer

● This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human

beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a licensing state.

_____
Name of manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 39.4(22)*"i"*(1) shall report in writing to the agency any changes in the information furnished in the "Certificate—In Vitro Testing with Radioactive Material Under General License," Agency Form V. The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of 39.4(22)*"i"*(1) is exempt from the requirements of 641—Chapter 40 with respect to radioactive material covered by that general license, except that such persons using the mock iodine-125 described in 39.4(22)*"i"*(1)"8" shall comply with the provisions of 641—subrule 40.70(1) and rules 40.95(136C) and 40.96(136C).

j. Ice detection devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the agency or an agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 39.4(22)*"j"*(1):

1. Shall, upon occurrence of visually observable damage such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 641—subrule 40.70(1);

2. Shall ensure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

3. Are exempt from the requirements of 641—Chapter 40 except that such persons shall comply with the provisions of 641—subrule 40.70(1), and rules 40.95(136C) and 40.96(136C).

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(4) This general license is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), and 641—39.5(136C).

k. Certain items and self-luminous products containing radium-226.

(1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with 39.4(22)*"k"*(2), (3), and (4), radium-226 contained in the following products manufactured prior to November 30, 2007.

1. Antiquities originally intended for use by the general public. For the purposes of this subrule, "antiquities" means products originally intended for use by the general public and distributed in the late nineteenth and early twentieth centuries including, but not limited to, radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

2. Intact and non-intact timepieces containing greater than 1 microcurie (0.037 megabecquerel), and timepiece hands and dials no longer installed in timepieces.

3. Luminous items installed in air, marine, or land vehicles.

4. All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

5. Small radium sources containing no more than 1 microcurie (0.037 megabecquerel) of radium-226. For the purposes of this subrule, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the agency.

(2) Persons who acquire, receive, possess, use, or transfer by-product material under the general license issued in 39.4(22)*"k"*(1) shall comply with the provisions of 641—40.95(136C) and 641—40.96(136C), but shall be exempt from the other requirements of 641—Chapter 40, to the extent that the receipt, possession, use, or transfer of by-product material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under 39.4(24).

(3) Any person who acquires, receives, possesses, uses, or transfers by-product material in accordance with the general license in 39.4(22)*"k"*(1) shall:

1. Notify the agency if there is any indication of possible damage to the product which could result in a loss of the radioactive material. A report containing a brief description of the event and the remedial action taken must be furnished to the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, 5th Floor, 321 East 12th Street, Des Moines, Iowa, within 30 calendar days.

2. Not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 641—40.77(136C) or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the agency.

3. Not export products containing radium-226 except in accordance with 10 CFR Part 110.

4. Dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under 39.4(24), or equivalent NRC or agreement state requirements, or as otherwise approved by the agency.

5. Respond in writing to a written request from the agency to provide information relating to the general license within 30 calendar days of the request, or other time specified in the request.

(4) The general license in 39.4(22)*"k"*(1) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

39.4(23) Reserved.

39.4(24) *Filing application for specific licenses.*

a. Applications for specific licenses shall be filed on a form prescribed by the agency and include the fee required in 641—subrule 38.8(2).

b. The agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

c. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's or licensee's behalf.

d. An application for a license may include a request for a license authorizing one or more activities.

e. Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

f. (1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Appendix G of this chapter, must contain either:

1. An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or
2. An emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation submitted under 39.4(24)*"f"*(1)"1" of this subrule:

1. The radioactive material is physically separated so that only a portion could be involved in an accident;
2. All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;
3. The release fraction in the respirable size range would be lower than the release fraction shown in Appendix G due to the chemical or physical form of the material;
4. The solubility of the radioactive material would reduce the dose received;
5. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Appendix G;
6. Operating restrictions or procedures would prevent a release fraction as large as that shown in Appendix G; or
7. Other factors appropriated for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under 39.4(24)*"f"*(1)"2" must include the following information:

1. Facility description. A brief description of the licensee's facility and area near the site.
2. Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.
3. Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.
4. Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.
5. Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.
6. Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.
7. Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the agency; also, responsibilities for developing, maintaining, and updating the plan.
8. Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.
9. Information to be communicated. A brief description of the types of information of facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the agency.
10. Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical, and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also,

the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

11. Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

12. Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

13. Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub.L.No. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the agency. The licensee shall provide any comments received within the 60 days to the agency with the emergency plan.

g. (1) Except as provided in 39.4(24)*"g"*(2), (3), and (4), an application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:

1. Identify the source or device by manufacturer and model number as registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an agreement state, or for a source or a device containing radium-226 or accelerator-produced radioactive material as registered with a state under provisions comparable to 10 CFR 32.210; or

2. Contain the information identified in 10 CFR 32.210(c).

(2) For sources or devices manufactured prior to November 5, 2014, that are not registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an agreement state, and for which the applicant is unable to provide all the categories of information specified in 10 CFR 32.210(c), the application must include:

1. All available information identified in 10 CFR 32.210(c) concerning the source and, if applicable, the device; and

2. Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a current leak test.

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

h. An application from a medical facility or an educational institution to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to licensees in the facility's

or educational institution's consortium authorized for medical use under 641—41.2(136C) or equivalent NRC or agreement state requirements shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under this chapter or equivalent NRC or agreement state requirements for a PET production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 39.4(29)*"j"*(1)"2."

(3) Identification of the individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in 39.4(29)*"j"*(2)"2."

(4) Information identified in 39.4(29)*"j"*(1)"3" on the PET drugs to be noncommercially transferred to members of the facility's consortium.

39.4(25) *General requirements for the issuance of specific licenses.* A license application will be approved if the agency determines that:

a. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with 641—Chapters 38, 39, 40, 41 and 45 in such a manner as to minimize danger to public health and safety or property;

b. The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

c. The issuance of the license will not be inimical to the health and safety of the public; and

d. The applicant satisfies any applicable special requirements in 39.4(26), 39.4(27), 39.4(28), 641—41.2(136C), or 641—Chapter 45.

e. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of any other activity which the agency determines will significantly affect the quality of the environment, the agency, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

39.4(26) *Financial assurance and record keeping for decommissioning.*

a. Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding $1.0E^5$ times the applicable quantities set forth in Appendix F of 641—Chapter 40 shall submit a decommissioning funding plan as described in 39.4(26)*"e."* The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix F.

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

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

1. Submit a decommissioning funding plan as described in 39.4(26)*"e"*; or

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

c. (1) Each holder of a specific license issued on or after July 1, 1993, which is of a type described in 39.4(26)*"a"* or *"b,"* shall provide financial assurance for decommissioning in accordance with the criteria set forth in this subrule.

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

(3) Each holder of a specific license issued before September 30, 1992, and of a type described in 39.4(36)*"b,"* shall submit, on or before July 1, 1993, a certificate of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this subrule.

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

(5) Waste collectors and waste processors must provide financial assurance in an amount based on a decommissioning funding plan as described in 39.4(26)*"e."* The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license, and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of 641—Chapters 39 and 40.

(6) If, in surveys made under 641—subrule 40.36(1), residual radioactivity in the facility and the environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the 641—40.29(136C) criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year of when the survey is completed.

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

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix F of 641—Chapter 40 in unsealed form. (For a combination of isotopes, if R, as defined in 39.4(26)*"a,"* divided by 10^4 is greater than 1, but R divided by 10^5 is less than or equal to 1.)	1,125,000
Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix F of 641—Chapter 40 in unsealed form. (For a combination of isotopes, if R, as defined in 39.4(26)*"a,"* divided by 10^3 is greater than 1, but R divided by 10^4 is less than or equal to 1.)	225,000
Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of Appendix F or 641—Chapter 40 in sealed sources or plated foils. (For a combination of	

isotopes, if R, as defined in 39.4(26)*"a,"* divided by 10^{10}
is greater than 1, but R divided by 10^{12} is less than or equal to 1.) 113,000

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

e. (1) Each decommissioning funding plan must be submitted for review and approval and must contain:

1. A detailed cost estimate for decommissioning, in an amount reflecting:

- The cost of an independent contractor to perform all decommissioning activities;
- The cost of meeting the 641—40.29(136C) criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 641—40.30(136C), the cost estimate may be based on meeting the 641—40.30(136C) criteria;
- The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and
- An adequate contingency factor;

2. Identification of and justification for using the key assumptions contained in the decommissioning cost estimate (DCE);

3. A description of the method of assuring funds for decommissioning from 39.4(26)*"f,"* including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

4. A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

5. A signed original of the financial instrument obtained to satisfy the requirements of 39.4(26)*"f"* (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed three years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

1. Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;
2. Waste inventory increasing above the amount previously estimated;
3. Waste disposal costs increasing above the amount previously estimated;
4. Facility modifications;
5. Changes in authorized possession limits;
6. Actual remediation costs that exceed the previous cost estimate;
7. Onsite disposal; and
8. Use of a settling pond.

f. The financial instrument must include the licensee's name, license number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix F of this chapter. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this subrule. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix H of this chapter. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix I of this chapter. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in Appendix J of this chapter. A guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of paragraph 39.4(26)*"f"* or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

1. The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the agency within 30 days after receipt of notification of cancellation.

2. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the agency. An acceptable trustee includes an appropriate state or federal government agency or an entity which has authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

3. The surety method or insurance must remain in effect until the agency has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in 39.4(26)*"f"*(2).

(4) In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the table in 39.4(26)*"d,"* and indicating that funds for decommissioning will be obtained when necessary.

(5) When a governmental entity assumes custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

g. Each person licensed under this chapter shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is released for unrestricted use. Before licensed activities are transferred or assigned to another licensee, the licensee shall transfer all records described in this subrule to the new licensee. In this case, the new licensee

will be responsible for maintaining these records until the license is terminated. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the agency considers important to decommissioning consists of:

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used, stored, or both, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(4) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, of the following:

1. All areas designated as restricted areas as defined under 641—38.2(136C);
2. All areas outside of restricted areas that require documentation under 641—39.4(26)*"g"*(1);
3. All areas outside of restricted areas where current and previous wastes have been buried as documented under 641—40.88(136C); and
4. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal in accordance with 641—40.71(136C).

39.4(27) *Special requirements for issuance of certain specific licenses for radioactive material.*

a. to *d.* Reserved.

e. Use of sealed sources in industrial radiography. In addition to the requirements set forth in 39.4(25), a specific license for use of sealed sources in industrial radiography will be issued if the application contains:

(1) A schedule or description of the program for training radiographic personnel which specifies:

1. Initial training,
2. Periodic training,
3. On-the-job training, and
4. Methods to be used by the licensee to determine the knowledge, understanding, and ability of radiographic personnel to comply with agency rules, licensing requirements, and the operating and emergency procedures of the applicant;

(2) Written operating and emergency procedures, including all items listed in Appendix D of 641—Chapter 45;

(3) A description of the internal inspection system or other management control to ensure that radiographic personnel follow license provisions, rules of the agency, and the applicant's operating and emergency procedures;

(4) A list of permanent radiographic installations and descriptions of permanent storage and use locations. Radioactive material shall not be stored at a permanent storage location or used at a permanent use location unless such storage or use location is specifically authorized by the license. A storage or use location is permanent if radioactive material is stored at the location for more than 90 days and any of the following applies to the location:

1. Non-wireless telephone service is established by the licensee;
2. Industrial radiographic services are advertised for or from the location;
3. Industrial radiographic operations are conducted at other sites due to arrangements made from the location;

(5) A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program;

(6) A description of the program for inspection and maintenance of radiographic exposure devices and transport and storage containers (including applicable items in 641—subrule 45.1(8) and 641—Chapter 45, Appendix A); and

(7) If a license application includes underwater radiography, a description of:

1. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;
2. Radiographic equipment and radiation safety equipment unique to underwater radiography; and
3. Methods for gas-tight encapsulation of equipment;

(8) If a license application includes offshore platform or lay-barge radiography, a description of:

1. Transport procedures for radioactive material to be used in industrial radiographic operations;
2. Storage facilities for radioactive material; and
3. Methods for restricting access to radiation areas.

39.4(28) *Special requirements for specific licenses of broad scope.* This subrule prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain rules governing holders of such licenses. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing by-product material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

a. The different types of broad scope licenses are set forth below:

(1) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(2) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Appendix D of this chapter, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Appendix D, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(3) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in Appendix D of this chapter, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Appendix D, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

b. An application for a Type A specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25);

(2) The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(3) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to ensure safe operations, including:

1. The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

2. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

3. The establishment of appropriate administrative procedures to ensure:

- Control of procurement and use of radioactive material;
- Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and
- Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 39.4(28)*"b"*(3)"3" prior to use of the radioactive material.

c. An application for a Type B specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25); and

(2) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to ensure safe operations, including:

1. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

2. The establishment of appropriate administrative procedures to ensure:

- Control of procurement and use of radioactive material;
- Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and
- Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 39.4(28)*"c"*(2)"2" prior to use of the radioactive material.

d. An application for a Type C specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25).

(2) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

1. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

2. At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used.

(3) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to ensure safe operations.

e. Specific licenses of broad scope are subject to the following conditions:

(1) Unless specifically authorized, persons licensed pursuant to 39.4(28) shall not:

1. Conduct tracer studies in the environment involving direct release of radioactive material;

2. Receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

3. Conduct activities for which a specific license issued by the agency under 39.4(27), 39.4(29) or 641—41.2(136C) is required; or

4. Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(2) Each Type A specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(3) Each Type B specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(4) Each Type C specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 39.4(28)*"d."*

39.4(29) *Special requirements for a specific license to manufacture, assemble, repair, or distribute commodities, products, or devices which contain radioactive material.*

a. Rescinded IAB 7/29/09, effective 9/2/09.

b. Rescinded IAB 3/30/05, effective 5/4/05.

c. Rescinded IAB 7/29/09, effective 9/2/09.

d. Licensing the manufacture and distribution of devices to persons generally licensed under 39.4(22)*"d."*

(1) An application for a specific license to manufacture or initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 39.4(22)*"d"* or equivalent regulations of the NRC, 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 one year a dose in excess of 10 percent of the annual limits specified in 641—40.15(136C); and
- Under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye ..... 15 rems (150 mSv)

Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter ..... 200 rems (2 Sv)

Other organs . . . . . 50 rems (500 mSv)

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 initial transferor may be omitted from this 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 initial transferor

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 641—subrule 40.60(1), and the name of the manufacturer or initial distributor;

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 641—subrule 40.60(1); and

6. The device has been registered in the Sealed Source and Device Registry.

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the agency will consider information which includes, but is not limited to:

1. Primary containment or source capsule;
2. Protection of primary containment;
3. Method of sealing containment;
4. Containment construction materials;
5. Form of contained radioactive material;
6. Maximum temperature withstood during prototype tests;
7. Maximum pressure withstood during prototype tests;

8. Maximum quantity of contained radioactive material;
9. Radiotoxicity of contained radioactive material; and
10. Operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under 39.4(22)*"d,"* or under equivalent regulations of the NRC, 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 dose in excess of 10 percent of the annual limits specified in 641—40.15(136C).

(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" does not apply to the particular device, those paragraphs may be omitted;
- A copy of 39.4(20), 39.4(52), 641—40.95(136C), and 641—40.96(136C);
- 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
- An indication that it is the policy of the NRC 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 the NRC or 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 NRC or agreement state's rules equivalent to 39.4(29)*"d."* If a copy of the NRC 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 telephone 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 telephone 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 a 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.

e. Special requirements for the manufacture, assembly, or repair of luminous safety devices for use in aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 39.4(22)*"e,"* will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25); and

(2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, and 32.56 of 10 CFR Part 32, or their equivalent.

f. An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226 for distribution to persons generally licensed under 39.4(22)*"g"* will be approved if:

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

(2) The applicant satisfies the requirements of Sections 32.57, 32.58, and 32.59 of 10 CFR Part 32, or their equivalent.

g. Reserved.

h. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 39.4(22)*"i"* will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25).

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

1. Carbon-14 in units not exceeding 10 microcuries (370 kBq) each.
2. Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.
3. Iodine-125 in units not exceeding 10 microcuries (370 kBq) each.
4. Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.
5. Iodine-131 in units not exceeding 10 microcuries (370 kBq) each.
6. Iron-59 in units not exceeding 20 microcuries (740 kBq) each.
7. Selenium-75 in units not exceeding 10 microcuries (370 kBq) each.
8. Cobalt-57 in units not exceeding 10 microcuries (370 kBq) each.

(3) Each prepackaged unit bears a durable, clearly visible label:

1. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and
2. Displaying the radiation caution symbol described in 641—subrule 40.60(1) and the words, "CAUTION—RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."

(4) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

1. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or an agreement state.

_____

Name of manufacturer

2. Rescinded IAB 3/30/05, effective 5/4/05.

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 641—subrule 40.70(1).

i. An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 to persons generally licensed under 39.4(22)*"j"* will be approved if the applicant satisfies the general requirements of 39.4(25) and the requirements of Sections 32.61 and 32.62 of 10 CFR Part 32, or their equivalent.

j. Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing by-product material for medical use under 641—41.2(136C).

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

1. The applicant satisfies the general requirements specified in subrule 39.4(25);

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

- Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);
- Registered or licensed with a state agency as a drug manufacturer;
- Licensed by the Iowa board of pharmacy as a nuclear pharmacy;
- Operating as a nuclear pharmacy within a federal medical institution; or
- A positron emission tomography (PET) drug production facility registered or licensed with a state agency;

3. The applicant submits information on the radionuclide: the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

4. The applicant satisfies the following labeling requirements:

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

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

1. May prepare radioactive drugs for medical use, as defined in 641—38.2(136C), provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 39.4(29)*"j"*(2)"2" and 39.4(29)*"j"*(2)"3" or an individual under the supervision of an authorized nuclear pharmacist as specified in 641—paragraph 41.2(11)*"c."*

2. May allow a pharmacist to work as an authorized nuclear pharmacist if:

- This individual qualifies as an authorized nuclear pharmacist as defined in 641—subrule 41.2(2),
- This individual meets the requirements specified in 641—subrules 41.2(77) and 41.2(78) and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or
- This individual is designated as an authorized nuclear pharmacist in accordance with 39.4(29)*"j"*(2)"3."

3. May designate a pharmacist (as defined in 641—subrule 41.2(2)) as an authorized nuclear pharmacist if the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material and the individual practiced at a pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

4. Shall permit the actions authorized in 39.4(29)*"j"*(2)"1" and "2" that are permitted in spite of more restrictive language in license conditions.

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

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

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

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

2. Check each instrument for constancy and proper operation at the beginning of each day of use.

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

k. Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material. Although the agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have their reagent kits approved by the agency for use by persons licensed pursuant to 641—subrule 41.2(33) may submit the pertinent information specified in 39.4(29)*"k."* An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to this chapter for the uses listed in 641—subrule 41.2(33) will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25);

(2) The applicant submits evidence that:

1. The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

2. The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(5) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

1. Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

2. A statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the agency pursuant to 641—subrule 41.2(33) or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state. The labels, leaflets, or brochures required by 39.4(29)*"k"* are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of the FDA, may be combined with the labeling required by the FDA.

l. Manufacture and distribution of sources or devices containing radioactive material for medical use.

(1) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 641—41.2(136C) for use as a calibration, transmission, or reference source or for the uses listed in 641—subrules 41.2(41), 41.2(43), 41.2(49), and 41.2(88) will be approved if:

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

2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

- The radioactive material contained, its chemical and physical form, and amount,
- Details of design and construction of the source or device,
- Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,
- For devices containing radioactive material, the radiation profile of a prototype device,
- Details of quality control procedures to ensure that production sources and devices meet the standards of the design and prototype tests,
- Procedures and standards for calibrating sources and devices,
- Legend and methods for labeling sources and devices as to their radioactive content, and
- Instructions for handling and storing the source or device from the radiation safety standpoint.

These instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device, provided that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

3. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the NRC, agreement state, or this agency has approved distribution of the source or device to persons licensed to use by-product material identified in 641—41.2(136C) and 641—subrules 41.2(41) and 41.2(43), as appropriate, and to persons who hold an equivalent license issued by the NRC or an agreement state; and

4. The source or device has been registered in the Sealed Source and Device Registry.

(2) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics

of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(3) In determining the acceptable interval for test of leakage of radioactive material, the agency will consider information that includes, but is not limited to:

1. Primary containment or source capsule,
2. Protection of primary containment,
3. Method of sealing containment,
4. Containment construction materials,
5. Form of contained radioactive material,
6. Maximum temperature withstood during prototype tests,
7. Maximum pressure withstood during prototype tests,
8. Maximum quantity of contained radioactive material,
9. Radiotoxicity of contained radioactive material, and
10. Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

m. Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 39.4(21)*"d"* or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state will be approved if:

1. The applicant satisfies the general requirements specified in 39.4(25);
2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10 percent of the limits specified in 641—40.15(136C) of these rules; and
3. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the agency will approve an application for a specific license under 39.4(29)*"m"* only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The agency may deny any application for a specific license under 39.4(29)*"m"* if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to 39.4(29)*"m"*(1) shall:

1. Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;
2. Label or mark each unit to:

- Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and
- State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an agreement state;

3. Ensure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium"

4. Furnish a copy of the general license contained in 39.4(21)*"d"* and a copy of the agency form used to register the device to each person to whom the person transfers depleted uranium in a product or device for use pursuant to the general license contained in 39.4(21)*"d,"* or furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or agreement state's regulation equivalent to 39.4(21)*"d"* and a copy of the U.S. Nuclear Regulatory Commission's or agreement state's certificate, or alternatively, furnish a copy of the general license contained in 39.4(21)*"d"* and a copy of the agency form used to register to each person to whom the person transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an agreement state, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an agreement state under requirements substantially the same as those in 39.4(21)*"d"*;

5. Report to the agency all transfers of industrial products or devices to persons for use under the general license in 39.4(21)*"d."* Such report shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 39.4(21)*"d"* during the reporting period, the report shall so indicate;

6. Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40; and shall report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 39.4(29)*"m"* for use under a general license in that state's regulations equivalent to 39.4(21)*"d."* Such report shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person. If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission. If no transfers have been made to general licensees within a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency upon the request of that agency; and

7. Keep records showing the name, address, and point of contact for each general licensee to whom the person transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 39.4(21)*"d"* or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of 641—Chapters 39 and 40.

n. Rescinded IAB 7/29/09, effective 9/2/09.

o. Acceptance sampling procedures under certain specific licenses. A random sample shall be taken from each inspection lot of devices licensed under 39.4(29) for which testing is required and meet the requirements pursuant to 10 CFR 32.110.

39.4(30) Reserved.

39.4(31) *Issuance of specific licenses.*

a. Upon a determination that an application meets the requirements of the Iowa Code and the rules of the agency, the agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

b. The agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this chapter as it deems appropriate or necessary in order to:

(1) Minimize danger to public health and safety or property;

(2) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) Prevent loss or theft of material subject to this chapter.

c. Specific license for industrial radiography. An application for a specific license for the use of licensed material in industrial radiography will be approved if the applicant meets the following requirements:

(1) The applicant satisfies the general requirements specified in 39.4(25).

(2) The applicant submits an adequate program for training radiographers and radiographers' assistants that meets the requirements of 641—subrule 45.1(10).

(3) The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

(4) The applicant submits written operating and emergency procedures as described in 641—subrule 45.2(4).

(5) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed six months as described in 641—subrule 45.1(11).

(6) The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation responsibilities in industrial radiography, including specified delegation of authority and responsibility.

(7) The applicant identifies and lists the qualifications of the individual(s) designated as the RSO (641—paragraph 45.1(10)*"d"*) and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

(8) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the instruments to be used, methods of performing the analysis, and pertinent experience of the person who will analyze the wipe samples.

(9) If the applicant intends to perform "in-house" calibrations of survey instruments, the applicant must describe the methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 641—subrule 45.1(5).

(10) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

(11) The applicant identifies the locations where all records required by 641—Chapters 38, 39, 40, and 45 will be located.

d. Specific licenses for well logging. The agency will approve an application for a specific license for the use of licensed material in well logging if the applicant meets the following requirements:

(1) The applicant shall satisfy the general requirements specified in 39.4(25) and all other requirements in 641—Chapter 39, as appropriate, and any special requirements contained in 39.4(31)*"d."*

(2) The applicant shall develop a program for training logging supervisors and logging assistants and submit to the agency a description of this program which specifies the following:

1. Initial training;
2. On-the-job training;
3. Annual safety reviews provided by the licensee;
4. The means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the agency's regulations and licensing requirements and the applicant's operating and emergency procedures; and
5. The means the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

(3) The applicant shall submit to the agency written operating and emergency procedures as described in 641—subrule 45.6(16) or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

(4) The applicant shall establish and submit to the agency its program for annual inspections of the job performance of each logging supervisor to ensure that the agency's regulations and license requirements and the applicant's operating and emergency procedures are followed. Inspection records must be retained for three years after each annual internal inspection.

(5) The applicant shall submit a description of its overall organizational structure as the organizational structure applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

(6) If an applicant wants to perform leak testing of sealed sources, the applicant shall identify the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures to the agency. The description must include the instruments to be used, methods of performing the analysis, and pertinent experience of the person who will analyze the wipe samples.

39.4(32) *Specific terms and conditions of licenses.*

a. Each license issued pursuant to this chapter shall be subject to all the provisions of the Iowa Code, now or hereafter in effect, and to all rules, regulations, and orders of the agency.

b. No license issued or granted under this chapter and no right to possess or utilize radioactive material granted by any license issued pursuant to this chapter shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the agency shall, after securing full information, find that the transfer is in accordance with the provisions of the Iowa Code, now or hereafter in effect, and to all valid rules, regulations, and orders of the agency, and shall give its consent in writing. An application for transfer of license must include:

(1) The identity and technical and financial qualifications of the proposed transferee; and

(2) The financial assurance for decommissioning information required by 39.4(26).

c. Each person licensed by the agency pursuant to this chapter shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

d. Each licensee shall notify the agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

e. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 641—subrule 41.2(34). The licensee shall record the results of each test and retain each record for three years after the record is made.

f. Each general licensee that is required to register by 39.4(21) or 39.4(22) and each specific licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary

petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) The licensee;

(2) An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(3) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

The notification specified in 39.4(32)*"f"* shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

g. (1) Authorization under 39.4(29)*"h"* to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in the licensee's consortium does not relieve the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

(2) Each licensee authorized under 39.4(29)*"h"* to produce PET radioactive drugs for noncommercial transfer to medical use licensees in the licensee's consortium shall:

1. Satisfy the labeling requirements in 39.4(29)*"j"*(1)"4" for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of the licensee's consortium.

2. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of the licensee's consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 39.4(29)*"j"*(3).

(3) A licensee that is a pharmacy authorized under 39.4(24)*"h"* to produce PET radioactive drugs for noncommercial transfer to medical use licensees in the pharmacy's consortium shall require that any individual who prepares PET radioactive drugs shall be:

1. An authorized nuclear pharmacist who meets the requirements in 39.4(29)*"j"*(2)"2," or

2. An individual under the supervision of an authorized nuclear pharmacist as specified in 641—subrule 41.2(11).

(4) A pharmacy authorized under 39.4(29)*"j"* to produce PET radioactive drugs for noncommercial transfer to medical use licensees in the pharmacy's consortium that allows an individual to work as an authorized nuclear pharmacist shall meet the requirements in 39.4(29)*"j"*(2)"5."

39.4(33) *Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.*

a. Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under 39.4(33) not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days before the expiration date stated in the existing license, the existing license expires at the end of the day on which the agency makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

b. Each specific license revoked by the agency expires at the end of the day on the date of the agency's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by agency order.

c. Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of by-product material until the agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(1) Limit actions involving by-product material to those related to decommissioning; and

(2) Continue to control entry to restricted areas until they are suitable for release in accordance with state of Iowa requirements.

d. Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with the state of Iowa requirements, or submit within 12 months of notification a decommissioning plan, if required by 39.4(33)*"j"* and begin decommissioning upon approval of that plan if:

(1) The license has expired pursuant to 39.4(33)*"a"* or *"b"*;

(2) The licensee has decided to permanently cease principal activities, as defined in 641—38.2(136C) at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with state of Iowa requirements;

(3) No principal activities under the license have been conducted for a period of 24 months; or

(4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area suitable for release in accordance with State of Iowa requirements.

e. Coincident with the notification required by 39.4(33)*"d,"* the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to subrule 39.4(26) in conjunction with a license issuance or renewal or as required by this subrule. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph 39.4(33)*"g."*

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective on July 9, 1997.

(2) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the agency.

f. The agency may grant a request to extend the time periods established in 39.4(33)*"d"* if the agency determines that this request is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to 39.4(33)*"d."* The schedule for decommissioning set forth in 39.4(33)*"d"* of this subrule may not commence until the agency has made a determination on the request.

g. A decommissioning plan must be submitted if required by license conditions or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the agency and these procedures could increase the potential health and safety impacts to workers or to the public.

(1) Procedures having potential health and safety impacts include, but are not limited to:

1. Procedures that would involve techniques not applied routinely during cleanup or maintenance operations;

2. Workers that would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

3. Procedures that could result in significantly greater airborne concentrations of radioactive material than are present during operation;

4. Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to 39.4(33)*"d"* of this subrule if the agency determines that the alternate schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(3) Procedures such as those listed in 39.4(33)*"g"* with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

1. A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

2. A description of planned decommissioning activities;

3. A description of the methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

4. A description of the planned final radiation survey; and

5. An updated detailed cost estimate for decommissioning, and a plan for ensuring the availability of adequate funds for completion of decommissioning.

6. A description of the physical security plan and material control and accounting plan provisions in place during decommissioning.

7. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include justification for the delay based on the criteria in paragraph *"i"* of this subrule.

(5) The proposed decommissioning plan will be approved by the agency if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

h. Except as provided in 39.4(33)*"i,"* licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning. When the decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

i. The agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the agency determines that the alternative is warranted by consideration of the following:

(1) It is technically feasible to complete decommissioning within the allotted 24-month period;

(2) Sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(3) A significant volume reduction exposure to workers can be achieved by allowing short-lived radionuclides to decay;

(4) A significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) Other site-specific factors which the agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, groundwater treatment activities, monitored natural groundwater restoration, actions that could result in more environmental harm than a deferred cleanup, and other factors beyond the controls of the licensee.

j. As the final step in decommissioning, the licensee shall:

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed IDPH Form 588-2793 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 641—40.28(136C) through 641—40.31(136C). The licensee shall, as appropriate:

1. Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report the level of radioactivity, including alpha and beta, in units of disintegrations per minute or microcuries (megabecquerels) per 100 square centimeters (removable and fixed) for surfaces, microcuries (megabecquerels) per liter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

2. Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

k. Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the agency determines that:

(1) By-product material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3) A radiation survey has been performed which demonstrates that the premises are suitable for release or other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 641—40.28(136C) through 641—40.31(136C).

(4) Records required by 39.4(52)*"e"* and 39.4(52)*"g"* have been received.

l. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the agency:

(1) Disposal of licensed material (including burials authorized before January 28, 1981), made under 641—40.71(136C) through 40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)*"d."*

m. If licensed activities are transferred or assigned in accordance with 39.4(32)*"b,"* each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material (including burials authorized before January 28, 1981), made under 641—40.71(136C) through 40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)*"d."*

n. Prior to license termination, each licensee shall forward the records required by 39.4(26)*"g"* to the agency.

39.4(34) *Renewal of licenses.*

a. Applications for renewal of specific licenses shall be filed in accordance with 39.4(24) and include the fees required in 641—subrule 38.8(2).

b. In any case in which a licensee, not less than 30 days prior to expiration of an existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the agency.

39.4(35) *Amendment of licenses at request of licensee.* Applications for amendment of a license shall be filed in accordance with 39.4(24), include the fees required in 641—subrule 38.8(2), and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

39.4(36) *Agency action on applications to renew or amend.* In considering an application by a licensee to renew or amend the license, the agency will apply the criteria set forth in 39.4(25), 39.4(27), 39.4(28), and 39.4(29) and in 641—Chapters 38, 40, 41, 42, 43, 44 and 45, as applicable.

39.4(37) *Persons possessing a license for source, by-product, or special nuclear material in quantities not sufficient to form a critical mass on effective date of these rules.* Any person who, on the effective date of these rules, possesses a general or specific license issued by the U.S. Nuclear Regulatory Commission for source, by-product, or special nuclear material in quantities not sufficient to form a critical mass, shall be deemed to possess a like license issued under this chapter and the Iowa Code, such license to expire either 90 days after receipt from the agency of a notice of expiration of such license, or on the date or expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

39.4(38) *Persons possessing naturally occurring and accelerator-produced radioactive material on effective date of these rules.* Any person who, on the effective date of these rules, possesses NARM for which a specific license is required by the Iowa Code or this chapter shall be deemed to possess such a license issued under the Iowa Code and this chapter. Such license shall expire 90 days after the effective date of these rules; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the agency.

39.4(39) *Requirements for license to initially transfer source material for use under a general license.* An application for a specific license to initially transfer source material for use under 39.4(21), or equivalent regulations of an agreement state or the Nuclear Regulatory Commission, will be approved if:

a. The applicant satisfies the general requirements specified in 39.4(25); and

b. The applicant submits adequate information on, and the agency approves the methods to be used for, quality control, labeling, and providing safety instructions to recipients.

39.4(40) *Conditions of licenses to initially transfer source material for use under general license: quality control, labeling, safety instructions, and records and reports.*

a. Each person licensed under 39.4(39) shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words "radioactive material."

b. Each person licensed under 39.4(39) shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

c. Each person licensed under 39.4(39) shall provide the information specified in this paragraph to each person to whom source material is transferred for use under 39.4(21) or equivalent provisions in agreement state or Nuclear Regulatory Commission regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(1) A copy of 39.4(21) and 39.4(41) or relevant equivalent regulations of the agreement state or Nuclear Regulatory Commission.

(2) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

d. Each person licensed under 39.4(39) shall report transfers as follows:

(1) File a report with the Iowa Department of Public Health, 321 East 12th Street, Des Moines, Iowa 50319. The report shall include the following information:

1. The name, address, and license number of the person who transferred the source material;

2. For each general licensee under 39.4(21) or equivalent agreement state or Nuclear Regulatory Commission provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name or position, or both, and telephone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

3. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(2) File a report with each responsible agreement state agency or the Nuclear Regulatory Commission that identifies all persons, operating under provisions equivalent to 39.4(21), to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the agreement state or Nuclear Regulatory Commission jurisdiction:

1. The name, address, and license number of the person who transferred the source material; and

2. The name and address of the general licensee to whom source material was distributed; a responsible agent, by name or position, or both, and telephone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

3. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the agreement state or Nuclear Regulatory Commission jurisdiction.

(3) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under 39.4(21) or equivalent agreement state or Nuclear Regulatory Commission provisions during the current period, a report shall be submitted to the agency indicating so. If no transfers have been made to general licensees in a particular agreement state or Nuclear Regulatory Commission jurisdiction during the reporting period, this information shall be reported to the responsible agreement state agency or Nuclear Regulatory Commission upon request.

e. Each person licensed under 39.4(39) shall maintain all information that supports the reports required by these rules concerning each transfer to a general licensee for a period of one year after the event is included in a report to the agency, the Nuclear Regulatory Commission or to an agreement state agency.

39.4(41) *Transfer of material.*

a. No licensee shall transfer radioactive material except as authorized pursuant to 39.4(41).

b. Except as otherwise provided in the license and subject to the provisions of 39.4(41)*"c"* and *"d,"* any licensee may transfer radioactive material:

(1) To the agency (a licensee may transfer material to the agency only after receiving prior approval from the agency);

(2) To the U.S. Department of Energy;

(3) To any person exempt from these rules to the extent permitted under such exemption;

(4) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the U.S. Nuclear Regulatory Commission, any agreement state or any licensing state, or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the agency, an agreement state, or a licensing state; or

(5) As otherwise authorized by the agency in writing.

c. Before transferring radioactive material to a specific licensee of the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, or to a general licensee who is required to register with the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

d. Any of the following methods for the verification required by 39.4(41)*"c"* is acceptable:

(1) The transferor may possess and read a current copy of the transferee's specific license or registration certificate.

(2) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.

(3) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date, provided that the oral certification is confirmed in writing within ten days.

(4) The transferor may obtain other information compiled by a reporting service from official records of the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state regarding the identity of licensees and the scope and expiration dates of licenses and registration.

(5) When none of the methods of verification described in 39.4(41)*"d"*(1) through (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up to date, the transferor may obtain and record confirmation from the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state that the transferee is licensed to receive the radioactive material.

e. Shipment and transport of radioactive material shall be in accordance with the provisions of 641—39.5(136C).

39.4(42) to **39.4(50)** Reserved.

39.4(51) *Modification and revocation of licenses.*

a. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Iowa Code, or by reason of rules, regulations, and orders issued by the agency.

b. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Iowa Code, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Iowa Code, or of the license, or of any rule, regulation, or order of the agency.

c. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

39.4(52) *Records.*

a. Each person who receives by-product material pursuant to a license shall keep records showing the receipt, transfer, and disposal of the by-product material as follows:

(1) The licensee shall retain each record of receipt of by-product material as long as the material is possessed and for three years following transfer or disposal of material.

(2) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of these rules dictates otherwise.

(3) The licensee who disposed of the material shall retain each record of disposal of by-product material until the agency terminates each license that authorizes disposal of the material.

b. The licensee shall retain each record that is required by these rules or by license condition for the period specified by the appropriate rule or license condition; the record must be retained until the agency terminates each license that authorizes the activity that is subject to the record-keeping requirements.

c. Records which must be maintained may be the original or a reproduced copy or microfilm if such reproduced copy or microfilm is duly authenticated by authorized personnel and the microfilm is capable of producing a clear and legible copy after storage for the period specified by agency regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

d. If there is a conflict between the agency's rules or other written agency approval or authorization pertaining to the retention period for the same type of record, the retention period specified in these rules for such records shall apply unless the agency has granted a specific exemption from the record retention requirements specified in agency rules.

e. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the agency:

(1) Records of disposal of licensed material made under 641—40.71(136C) (including burials authorized before January 28, 1981) to 641—40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)*"d."*

f. If licensed activities are transferred or assigned, each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under 40.71(136C) (including burials authorized before January 28, 1981) to 641—40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)*"d."*

g. Prior to license termination, each licensee shall forward the records required by subrule 39.4(26) to the agency.

39.4(53) to **39.4(89)** Reserved.

39.4(90) *Reciprocal recognition of licenses.*

a. Licenses of by-product, source, and special nuclear material in quantities not sufficient to form a critical mass.

(1) Subject to 641—Chapter 39, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in a one-year period. The one-year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 38.8(8), is received by the agency and ends exactly 365 days later. Licensees are responsible for ensuring they do not exceed the 180-day limit within the one-year period and must apply for renewal 30 days prior to the expiration date of the one-year reciprocal recognition period. Out-of-state persons wishing to operate in the state in excess of 180 calendar days must obtain an Iowa radioactive materials license.

(2) The licensing document referenced in 39.4(90)*"a"*(1) shall not limit the activity authorized by such document to specified installations or locations.

(3) The out-of-state licensee shall notify the agency in writing at least three working days prior to engaging in activities in the state. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document initially. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the one-year reciprocity period following the receipt of the initial notification from a person engaging in activities under the general license provided by 39.4(90)*"a."*

(4) The out-of-state licensee shall comply with all applicable rules of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the agency.

(5) The out-of-state licensee shall supply other information as the agency may request.

(6) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided by 39.4(90)*"a"* except by transfer to a person specifically licensed by the agency, another agreement state or the U.S. Nuclear Regulatory Commission to receive such material.

(7) Notwithstanding the provisions of 39.4(90)*"a"*(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 39.4(22)*"d"*(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

1. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement state;

3. Such person shall ensure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

4. The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in 39.4(22)*"d"* or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(8) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(9) The agency may revoke or suspend an out-of-state radiographer's ID card issued by the U.S. Nuclear Regulatory Commission, a licensing state, or another agreement state in accordance with the provisions of 641—45.1(10)*"h."*

b. Licenses of naturally occurring or accelerator-produced radioactive material.

(1) Subject to 641—Chapter 39, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in a one-year period. The one-year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 38.8(8), is received by the agency and ends exactly 365 days later. Licensees are responsible for ensuring they do not exceed the 180-day limit within the one-year period and must apply for renewal 30 days prior to the expiration date of the one-year reciprocal recognition period. Out-of-state persons wishing to operate in the state in excess of 180 calendar days must obtain an Iowa radioactive materials license, which requires that the person have a permanent office in Iowa where records are maintained pertaining to licensed activities and where material can be stored, and must have at least one full-time employee and a telephone.

(2) The licensing document referenced in 39.4(90)*"a"*(1) shall not limit the activity authorized by such document to specified installations or locations.

(3) The out-of-state licensee shall notify the agency in writing at least three days prior to engaging in activities in the state. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document initially. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the one-year reciprocity period following the receipt of the initial notification from a person engaging in activities under the general license provided by 39.4(90)*"b."*

(4) The out-of-state licensee shall comply with all applicable rules of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the agency.

(5) The out-of-state licensee shall supply other information as the agency may request.

(6) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided by 39.4(90)*"b"* except by transfer to a person:

1. Specifically licensed by the agency, another agreement state or the U.S. Nuclear Regulatory Commission to receive such material, or

2. Exempt from the requirements for a license for such material under 39.4(3)*"a."*

(7) Notwithstanding the provisions of 39.4(90)*"b"*(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 39.4(22)*"d"*(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

1. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement state;

3. Such person shall ensure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

4. The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in 39.4(22)*"d"* or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(8) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(9) The agency may revoke or suspend an out-of-state radiographer's ID card issued by the U.S. Nuclear Regulatory Commission, a licensing state, or another agreement state in accordance with the provisions of 641—45.1(10)*"h."*

39.4(91) to **39.4(104)** Reserved.

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