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. Certain devices and equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(3)*"a"*(2), 39.4(32), 39.4(41), 39.4(51), 641—39.5(136C), and 641—Chapter 40. Attention is directed particularly to the provisions of 641—Chapter 40, which relate to the labeling of containers.

(1) Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device.

(2) Ion generating tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device or a total of not more than 50 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device.

b. Reserved.

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, 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 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"*;

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 containing at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37 MBq) of cobalt-60, 1 mCi (37 MBq) of americium-241, .01 mCi (.37 MBq) of radium-226, or 1 mCi (37 MBq) of any other transuranic (i.e., element with atomic number greater than uranium (92)), or 1000 times the activity indicated in Appendix B of 641—Chapter 39 (excluding hydrogen-3), based on the activity indicated on the label. Each address for a location of use, as described in 39.4(22)*"d"*(3)"13," represents a separate general licensee and requires a separate registration and fee;

• If in possession of 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).

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.

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. 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. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of 39.4(26)*"f"* is submitted to the agency.

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 July 1, 1993, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to $750,000 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.

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

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix F of 641—Chapter 40 in unsealed form. (For a combination of isotopes, if R, as defined in 39.4(26)*"a,"* divided by 10^4 is greater than 1, but R divided by 10^5 is less than or equal to 1.)	750,000
Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix F of 641—Chapter 40 in unsealed form. (For a combination of isotopes, if R, as defined in 39.4(26)*"a,"* divided by 10^3 is greater than 1, but R divided by 10^4 is less than or equal to 1.)	150,000

Greater than 10^{10} 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.) 75,000

e. Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from 39.4(26)*"f,"* including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate and a signed original of the financial instrument obtained to satisfy the requirements of 39.4(26)*"f."*

f. 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. Licensing the introduction of radioactive material into products in exempt concentrations.

(1) In addition to the requirements set forth in 39.4(25), a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under 39.4(3)*"a"*(1) will be issued if:

1. The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to ensure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

2. The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Appendix A of this chapter, that reconcentration of the radioactive material in concentrations exceeding those in Appendix A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(2) Each person licensed under 39.4(29)*"a"* shall file an annual report with the agency which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to 39.4(29)*"a"* during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

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

c. Resins containing scandium-46 and designed for sand consolidation in oil wells: requirements for license to manufacture, or initially transfer for sale or distribution. An application for a specific license to manufacture, or initially transfer for sale or distribution, synthetic plastic resins containing scandium-46 for use pursuant to 39.4(3)*"c"*(4) will be approved if the applicant satisfies the general requirements of 39.4(25) and the criteria of Section 32.16 of 10 CFR Part 32.

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; and

5. Each device meeting the criteria of 39.4(22)*"d"*(3)"13" bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution—Radioactive Material," and, if practicable, the radiation symbol described in 641—subrule 40.60(1).

(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, 32.56, and 32.101 of 10 CFR Part 32, or their equivalent.

f. Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under 39.4(22)*"g."* An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 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, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70, 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.

(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. Licensing the manufacture and distribution of ice detection devices. 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 criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32.

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 or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;
- Registered or licensed with a state agency as a drug manufacturer;
- Licensed by the Iowa board of pharmacy examiners as a nuclear pharmacy; or
- Operating as a nuclear pharmacy within a federal medical institution;