Subchapter II — Licensing of Radioactive Material

DHS 157.09 **Exemptions. (1)** EXEMPTIONS OF SOURCE MATERIAL. (a) A person is exempt from subchs. III and X if the person receives, possesses, uses, owns or transfers any of the following types and forms of source material:

1. Any chemical mixture, compound, solution or alloy in which the source material by weight is less than 1/20 of one percent of the mixture, compound, solution or alloy.

2. Unrefined and unprocessed ore containing source material provided that, except as authorized in a specific license, the person does not refine or process the ore.

3. Rare earth metals and compounds, mixtures and products containing not more than 0.25% by weight thorium, uranium or any combination of these.

4. Any quantities of thorium contained in any of the following:

a. Incandescent gas mantles.

b. Vacuum tubes.

c. Welding rods.

d. Electric lamps for illuminating purposes provided that a lamp does not contain more than 50 milligrams of thorium.

e. Germicidal lamps, sunlamps and lamps for outdoor or industrial lighting provided that a lamp does not contain more than 2 grams of thorium.

f. Personnel neutron dosimeters, provided that a dosimeter does not contain more than 50 milligrams of thorium.

5. Source material contained in any of the following products:

a. Glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20% by weight source material.

b. Glassware containing not more than 2% by weight source material, or for glassware manufactured before August 27, 2013, 10% by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction.

c. Glass enamel or glass enamel frit containing not more than 10% 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.

d. Piezoelectric ceramic containing not more than 2% by weight source material.

6. Photographic film, negatives and prints containing uranium or thorium.

7. Any finished product or part fabricated of tungsten-thorium or magnesium-thorium alloys, or containing tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4% by weight and that this exemption is not deemed to authorize the chemical, physical or metallurgical treatment or processing of any product or part.

8. Uranium contained in counterweights installed in aircraft, rockets, projectiles or missiles or stored or handled in connection with installation or removal of the counterweights, under all of the following conditions:

a. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: “DEPLETED URANIUM". This requirement need not be met by counterweights manufactured prior to December 31, 1969 provided that the counterweights are impressed with the legend “CAUTION — RADIOACTIVE MATERIAL — URANIUM".

b. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement, “UNAUTHORIZED ALTERATIONS PROHIBITED". This requirement need not be met by counterweights manufactured prior to December 31, 1969 provided that the counterweights are impressed with the legend “CAUTION — RADIOACTIVE MATERIAL — URANIUM".

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

9. Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that the shipping container is conspicuously and legibly impressed with the legend “CAUTION — RADIOACTIVE SHIELDING — URANIUM"; and the uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 3.2 millimeter (one-eighth inch).

10. Thorium or uranium contained in or on finished optical lenses and mirrors, provided that a lens or mirror does not contain more than10% by weight of thorium or uranium or for lenses manufactured before August 27, 2013, 30% by weight of thorium and that this exemption is not deemed to authorize either of the following:

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

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

11. Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that the thorium is dispersed in the alloy in the form of finely divided thoria, and the thorium content in the nickel-thoria alloy does not exceed 4% by weight.

12. Only persons authorized by a license issued under 10 CFR 40.52, may initially transfer for sale or distribution such products containing source material to a person exempt under this subsection.

13. Persons authorized by an agreement state to manufacture, process, or produce materials or products containing source material, and persons who import finished products or parts for sale or distribution, shall be licensed for distribution only under 10 CFR 40.52, and are exempt from s. DHS 157.13 (2) (a) and (b) and subchs. III and X.

(b) The exemptions in par. (a) do not authorize the manufacture of any of the products described.

(2) EXEMPTIONS OF RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL. (a) *Exempt concentrations.* Except as provided in this paragraph, a person is exempt from this subchapter to the extent that the person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations no greater than those listed in ch. DHS 157 Appendix A. A person may not introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this paragraph or equivalent regulations of the NRC, any agreement state or licensing state, except under a specific license issued under 10 CFR 32.11 or s. DHS 157.13 (4) (a).

1. This paragraph does not authorize the import of radioactive material or products containing radioactive material.

2. A manufacturer, processor or producer of a product or material is exempt from the requirements of subch. II if they transfer radioactive material contained in a product or material in concentrations not in excess of those in ch. DHS 157 Appendix A and introduced into the product or material by a licensee holding a specific license issued by the department, the NRC or another agreement state 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.* Except as provided in this paragraph, a person is exempt from this subchapter to the extent that the 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 ch. DHS 157 Appendix B.

1. This paragraph does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution or the incorporation of radioactive material into products intended for commercial distribution.

2. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in ch. DHS 157 Appendix B to any person exempt from this chapter or equivalent regulations of the NRC, an agreement state or a licensing state, except under a specific license issued by the NRC under 10 CFR 32.18, or by the department under s. DHS 157.13 (4) (b) which license states that the radioactive material may be transferred by the licensee to persons exempt under this paragraph or the equivalent regulations of the NRC, an agreement state or a licensing state.

3. A person, who possesses byproduct material received or acquired before September 25, 1971, under the general license then provided in 10 CFR 31.4 or similar general license of a State, is exempt from the requirements of this subchapter to the extent that this person possesses, uses, transfers, or owns byproduct material.

Note: Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the NRC, Washington, D.C. 20555.

(c) *Certain items containing radioactive material.* Except for persons who apply radioactive material to the following products, or incorporate radioactive material into the following products, or initially transfer for sale or distribution the following products, a person is exempt from this subchapter if the person receives, possesses, uses, transfers, owns or acquires any of the following products:

1. Timepieces, hands or dials containing not more than the following specified quantities of radioactive material:

a. 925 MBq (25 millicuries) of tritium per timepiece.

b. 185 MBq (5 millicuries) of tritium per hand.

c. 555 MBq (15 millicuries) of tritium per dial.

Note: Bezels, when used, should be considered as part of the dial.

d. 3.7 MBq (100 microcuries) of promethium-147 per watch or 7.4 MBq (200 microcuries) of promethium-147 per any timepiece.

e. 0.74 MBq (20 microcuries) of promethium-147 per watch hand or 1.48 MBq (40 microcuries) of promethium-147 per other timepiece hand.

f. 2.22 MBq (60 microcuries) of promethium-147 per watch dial or 4.44 MBq (120 microcuries) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).

2. Timepieces, hands or dials containing promethium-147, when measured through 50 milligrams per square centimeter of absorber, not exceeding the following radiation dose rate:

a. For wrist watches, one microgray~~Gy~~ (0.1 millirad) per hour at 10 centimeters from any surface.

b. For pocket watches, one microgray~~Gy~~ (0.1 millirad) per hour at one centimeter from any surface.

c. For any other timepiece, 2 microgray~~Gy~~ (0.2 millirad) per hour at 10 centimeters from any surface.

3. Timepieces containing up to 37 kBq (1.0 microcurie) of radium-226 per timepiece acquired prior to November 30, 2007.

4. Ionization chamber smoke detectors containing not more than 37 kBq (1 microcurie) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

5. Precision balances containing not more than 37 MBq (1 millicurie) of tritium per balance or not more than 18.5 MBq (0.5 millicurie) of tritium per balance part.

6. Marine compasses containing not more than 27.8 GBq (750 millicuries) of tritium gas and other marine navigational instruments containing not more than 9.25 GBq (250 millicuries) of tritium gas.

7. Electron tubes, including 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, provided that the radiation dose rate from each electron tube containing radioactive material does not exceed 10 microgray (1 millirad) per hour at one centimeter from any surface when measured through 7 milligrams per square centimeter of absorber and that each tube does not contain more than one of the following specified quantities of radioactive material:

a. 5.55 GBq (150 millicuries) of tritium per microwave receiver protector tube or 370 MBq (10 millicuries) of tritium per any other electron tube.

b. 37 kBq (1 microcurie) of cobalt-60.

c. 185 kBq (5 microcuries) of nickel-63.

d. 1.11 MBq (30 microcuries) of krypton-85.

e. 185 kBq (5 microcuries) of cesium-137.

f. 1.11 MBq (30 microcuries) of promethium-147.

8. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided all the following conditions are met:

a. Each source contains no more than one exempt quantity set forth in ch. DHS 157 Appendix B.

b. Each instrument contains no more than 10 exempt quantities. For the purposes of this subd. par., an instrument's source or sources may contain either one 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 ch. DHS 157 Appendix B, provided that the sum of the fractions does not exceed unity.

c. For purposes of this subdivision, 1.85 kBq (0.05 microcurie) of americium-241 is considered to be an exempt quantity.

9. Static elimination devices which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 microcuries) of polonium-210 per device.

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

11. Devices authorized before October 23, 2012 for use under the general license then provided in DHS 157.11 (2) (a), equivalent regulations of the NRC, or other agreement states, and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the NRC.

(d) *Self-luminous products containing tritium, krypton-85,or promethium-147.* 1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution of self-luminous products containing tritium, krypton-85 or promethium-147, and except as provided in subd. 3., any person is exempt from this subchapter 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 or initially transferred under a specific license issued by the NRC according to 10 CFR 32.22, which authorizes the initial transfer of the product for use under this subdivision.

2. 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, or to transfer such products for use according to subd. 1., shall apply for a license issued by the NRC according to 10 CFR 32.22, which states that the product may be transferred by the licensee to persons exempt from this subchapter according to subd. 1. or equivalent regulations of the NRC or an agreement state.

3. The exemption in subd. 1. does not apply to tritium, krypton-85 or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

(e) *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, a person is exempt from this subchapter if the person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that the detectors containing radioactive material have been manufactured, processed, produced or initially transferred for sale or distribution under a specific license issued by the NRC under 10 CFR 32.26, a licensing state, other agreement state or the department under s. DHS 157.13 (4) (c), which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by an agreement state under comparable provisions under 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

2. Gas and aerosol detectors previously manufactured and distributed to general licensees under the specific license issued by an agreement state shall be considered exempt under this subdivision provided that the device is labeled under the specific license authorizing distribution of the generally licensed device and provided further that they meet the requirements of s. DHS 157.13 (4) (c).

3. Gas and aerosol detectors containing NARM previously manufactured and distributed under a specific license issued by a licensing state shall be considered exempt under this subdivision provided the devices are labeled under the specific license authorizing distribution, and provided further that they meet the requirements of s. DHS 157.13 (4) (c).

4. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use according to subd. 1., shall apply for a license issued by the NRC according to 10 CFR 32.26 and certificate of registration in accordance with 10 CFR 32.210, which states that the product may be transferred by the licensee to persons exempt from this subchapter according to subd. 1. or equivalent regulations of the NRC or an agreement state.

(f) *Radioactive drug capsules containing no more than 37 kBq (1 microcurie) carbon-14 urea each for in vivo diagnostic use for humans.* 1. Except as provided in subds. 2. and 3., a person is exempt from this subchapter provided that the person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 microcurie*)* 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 according to s. DHS 157.13.

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 according to 10 CFR 32.21.

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

(g) *Industrial use devices containing exempt quantities or ~~disturbed~~ distributed under a general license.* 1. Except for persons who manufacture, process, produce or initially transfer for sale or distribution of industrial 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 an ionized atmosphere containing radioactive material, a person is exempt from this subchapter if the 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 have been manufactured, processed, produced, or initially transferred for sale or distribution under a specific license issued by the NRC under 10 CFR 32.30, a licensing state, other agreement state or the department under s. DHS 157.13 (4) (c), which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

2. Industrial devices previously manufactured and distributed to general licensees under the specific license issued by an agreement state shall be considered exempt under this subdivision provided that the device is labeled under the specific license authorizing distribution of the generally licensed device and provided further that they meet the requirements of s. DHS 157.13 (4) (c).

3. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution of industrial devices containing byproduct material for use according to subd. 1., shall apply for a license issued by the NRC according to 10 CFR 32.30 and certificate of registration in accordance with 10 CFR 32.210, which states that the product may be transferred by the licensee to persons exempt from this subchapter according to subd. 1. or equivalent regulations of the NRC or an agreement state.

(3) EXEMPTIONS OF CATEGORY 1 OR CATEGORY 2 QUANTITIES OF RADIOACTIVE WASTE. A licensee that possesses radioactive waste that contains category 1 or category 2 quantities of radioactive material, other than waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs), is exempt from the requirements of ss. DHS 157.9700 to 157.9722 and shall implement all the following requirements to secure the radioactive waste:

(a) Use continuous physical barriers that allow access to the radioactive waste only through established access control points.

(b) Use a locked door or gate with monitored alarm at the access control point.

(c) Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred.

(d) Immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains category 1 or category 2 quantities of radioactive material.

Note: Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the NRC, Washington, D.C. 20555.

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter; CR 06-021: r. and recr. (2) (a) 2., am. (2) (c) (intro.), 1. a. and 9. a., r. (2) (c) 12. and 15., cr. (2) (d) and (g), renum. (2) (c) 13. and 14. to be (2) (e) and (f) and am. (2) (e) 1. and (f) Register October 2006 No. 610, eff. 11-1-06; CR 09-062: r. and recr. (2) Register April 2010 No. 652, eff. 5-1-10; **CR 16-078: am. (1) (a) (intro.), 5. a., b., r. (1) (a) 8. a., renum. (1) (a) 8. b. to d. to (1) (a) 8. a. to c., am. (1) (a) 10. (intro.), r. and recr. (1) (a) 11., 12., cr. (1) (a) 13., am. (2) (c) 7. (intro.), cr. (2) (c) 9. to 11., am. (2) (d) 1., 2., (e) 1., cr. (2) (e) 4., (g), (3) Register January 2018 No. 745, eff. 2-1-18; correction in (1) (a) (intro.), 13., (2) (a) (intro.), (c) 8. a., (g) (intro.), 2. made under s. 35.17, Stats., and correction in (3) made under s. 13.92 (4) (b) 7., Stats., Register January 2018 No. 745.**

DHS 157.10 **License types and fees. (1)** TYPES OF LICENSES. A license for radioactive materials may be one of the following:

(a) *General.* A general license is effective without the filing of an application with the department or the issuance by the department of licensing documents to the particular person, although the filing of a certificate with the department may be required by the particular general license. The general licensee is subject to all other applicable parts of this chapter and any limitations of the general license.

(b) *Specific.* A specific license requires the submission of an application to the department and the issuance of a licensing document by the department. A licensee is subject to all applicable parts of this chapter as well as any limitations specified in the licensing document. A licensee shall pay the license fees as specified in sub. (3).

(2) PAYMENT OF FEES. (a) *Application fee.* An application for a specific license shall be accompanied by payment in the full amount of the fee specified in sub. (3). The department may not process the application prior to receipt of the required fee. The application fee is not refundable except in those cases where the department determines that a license is not required. The department will consider any application abandoned if the department does not receive a reply within 90 days of its most recent

request for additional information. In such cases, the applicant shall submit a new application with the application fee specified in sub. (3).

(b) *Annual fee.* A person holding a specific license in effect prior to the effective date of August 1, 2002, or a specific license issued after the effective date of August 1, 2002, shall pay the annual fee specified in sub. (3) at least 60 days prior to the anniversary date of the issuance of the license. The annual fee is not refundable except in those cases where the department determines that the fee is not required.

(c) *Amendment fee.* An application for amendment to a specific license shall be accompanied by payment in full of the fee specified in sub. (3). The department may not process the application prior to the department's receipt of the required fee. The department may not charge an amendment fee to modify a license on its own initiative.

(d) *Reciprocity fee.* A person submitting an application for reciprocal recognition of a materials license issued by an agreement state or the nuclear regulatory commission shall include remittance for the full amount of the fee specified in sub. (3). The department may not process the application prior to the department's receipt of the appropriate fee. Requests for reciprocal recognition approved by the department prior to November 1 shall remain in effect until December 31 of that year. Requests for reciprocal recognition approved on or after November 1 shall remain in effect until December 31 of the subsequent year.

(3) FEE SCHEDULE. The following is the schedule of application, annual, amendment, and reciprocity fees for specific radioactive material licenses.

Category	License Type	Application & Annual Fee
1.	**Special Nuclear Material (SNM)**	
A.	License for possession and use of SNM in sealed sources contained in devices used in measuring systems	$1,000
B.	License for use of SNM to be used as calibration and reference sources	$300
C.	SNM – all other, except license authorizing special nuclear material in unsealed form that would constitute a critical mass [Fee waived if facility holds additional license category]	$1,500
2.	**Source Material**	
A.	Source material processing and distribution	$4,000
B.	Source material in shielding [Fee waived if facility holds additional license category]	$400
C.	Source material – all other, excluding depleted uranium used as shielding or counterweights	$3,000
3.	**Byproduct, NARM**	
A.	License of broad scope for processing or manufacturing of items for commercial distribution	$20,000
B.	License for processing or manufacturing and commercial distribution of radiopharmaceuticals,	$12,000

	generators, reagent kits and sources or devices	
C.	License for commercial distribution or redistribution of radiopharmaceuticals, generators, reagent kits and sources or devices	$3,000
D.	Other licenses for processing or manufacturing of items for commercial distribution	$4,000
E.	License for industrial radiography operations performed only in a shielded radiography installation	$3,000
F.	License for industrial radiography performed only at the address indicated on the license, and at temporary job sites	$5,000
G.	License for possession and use of less than 370 TBq (10,000 curies) of radioactive material in sealed sources for irradiation of materials where the source is not removed from the shield [Fee waived if facility holds additional irradiator license category]	$2,000
H.	License for possession and use of less than 370 TBq (10,000 curies) of radioactive material in sealed sources for irradiation of materials where the source is exposed for irradiation purposes. The category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation	$3,000
I.	License for possession and use of at least 370 TBq (10,000 curies) and less than 3.7 PBq (100,000 curies)of radioactive material in sealed sources for irradiation of materials	$5,000
J.	License for possession and use of 3.7 PBq (100,000 curies) or more of radioactive material in	$12,000

	sealed sources for irradiation of materials	
K.	License to distribute items containing radioactive materials to persons under a general license	$2,000
L.	License to possess radioactive materials intended for distribution to persons exempt from licensing	$2,500
M.	License of broad scope for research and development that does not authorize commercial distribution	$6,000
N.	Other licenses for possession and use of less than 0.185 TBq (5 curies) of radioactive material in possession and use of less than 0.185 TBq (5 curies) of radioactive material in licenses for research and development that do not authorize commercial distribution	$1,800
O.	License for installation, repair, maintenance leak testing or other service of devices or items containing radioactive material, or to perform services for other persons, including testing of sealed sources for leakage or contamination, instrument calibration, and sample analysis, excluding waste transportation or broker services	$1,800
P.	License for portable gauges, including industrial Lixiscope ®	$1,400
Q.	License for portable x-*ray fluorescence analyzer calibration flood source, dewpointer or gas chromatograph	$200
R.	All other byproduct, naturally -*occurring or accelerator-* produced material licenses, except as otherwise noted	$2,000
S.	Other license for possession and use of 0.185 TBq (5 curies) or	$3600

	more of radioactive material in research and development that do not authorize commercial distribution	
4.	**Waste Processing**	
A.	Commercial waste treatment facilities, including incineration	$200,000
B.	All other commercial facilities involving waste compaction, repackaging, storage or transfer	$25,000
C.	Waste processing – all other, including decontamination service	$5,000
5.	**Well Logging**	
A.	License for well logging using sealed sources or sub-surface tracer studies	$4,000
B.	License for well logging using sealed sources and sub-surface tracer studies	$5,000
6.	**Nuclear Laundry**	
A.	License for commercial collection and laundry of items contaminated with radioactive material	$16,000
7.	**Medical/Veterinary**	
A.	License for human use of byproduct, source, special nuclear or NARM material in sealed sources contained in teletherapy or stereotactic radiosurgery devices, including mobile therapy	$12,000
B.	License of broad scope for human use of byproduct, source, special nuclear or NARM materials used in medical diagnosis, treatment, research and development, excluding teletherapy, or stereotactic radiosurgery devices	$20,000
C.	License for mobile nuclear medicine	$2,500
D.	Medical – all others, including SNM pacemakers and high dose rate remote afterloading devices	$5,000
E.	License for veterinary use of radioactive materials	$2,000
8.	**Academic**	

A.	License for possession and use of byproduct, naturally-*occurring or accelerator produced radioactive material for educational use or academic research and development that does not authorize commercial distribution, excluding broad scope or human use licenses, with a combined possession limit of 12 isotopes and 37 GBq (1 curie) total activity	$1,000
9.	**Accelerator**	
A.	License for accelerator production of radioisotopes with commercial distribution	$4,000
B.	Accelerator isotope production -* all other [Fee waived if facility holds medical broad scope license with no commercial distribution]	$2,000
10.	**Reciprocity**	
A.	Reciprocal recognition of an out-of-state specific license	50% of annual fee of applicable category
11.	**Amendments**	
A.	Request to amend specific license-*no license review	$0
Note: Examples include spelling corrections and adding or removing previously authorized users.		
B.	Request to amend specific license -* license review required	$200
Note: Examples include new isotopes, license termination not requiring a site visit and procedural changes.		
C.	Request to amend specific license - license review and site visit required	$400
Note: Examples include a facility move, license termination requiring a site visit and new processes.		
12.	**Multiple Sites**	
A.	Each noncontiguous location listed on a license above two where licensed material is used or stored. Temporary job sites and broad scope licensees are exempt from this fee category.	25% of annual fee of applicable category authorized at the site

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter; CR 06-021: am. (3) Register October 2006 No. 610, eff. 11-1-06; **CR 16-078: r. and recr. (3) Register January 2018 No. 745, eff. 2-1-18.**

DHS 157.11 **General licenses. (1)** GENERAL LICENSES — SOURCE MATERIAL. (a) *General license for certain organizations to use and transfer limited amounts of source material.* A general license is issued authorizing commercial and

industrial firms, research, educational and medical institutions and 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.

1. The general license issued under this paragraph shall be limited to the following forms and quantities:

a. No more than 1.5 kg (3.3 lbs) 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 shall 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 lbs) of uranium and thorium in any one calendar year.

b. No more than a total of 7 kg (15.4 lbs) 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 lbs) 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 subsection unless it is accounted for under the limits of subd. 1. a.

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

d. No more than 7 kg (15.4 lbs) 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 lbs) of source material in any one calendar year.

2. A person who receives, possesses, uses or transfers source material under the general license issued under this paragraph shall comply with all the following:

a. Not administer source material under the general license issued under this paragraph, or radiation from the source material, either externally or internally, to human beings except as authorized by the department in a specific license.

b. Not export source material under the general license issued under this paragraph except as allowed under 10 CFR Part 110.

c. Not abandon source material under the general license issued under this paragraph.

3. Source material may be disposed of by any of the following methods:

a. A cumulative total of 0.5 kg (1.1 lbs) of source material in a solid, non-dispersible 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. A person is exempt from the requirement to obtain a license under this subchapter if source material is transferred to the person for permanent disposal under the provisions of this paragraph, and the person is not authorized to possess source material under a specific license issued under this chapter.

b. In accordance with s. DHS 157.30 (1).

4. A person who receives, possesses, uses or transfers source material under the general license issued under this paragraph is subject to the provisions in ss. DHS 157.01 to 157.03, 157.05 (2), 157.06 (1) to (3), 157.13 (9), (10), (15), and (16), 157.31, 157.32, 157.89 (4) (b), and 157.90 to 157.91.

5. A person who receives, possesses, uses, or transfers source material under the general license issued under this paragraph shall conduct activities so as to minimize contamination of the facility and the environment. The general licensee shall notify the department immediately if evidence of contamination is identified when activities at any site involving source materials have permanently ceased. The department may offer consultation to the general licensee regarding the appropriateness of sampling and restoration activities to ensure that contamination or residual source material remaining at the site is not likely to result in exposures that exceed the limits in s. DHS 157.33 (2).

6. A person who receives, possesses, uses or transfers source material pursuant to the specific terms of a general license issued under this paragraph, and who does not possess source material under a specific license issued under this chapter, is exempt from subchs. III and X, except that such person shall comply with ss. DHS 157.30 (1) and 157.33 (2)

7. No person may initially transfer or distribute source material to persons in possession of a general license issued in subd. 1. a. or b., or equivalent regulations of the NRC or another agreement state, unless authorized by a specific license issued by the department, the NRC, or another agreement state. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample.

(b) *General license authorizing receipt of title to source material without regard to quantity.* A general license is 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.

Note: A person may take title to source material under a general license. In order to receive, possess, use or transfer source material, he or she must obtain a specific license under s. DHS 157.13.

(c) *General license relating to depleted uranium in industrial products and devices.* 1. A general license is issued to receive, acquire, possess, use or transfer, under the provisions of subds. 2., 3., 4., 5. and 6., 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 issued under this paragraph applies only to industrial products or devices that have been manufactured or initially transferred either under a specific license issued to the manufacturer of the products or devices under s. DHS 157.13 (4) (k) or under a specific license issued to the manufacturer by the NRC or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the NRC or the agreement state.

3. A person who receives, acquires, possesses or uses depleted uranium under the general license under this paragraph shall file a “Certificate — Use of Depleted Uranium Under General License" form with the department. The form shall be filed within

30 days after the first receipt or acquisition of depleted uranium and is considered filed when it is received by the department. The general licensee shall furnish on the "Certificate — Use of Depleted Uranium Under General License" all of the following information and any other information required by that form:

a. Name and address of the general licensee.

b. A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in this paragraph and designed to prevent transfer of the depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium.

c. 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 subd. 3. b.

4. The general licensee possessing or using depleted uranium under the general license established under this paragraph shall report in writing to the department any changes in information furnished by that person in the "Certificate — Use of Depleted Uranium Under General License". The report shall be filed within 30 days after the effective date of the change.

5. A person who receives, acquires, possesses or uses depleted uranium under the general license established under this paragraph shall comply with all of the following:

a. Not introduce the 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.

b. Not abandon the depleted uranium.

c. Transfer or dispose of the depleted uranium only under the provisions of s. DHS 157.13 (15). In the case where the transferee receives the depleted uranium under the general license established under this paragraph, the party making the transfer shall furnish the transferee a copy of this subsection and a copy of the "Certificate — Use of Depleted Uranium Under General License". In the case where the transferee receives the depleted uranium under a general license contained in the NRC or agreement state regulations equivalent to this paragraph, the party making the transfer shall furnish the transferee a copy of this subsection and a copy of "Certificate — Use of Depleted Uranium Under General License" accompanied by a note explaining that use of the product or device is regulated by the NRC or an agreement state under requirements substantially the same as those in this subsection.

d. Within 30 days following a transfer, report in writing to the department the name and address of the person receiving the depleted uranium under the transfer.

e. Not export the depleted uranium except under a license issued by the NRC under 10 CFR 110.

6. A person receiving, acquiring, possessing, using or transferring depleted uranium under the general license established under this paragraph is exempt from the requirements of subchs. III and X with respect to the depleted uranium covered by that general license.

Note: The "Certificate — Use of Depleted Uranium Under General License" form may be obtained by writing the Department at: Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701-2659; or by downloading from the Department website at: http://dhs.wisconsin.gov/radiation/radioactivematerials/index.htm. Completed forms may be mailed to the Department at the same address.

(2) GENERAL LICENSES — RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL. (a) *General license relating to certain devices and equipment.* A general license is issued to transfer, receive, acquire, own, possess and use radioactive material incorporated in all the following devices or equipment which have been manufactured, tested and labeled by the manufacturer under a specific license issued to the manufacturer by the NRC. This general license is exempt from the requirements of subch. III, with the exception of ss. DHS 157.30 (1), 157.32 (1) and (2), and subch. X.

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 18.5 MBq (500 microcuries) 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 not more than 18.5 MBq (500 microcuries) of polonium-210 per device or a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 per device.

(b) *General license relating to certain measuring, gauging or controlling devices.* 1. A general license is issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business and state or local government agencies to own, receive, acquire, possess, use or transfer under the provisions of subds. 1. to 4., radioactive material, excluding special nuclear 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 issued under this paragraph applies only to radioactive material contained in devices that have been manufactured and labeled under the specifications contained in a specific license issued by the department under s. DHS 157.13 (4) (d) or under the specifications contained in a specific license issued by the NRC, an agreement state or a licensing state, which authorizes distribution of devices to persons generally licensed by the NRC, an agreement state or a licensing state.

Note: Regulations under the Federal Food, Drug and Cosmetic Act authorizing the use of radioactive control devices in food production required certain additional labeling thereon which is found in 21 CFR 179.21.

3. A person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device under the general license under this paragraph shall do all the following:

a. 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 on the device and shall comply with all instructions and precautions provided by such labels.

b. 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 6-month intervals or at such other intervals as are specified in the label, except for devices

containing only tritium, not more than 3.7 MBq (100 microcuries) of other beta and gamma-emitting material, or 0.37 MBq (10 microcuries) of alpha-emitting material, and devices held in storage in the original shipping container prior to the initial installation. Devices containing only krypton need not be tested for leakage of radioactive material.

c. Ensure that the tests required by subd. 3. b. and other testing, installation, servicing and removal from installation involving the radioactive material, its shielding or containment, are performed under the instructions provided by the labels, or by a person holding an applicable specific license from the department, the NRC, an agreement state or a licensing state to perform such activities.

d. Maintain records showing compliance with the requirements of subd. 3. b. and c. The records shall show the results of tests. The records shall also show the dates of performance of tests, and the names of persons performing, testing, installation, servicing and removal from installation of the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by subd. 3. b. shall be maintained for 3 years or until the sealed source is transferred or disposed of. Records of tests of the "on-off" mechanism and indicator required by subd. 3. b. shall be maintained for 3 years or until the sealed source is transferred or disposed of. Records that are required by subd. 3. c. shall be maintained for a period of 3 years from the date of the recorded event or until the device is transferred or disposed of.

e. Upon the occurrence of 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 185 Bq (0.005 microcurie) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the department, the NRC, an agreement state or a licensing state to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device. The licensee shall file a written report containing a brief description with the department within 30 days of the event.

f. Not abandon the device containing radioactive material.

g. Except as provided in subd. 3. h. and j., transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the department, the NRC, an agreement state or a licensing state whose specific license authorizes that person to receive the device and within 30 calendar days after transfer of a device to a specific licensee or export of the device shall furnish to the department a written report containing identification of the device by manufacturer's or initial ~~transferer's~~ transferor's name, model and serial number, the name, address and license number of the person receiving the device, and the date of the transfer.

h. Transfer the device to another general licensee only where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee, or where the device remains in use at a particular location. In the latter case, the transferor shall give the transferee a copy of sub. (2) (b) and any safety documents identified in the label on the device and within 30 calendar days of the transfer. The licensee shall report to the department the manufacturer's name, model and serial number of device transferred, the name and address of the transferee, and the name, phone number and position of an individual who may constitute a point of contact between the department and the transferee.

i. Comply with the provisions of s. DHS 157.32 (1) and (2) for reporting radiation incidents, theft or loss of licensed material, but is exempt from the other requirements of subchs. III and X.

j. Not export the device containing byproduct material except as allowed under 10 CFR Part 110.

k. Respond to written requests from the department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within the same time period, request in writing a longer time period and provide written justification why it cannot comply.

L. Appoint an individual responsible for having knowledge of the appropriate requirements of this chapter and the authority for taking required actions to comply with these requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with the appropriate requirements of this chapter. This appointment does not relieve the general licensee of any of its responsibility under this chapter.

m. May not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter shall be locked in the closed position. The testing required under subd. 3. b. need not be performed during the period of storage only. When devices are put back into service or transferred to another person, and have not been tested within the required time interval, they shall 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 under this paragraph does not authorize the manufacture or import of devices containing radioactive material.

5. The general license under this paragraph is exempt from the requirements of subchs. III and X, with the exception of ss. DHS 157.30 (1), 157.32 (1) and (2).

(c) *General license relating to luminous safety devices for aircraft.* A general license is issued to own, receive, acquire, possess and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided that each device contains not more than 370 GBq (10 curies) of tritium or 11.1 GBq (300 millicuries) of promethium-147, and that each device has been manufactured, assembled or imported under a specific license issued by the NRC, or manufactured or assembled under the specifications contained in a specific license issued by the department or any agreement state to the manufacturer or assembler of such device under licensing requirements equivalent to those in 10 CFR 32.53.

1. A person who owns, receives, acquires, possesses or uses luminous safety devices under the general license under this paragraph is exempt from the requirements of subchs. III and X except that they shall comply with the provisions of s. DHS 157.32 (1) and (2).

2. The general license under this paragraph does not authorize the manufacture, assembly or repair of luminous safety devices containing tritium or promethium-147.

3. The general license under this paragraph does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

4. The general license under this paragraph is exempt from the requirements of subchs. III and X, with the exception of ss. DHS 157.30 (1), 157.32 (1) and (2).

(d) *General license relating to ownership of radioactive material.* A general license is issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this section, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

Note: A person may own radioactive material without the material being in their immediate possession. This general license does not allow the person to manufacture, produce devices containing material, transfer, receive, possess or use the material. A specific license is required for these activities.

(e) *General license relating to calibration and reference sources.* A general license is issued to own, receive, acquire, possess, use and transfer americium-241, plutonium or radium-226 in the form of calibration or reference sources, under the provisions of subds. 1. to 5., to any person who holds a specific license issued by the department or the NRC which authorizes the person to receive, possess, use and transfer radioactive material.

Note: For Americium-241 and plutonium, a specific license issued by the NRC is also required for any person to receive, possess or use and transfer special nuclear material.

1. The general license under this paragraph applies only to calibration or reference sources that have been manufactured under the specifications contained in a specific license issued to the manufacturer or importer of the sources by the NRC under 10 CFR 32.57 or 10 CFR 70.39 or that have been manufactured under the specifications contained in a specific license issued to the manufacturer by the department, an agreement state or licensing state under licensing requirements equivalent to those contained in 10 CFR 32.57 or 10 CFR 70.39.

2. The general license under this paragraph is subject to the requirements of subchs. III and X.

3. A person who owns, receives, acquires, possesses, uses or transfers one or more calibration or reference sources under the general licenses provided under this paragraph may not receive, possess, use or transfer the 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:

a. The receipt, possession, use and transfer of this source, Model ____, Serial No. _____, is subject to a general license and the regulations of the NRC or of a state with which the NRC 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) DO NOT TOUCH RADIOACTIVE
PORTION OF THIS SOURCE.

_____
Name of manufacturer or importer

Note: The label is to show only the name of the appropriate material.

b. The receipt, possession, use and transfer of this source, Model _____, Serial No. ____, is 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

4. A person who owns, receives, acquires, possesses, uses or transfers one or more calibration sources under the general license under this paragraph shall do all the following:

a. Not transfer, abandon or dispose of the source except by transfer to a person authorized by a license from the department, the NRC, an agreement state or a licensing state to receive the source.

b. Store the source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium or radium-226 that might otherwise escape during storage.

c. Not use the source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

d. Not possess at any one time, at any one location of storage or use, more than 185 kBq (5 microcuries) of americium-241, plutonium or radium-226.

5. The general license under this paragraph does not authorize the manufacture of calibration or reference sources containing americium-241, plutonium or radium-226.

(f) *General license for use of radioactive material for certain in vitro clinical or laboratory testing.* 1. A general license is issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, under the provisions of subds. 2. to 6., the following radioactive materials in prepackaged units for use as in

vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

a. Carbon-14, in units not exceeding 370 kBq (10 microcuries) each.

b. Cobalt-57, in units not exceeding 370 kBq (10 microcuries) each.

c. Hydrogen-3, in units not exceeding 1.85 MBq (50 microcuries) each.

d. Iodine-125, in units not exceeding 370 kBq (10 microcuries) each.

e. Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 185 Bq (0.005 microcurie) of americium-241 each.

f. Iodine-131, in units not exceeding 370 kBq (10 microcuries) each.

g. Iron-59, in units not exceeding 740 kBq (20 microcuries) each.

h. Selenium-75, in units not exceeding 370 kBq (10 microcuries) each.

Note: 21 USC 301 also governs the availability and use of any specific diagnostic drugs in interstate commerce.

2. No person may receive, acquire, possess, use or transfer radioactive material under the general license established under this paragraph until the person has filed a "Certificate — In Vitro Testing with Radioactive Material Under General License" form with the department and received from the department a validated copy of the form with certification number assigned. A physician, veterinarian, clinical laboratory or hospital shall furnish on the "Certificate — In Vitro Testing with Radioactive Material Under General License" all the following information and such other information as may be required by that form:

a. Name and address of the physician, veterinarian, clinical laboratory or hospital.

b. The location of use.

c. 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 by the general license under this paragraph and that the tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

Note: The "Certificate — In Vitro Testing with Radioactive Material Under General License" form may be obtained by writing the Department at: Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701-2659; or by downloading from the Department website at: http://dhs.wisconsin.gov/radiation/radioactivematerials/index.htm.

3. A person who receives, acquires, possesses or uses radioactive material under the general license under this paragraph shall comply with all the following:

a. The general licensee may not possess at any one time, under the general license under this paragraph, at any one location for storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, or cobalt-57 in excess of 7.4 MBq (200 microcuries).

b. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

c. The general licensee shall use the radioactive material only for the uses authorized by subd. 1.

d. The general licensee may not transfer the radioactive material to a person who is not authorized to receive it under a license issued by the department, the NRC, any agreement state or a licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

e. The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in subd. 1. e. as required by s. DHS 157.30 (1).

4. The general licensee may not receive, acquire, possess, or use radioactive material under subd. 1. except in prepackaged units which are labeled under the provisions of an applicable specific license issued under s. DHS 157.13 (4) (g) or under the provisions of a specific license issued by the NRC, any agreement state or a licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3, iron-59, selenium-75, cobalt-57 or Mock Iodine-125 to persons generally licensed under subd. 1. or its equivalent and one of the following statements or a substantially similar statement that 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:

a. 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 NRC or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

_____

Name of manufacturer

b. 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 under this paragraph shall report in writing to the department any changes in the information furnished by that person in the

"Certificate — In Vitro Testing with Radioactive Material Under General License". The report shall be furnished to the department within 30 days after the effective date of such change.

6. Any person using radioactive material under the general license under this paragraph is exempt from the requirements of subchs. III and X with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in subd. 1. e. shall comply with the provisions of ss. DHS 157.30 (1) and 157.32 (1) and (2).

(g) *General license relating to ice detection devices.* A general license is issued to own, receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 1.85 MBq (50 microcuries) of strontium-90 and each device has been manufactured or imported under a specific license issued by the NRC or each device has been manufactured under the specifications contained in a specific license issued by the department or an agreement state to the manufacturer of the device under licensing requirements equivalent to those in 10 CFR 32.61.

1. A person who owns, receives, acquires, possesses, uses or transfers strontium-90 contained in ice detection devices under the general license under this paragraph shall do all the following:

a. 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 NRC or an agreement state to manufacture or service the devices; or shall dispose of the device under the provisions of s. DHS 157.30 (1).

b. Assure that all labels affixed to the device at the time of receipt and which bear a statement that prohibits removal of the labels, are maintained on the device.

2. A person who owns, receives, acquires, possesses, uses or transfers strontium-90 contained in ice detection devices under the general license under this paragraph are exempt from the requirements of subchs. III and X except that the person shall comply with the provisions of ss. DHS 157.30 (1) and 157.32 (1) and (2).

3. The general license in this paragraph does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

4. The general license in this paragraph is exempt from the requirements of subchs. III and X with the exception of ss. DHS 157.30 (1), 157.32 (1) and (2).

(h) *General license relating to certain items and self-luminous products containing radium-226.* 1. A general license is issued to own, receive, acquire, possess, use or transfer radium-226 contained in the following products:

a. Antiquities originally intended for use by the general public that were manufactured in the 19th and 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts and healing pads.

b. Intact timepieces containing greater than 37 kBq (1 microcurie) of radium-226, nonintact timepieces, and timepiece dials and hands no longer installed in timepieces.

c. Self-luminous items installed in air, marine or land vehicles.

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

e. Small radium sources, such as discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations, electron tubes, lightning rods, ionization sources or static eliminators, containing no more than 37 kBq (1 microcurie) of radium-226.

2. The general license in this paragraph is exempt from the requirements of subchs. III and X with the exception of ss. DHS 157.30 (1) and 157.32 (1) and (2). This exemption does not apply to any person specifically licensed under this chapter.

3. A person who owns, receives, acquires, possesses, uses or transfers radium-226 under the general license in subd. 1. shall do all of the following:

a. Report to the department under s. DHS 157.32 any stolen, lost or missing radioactive material.

b. Not abandon the product containing radium-226. The product, and any radioactive material from the product, shall be disposed of according to the requirements of s. DHS 157.30 (8), by transfer to a person authorized under a specific license to receive the radium-226, or as approved by the department.

c. Not export products containing radium-226 except under 10 CFR 110.

d. Respond to written requests from the department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within the same time period, request in writing a longer time period and provide written justification why it cannot comply.

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

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter; corrections in (1) (c) 3. c. and (2) (g) 1. a. made under s. 13.93 (2m) (b) 7., Stats., Register July 2002 No. 559; CR 06-021: am. (2) (b) 5., (c) 4., (e) 2., (f) 3. e. and 6., (g) 1. a., 2. and 4. Register October 2006 No. 610, eff. 11-1-06; CR 09-062: am. (2) (b) 3. b., c., g., h. and 4., cr. (2) (b) 3. j. to m. and (h) Register April 2010 No. 652, eff. 5-1-10; **CR 16-078: r. and recr. (1) (a), am. (2) (a) Register January 2018 No. 745, eff. 2-1-18; correction in (1) (a) 4., 6., 7. made under s. 35.17, Stats., Register January 2018 No. 745, eff. 2-1-18.**

DHS 157.12 **Registration of generally licensed devices. (1)** REGISTRATION REQUIREMENT. (a) No person may possess, receive, use, own or transfer a device purchased under a general license that contains at least 370 MBq (10 millicuries) of cesium-137, 3.7 MBq (0.1 millicurie) of strontium-90, 37 MBq (1 millicurie) of cobalt-60, 3.7 MBq (0.1 millicurie) of radium-226 or 37 MBq (1 millicurie) of americium- 241 or any other transuranic unless that person registers annually with the department and

pays a fee as prescribed in sub. (6). Each address for a location of use as described in sub. (3) (d) represents a separate general licensee and requires a separate registration.

(b) A person in possession of devices that meet the criteria for registration under par. (a) shall notify the department of bankruptcy as specified in s. DHS 157.13 (10) (e) and (f).

(2) EXEMPTIONS. A person who possesses, receives, uses, owns or transfers a device purchased under a general license that is included under a new or existing specific license or that contains isotopes different from those listed in sub. (1) is exempt from the requirements of this section.

(3) INFORMATION REQUIREMENTS. A general licensee shall furnish the following information and any other information specifically requested by the department:

(a) Name and mailing address of the general licensee.

(b) Information about each device: the manufacturer, model number, serial number, radioisotope and activity as indicated on the label.

(c) Name and telephone number of the individual designated by management as a representative of the general licensee.

(d) Address at which the device is used or stored. For a portable device, the address of the primary place of storage.

(e) Certification by signature from the individual representing the general licensee that the information concerning the device or devices has been verified through a physical inventory and check of label information.

(f) Certification by signature from the individual designated by management to represent the general licensee that the individual is aware of the requirements of the general license.

(4) CHANGE OF ADDRESS. A general licensee shall report, in writing, an address change to the department within 30 calendar days after moving the devices. In the case of portable devices, a general licensee shall report the device's primary storage location.

(6) FEES. (a) A general licensee shall pay an annual registration fee of $100 per site and $50 per device specified in sub. (1). The department may not assess an additional fee for recording changes in registration information.

(b) The annual registration fee for the next year shall be paid by December 31 of the prior year of registration. The department shall issue a notice of registration following receipt of the registration fee. If the annual registration fee for the next year is not received by the department by December 31 of the prior year of registration, a licensee shall pay a penalty fee of $25, in addition to the registration fee and regardless of the number of devices, before the department will issue a new notice of registration.

(7) INSPECTION BY MAIL. (a) A general licensee shall complete an inspection by mail form, provided by the department with each annual registration renewal, and return it to the department by December 31 of that year. The form shall include information deemed necessary by the department.

(b) No additional fee may be required for this form.

(c) A general licensee who fails to complete this form may be subject to a site inspection.

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter; CR 06-021: am. (3) (intro.), r. (5) Register October 2006 No. 610, eff. 11-1-06; CR 09-062: renum. (1) to be (1) (a) and am., cr. (1) (b) Register April 2010 No. 652, eff. 5-1-10.

DHS 157.13 **Specific licenses. (1)** FILING APPLICATION FOR SPECIFIC LICENSES. (a) An application for a specific license shall be filed on a form prescribed by the department.

Note: A specific license application form may be obtained by writing the Department, including a description of the proposed activity to be licensed. The Department's address is: Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701-2659; or by downloading from the Department's website at: http://dhs.wisconsin.gov/radiation/radioactivematerials/index.htm.

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

(c) The applicant, licensee or a person authorized to act on behalf of the applicant or licensee shall sign the application.

(d) A license application may include a request for a license authorizing one or more activities.

(e) In the application, the applicant may incorporate by reference information contained in previous applications, statements or reports filed with the department provided such references are clear and specific.

(f) The department shall make applications and documents submitted to the department available for public inspection under ss. 19.32 to 19.39, Stats.

(g) Each application to possess radioactive material in unsealed form, on a foil or plated source, or sealed in glass in excess of the quantities in ch. DHS 157 Appendix P, "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release", shall contain one of the following:

1. An evaluation showing that the projected dose to a person offsite due to a release of radioactive material would not exceed 0.01 Sievert (1 rem) total effective dose equivalent or 0.05 Sievert (5 rem) to the thyroid.

2. An emergency plan, reviewed and commented on by offsite response organizations expected to respond in the event of an accident, that contains the information described in ch. DHS 157 Appendix Q for responding to any event in which radioactive material could be released from the site.

(h) Each application to use radioactive material in the form of a sealed source or in a device that contains a sealed source shall contain one of the following:

1. Information that identifies the source or device by manufacturer and model number as registered with the NRC under 10 CFR 32.210 or an agreement state, or for a source or device containing radium-226 or accelerator-produced radioactive material,

information that identifies the source or device by manufacturer and model number as registered with a state under provisions comparable to 10 CFR 32.210.

2. The information identified in 10 CFR 32.210(c).

3. For sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007 that are not registered with the NRC under 10 CFR 32.210 or with an agreement state, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210 (c), the applicant shall provide all available categories of information identified in 10 CFR 32.210 (c) concerning the source, and, if applicable, the device. For any unavailable categories of information specified in 10 CFR 32.210 (c), the applicant shall provide 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 shall 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 recent leak test.

4. 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.

5. 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.

(i) Each application for a specific license, other than a renewal, shall contain information describing how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning and minimize, to the extent practicable, the generation of radioactive waste. Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in s. DHS 157.21 and the radiological criteria for license termination in s. DHS 157.33.

(j) Each application to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in a consortium authorized for medical use under subch. VI or equivalent NRC or agreement state requirements shall include all the following:

1. A request for authorization for the production of PET radionuclides or evidence of an existing license issued by the department, NRC or an agreement state under this chapter or equivalent regulations for a PET radionuclide 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 sub. (4) (i).

3. Identification of any individual 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 s. DHS 157.68.

4. Information identified in sub. (4) (i) 3. on the PET drugs to be noncommercially transferred to members of a consortium.

(2) GENERAL REQUIREMENTS FOR THE ISSUANCE OF SPECIFIC LICENSES. The department shall approve a license application within 180 working days of filing of a complete application if the department determines that all the following apply:

(a) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested under the requirements of this chapter in a manner that minimizes 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) 1. 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 department determines will significantly affect the quality of the environment, the department, 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.

2. Commencement of construction prior to the department's conclusion in subd. 1. 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 pre-construction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

(d) The applicant satisfies any applicable requirements in subs. (3), (4) and (6), s. DHS 157.15 and subchs. IV, V and VI.

(e) The applicant pays all applicable fees as specified in s. DHS 157.10.

(f) In the case of an application for a license to possess and use an x-ray fluorescence analyzer (XRF) for the detection of lead in paint or portable gauges using sealed sources, the applicant shall verify that the operator training requirements of ch. DHS 157 Appendix S are met prior to the operator using the device.

(3) SPECIAL REQUIREMENTS FOR SPECIFIC LICENSES OF BROAD SCOPE. (a) This subsection prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of the licenses.

(b) The different types of broad scope licenses are as follows:

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, but may be limited based on types of radioactive materials, proposed use and the training and experience of users.

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 ch. DHS 157 Appendix C, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed under the license, is the quantity specified for that radionuclide in ch. DHS 157 Appendix C, Column I. If 2 or more radionuclides are possessed under the license, 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 ch. DHS 157 Appendix C, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license may 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 ch. DHS 157 Appendix C, 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 ch. DHS 157 Appendix C, Column II. If 2 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 ch. DHS 157 Appendix C, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license may not exceed unity.

(c) The department shall approve an application for a Type A specific license of broad scope if all the following occurs:

1. The applicant satisfies the general requirements specified in sub. (2).

2. The applicant has engaged in a reasonable number of activities involving the use of radioactive material.

3. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control, accounting and management review that are necessary to assure safe operations, including all of the following:

a. 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.

b. 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.

c. The establishment of appropriate administrative procedures to assure 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 prior to use of the radioactive material.

(d) The department shall approve an application for a Type B specific license of broad scope if all the following occurs:

1. The applicant satisfies the general requirements specified in sub. (2).

2. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control, accounting and management review that are necessary to assure safe operations, including all the following:

a. 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.

b. The establishment of appropriate administrative procedures to assure 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 prior to use of the radioactive material.

(e) The department shall approve an application for a Type C specific license of broad scope if all the following occurs:

1. The applicant satisfies the general requirements specified in sub. (2).

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

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

b. 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, accounting and management review necessary to assure safe operations.

(f) A specific license of broad scope is subject to all of the following conditions:

1. Unless specifically authorized, a person licensed under sub. (3) may not do any of the following:

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

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

c. Conduct activities for which a specific license issued by the department under sub. (4) or subch. VI is required.

d. 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. A Type A specific license of broad scope issued under this section 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. A Type B specific license of broad scope issued under this section 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. A Type C specific license of broad scope issued under this section 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 par. (e).

(4) 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 sub. (2), a specific license authorizing the introduction of radioactive material, excluding byproduct material, into a product or material owned by or in the possession of the licensee or another to be transferred to a person exempt under s. DHS 157.09 (2) (a) shall be issued only under all the following conditions:

a. 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 assure 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.

b. The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in ch. DHS 157 Appendix A, that reconcentration of the radioactive material in concentrations exceeding those in ch. DHS 157 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. A person licensed under this paragraph shall file an annual report with the department 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 under par. (a) during the reporting period, the report shall so indicate. The report shall cover the previous 12-month period ending June 30 and shall be filed within 30 days thereafter.

Note: Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the Nuclear Regulatory Commission, Washington, D.C. 20555.

(b) *Licensing the commercial distribution of radioactive material in exempt quantities.* 1. The department shall approve an application for a specific license to distribute NARMs to persons exempted from this chapter under s. DHS 157.09 (2) (b) only under all the following conditions:

a. The radioactive material is not contained in any food, beverage, cosmetic, drug or other commodity designed for ingestion, inhalation by or application to a human being.

b. The radioactive material is in the form of processed chemical elements, compounds or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.

c. The applicant submits copies of prototype labels and brochures and the department approves such labels and brochures.

d. Out of state manufacturers of the product hold a license issued by a licensing or agreement state.

2. The license issued under this paragraph is subject to all the following conditions:

a. No more than 10 exempt quantities may be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions do not exceed unity.

b. Each exempt quantity shall be separately and individually packaged. No more than 10 packaged exempt quantities may be contained in any outer package for transfer to persons exempt under s. DHS 157.09 (2) (b). The outer package shall be such that the dose rate at the external surface of the package does not exceed 5 μSv (0.5 millirem) per hour.

c. The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label that identifies the radionuclide and the quantity of radioactivity and bears the words "Radioactive Material".

d. In addition to the labeling information required by this subd. 2. c., the label affixed to the immediate container or an accompanying brochure shall state that the contents are exempt from licensing or agreement state requirements; the words "Radioactive Material — Not for Human Use — Introduction into Foods, Beverages, Cosmetics, Drugs or Medicinals or into Products Manufactured for Commercial Distribution is Prohibited — Exempt Quantities Should Not Be Combined"; and

appropriate additional radiation safety precautions and instructions relating to the handling, use, storage and disposal of the radioactive material.

3. A person licensed under this paragraph shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under s. DHS 157.09 (2) (b) or the equivalent regulations of a licensing or agreement state and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the department. Each report shall cover the year ending June 30 and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made under this paragraph during the reporting period, the report shall so indicate.

(c) *Licensing the incorporation of NARM into gas and aerosol detectors.* The department shall approve an application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under s. DHS 157.09 (2) (e) if the application satisfies requirements equivalent to those contained in 10 CFR 32.26. The maximum quantity of radium-226 in each device may not exceed 3.7 kBq (0.1 microcurie).

(d) *Licensing the manufacture and initial distribution of devices to persons generally licensed under s. DHS 157.11 (2) (b).* 1. The department shall approve an application for a specific license to manufacture or initially distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under s. DHS 157.11 (2) (b) or equivalent regulations of the NRC, another agreement state or a licensing state only under all the following conditions:

a. The applicant satisfies the general requirements of sub. (2).

b. 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 may be safely operated by persons not having training in radiological protection.

c. The applicant submits sufficient information, as specified in subd. 1. b., to provide reasonable assurance that 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% of the annual limits specified in s. DHS 157.22 (1) (a).

d. The applicant submits sufficient information, as specified in subd. 1. b., to provide reasonable assurance that 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 150 mSv (15 rems)

Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter .....2000 mSv (200 rems)

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

e. Each device bears a durable, legible, clearly visible label or labels approved by the department, which contain in a clearly identified and separate statement, the following information: instructions and precautions necessary to assure safe installation, operation and servicing of the device; and 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.

Note: Documents such as operating and service manuals may be identified in the label and used to provide instructions and precautions necessary to assure safe installation, operation and servicing of the device.

f. 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 DHS 157.29 (1); and the name of the manufacturer or initial distributor.

g. Each device meeting the criteria of s. DHS 157.11 (2) (b), 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 s. DHS 157.29 (1).

h. Each device has been registered in the sealed source and device registry.

2. Unless the model, serial number and name of the manufacturer or distributor is specified elsewhere in labelling affixed to the device, the label or labels identified in subd. 1. e. shall also contain one of the following statements, as appropriate, in the same or substantially similar form:

a. The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the NRC or a state with which the NRC 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 distributor

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

CAUTION — RADIOACTIVE MATERIAL

_____

Name of manufacturer or initial distributor

3. If the applicant desires that the device be required to be tested at intervals longer than 6 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 that 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 applicant shall submit all of the following information:

a. Primary containment of the source capsule.

b. Protection of primary containment.

c. Method of sealing containment.

d. Containment construction materials.

e. Form of contained radioactive material.

f. Maximum temperature withstood during prototype tests.

g. Maximum pressure withstood during prototype tests.

h. Maximum quantity of contained radioactive material.

i. Radiotoxicity of contained radioactive material.

j. Operating experience with identical devices or similarly designed and constructed devices.

4. If the applicant desires that the general licensee under s. DHS 157.11 (2) (b) or 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 the estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10% of the limits specified in s. DHS 157.22 (1) (a).

5. A person licensed under this paragraph to distribute devices to generally licensed persons shall do all the following:

a. Furnish a copy of the general license contained in ss. DHS 157.11 (2) (b), 157.02, 157.06 (1), 157.13 (18) and 157.32 (1) and (2), notification of the registration requirement contained in s. DHS 157.12 (1), a list of the services that can only be performed by a specific licensee, information on disposal options including estimated costs of disposal and the penalties for improper disposal under s. DHS 157.90 to each person to whom he or she directly or through an intermediate person transfers radioactive material in a device for use under the general license contained in s. DHS 157.11 (2) (b). Section DHS 157.11 (2) (b) 3. b. to 3. d. may be omitted from a copy of the general license, or notification of the registration requirements of s. DHS 157.12 (1) may be omitted if the requirements do not apply to a particular device.

b. Furnish a copy of the general license contained in the NRC’s, agreement state’s or licensing state’s regulation equivalent to ss. DHS 157.02, 157.06 (1), 157.11 (2) (b), 157.13 (18) and 157.32 (1) and (2), notification of the registration requirement equivalent to s. DHS 157.12 (1), a list of the services that can only be performed by a specific licensee, information on disposal options including estimated costs of disposal, and the name or title, address, and phone number of the contact at the agreement state or NRC from which additional information may be obtained to each person to whom he or she directly or through an intermediate person transfers radioactive material in a device for use under the general license of the NRC, the agreement state or the licensing state prior to the transfer. If a copy of the general license in s. DHS 157.11 (2) (b) is furnished to the person, it shall be accompanied by a note explaining that the use of the device is regulated by the NRC, agreement state or licensing state under requirements substantially the same as those in s. DHS 157.11 (2) (b). Regulations from the NRC, agreement state or licensing state that are equivalent to s. DHS 157.11 (2) (b) 3. b. to 3. d., may be omitted from a copy of the general license if the requirements do not apply to a particular device. Notification of the registration requirement equivalent to s. DHS 157.12 (1) may also be omitted if it does not apply to a particular device.

c. Report to the department all transfers of such devices to persons for use under the general license in s. DHS 157.11 (2) (b). The report shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact and relationship to the intended user. If no transfers have been made to persons generally licensed under s. DHS 157.11 (2) (b) during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter.

d. Report to the NRC all transfers of such devices to persons for use under the NRC general license in 10 CFR 31.5. If no transfers have been made to NRC licensees during the reporting period, the report shall so indicate and be reported to the NRC.

e. For devices shipped to another state, report to the responsible state agency all transfers of devices manufactured and distributed under this paragraph for use under a general license in that state’s regulations equivalent to s. DHS 157.11 (2) (b). If no transfers have been made to general licensees within a particular state during the reporting period, the report shall so indicate and be sent to the responsible state agency upon request of that agency.

f. The reports in subd. 5. d. and e. shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact and relationship to the intended user. If any changes are made to a device, such that the label is changed to update required information, the report shall identify the general licensee, the device, and the changes in information on the device label. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person, cover each calendar quarter and clearly indicate the period covered by the report.

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

h. Retain records showing the name, address, and the point of contact for each general licensee to whom he or she directly or through an intermediate person transfers radioactive material in devices for use under the general license provided in s. DHS 157.11 (2) (b) or equivalent regulations of the NRC, an agreement state or a licensing state. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, compliance with the report requirements of this subdivision and be retained for 5 years from the date of transfer.

i. If a notification of bankruptcy has been made under s. DHS 157.13 (10) or the license is to be terminated, a person licensed under this paragraph shall provide, upon request, to the department and to the appropriate regulatory agency, NRC or other agreement state having jurisdiction at the device's location, records of final disposition required under subd. 5. h.

(e) *Special requirements for the manufacture, assembly or repair of luminous safety devices for use in aircraft.* The department shall approve 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 s. DHS 157.11 (2) (c) if the applicant satisfies the general requirements specified in sub. (2) and the requirements of 10 CFR 32.53 to 32.56, or their equivalent.

(f) *Special requirements for license to manufacture calibration or reference sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under s. DHS 157.11 (2) (e).* The department shall approve an application for a specific license to manufacture calibration or reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under s. DHS 157.11 (2) (e) if the applicant satisfies the general requirement of sub. (2) and the requirements of 10 CFR 32.57 to 32.59 and 10 CFR 70.39 or their equivalent.

(g) *Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license.* The department shall approve an application for a specific license to manufacture or distribute radioactive material for use under the general license of s. DHS 157.11 (2) (f) if all of the following conditions are satisfied:

1. The applicant satisfies the general requirements specified in sub. (2).

2. The radioactive material is to be prepared for distribution in prepackaged units of one of the following:

a. Carbon-14 in units not exceeding 370 kBq (10 microcuries) each.

b. Cobalt-57 in units not exceeding 370 kBq (10 microcuries) each.

c. Hydrogen-3 in units not exceeding 1.85 MBq (50 microcuries) each.

d. Iodine-125 in units not exceeding 370 kBq (10 microcuries) each.

e. Mock Iodine-125 in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 185 Bq (0.005 microcurie) of americium-241 each.

f. Iodine-131 in units not exceeding 370 kBq (10 microcuries) each.

g. Iron-59 in units not exceeding 740 kBq (20 microcuries) each.

h. Selenium-75 in units not exceeding 370 kBq (10 microcuries) each.

3. Each prepackaged unit bears a durable, clearly visible label that does all the following:

a. Identifies the radioactive contents as to chemical form and radionuclide, and indicates that the amount of radioactivity does not exceed 370 kBq (10 microcuries) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 MBq (50 microcuries) of hydrogen-3; 740 kBq (20 microcuries) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 185 Bq (0.005 microcurie) of americium-241 each.

b. Displays the radiation caution symbol described in s. DHS 157.29 (1) (a) 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 that 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:

a. 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 from the material, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority.

_____

Name of manufacturer

b. 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 a licensing state.

_____
Name of manufacturer

5. The label affixed to the unit or the leaflet or brochure that 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 shall also contain directions to the licensee regarding the waste disposal requirements set out in s. DHS 157.30 (1).

(h) *Licensing the manufacture and distribution of ice detection devices.* The department shall approve an application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under s. DHS 157.11 (2) (g) if all the following applies:

1. The applicant satisfies the general requirements of sub. (2) and ch. 450, Stats.

2. The criteria of 10 CFR 32.61 and 32.62 are met.

(i) *Manufacture, preparation, or transfer for commercial distribution or noncommercial transfer to medical use licensees in a consortium of radioactive drugs containing radioactive material for medical use under subchapter VI.* The department shall approve an application for a specific license to manufacture, prepare, or transfer for commercial distribution or noncommercial transfer to medical use licensees in a consortium drugs containing radioactive material for use by a person authorized under subch. VI if all of the following conditions are satisfied:

1. The applicant satisfies the general requirements specified in sub. (2).

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

a. Registered or licensed with the 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).

b. Registered or licensed with a state agency as a drug manufacturer.

c. Licensed as a pharmacy by a state board of pharmacy.

d. Operating as a nuclear pharmacy within a Federal medical institution.

e. Registered with a state agency as a positron emission tomography (PET) drug production facility.

3. The applicant submits all of the following information on the radionuclide:

a. The chemical and physical form of the radiopharmaceutical.

b. The maximum activity per vial, syringe, generator, or other container of the radioactive drug and the shielding provided by the packaging to show medical use licensees that it is safe to handle and store.

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

a. A label is affixed to each transport radiation shield, whether the shield is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution or noncommercial transfer to medical use licensees in a consortium. The label shall 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.

b. A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution or noncommercial transfer to medical use licensees in a consortium. 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 may be correlated with the information on the transport radiation shield label.

5. The applicant submits information to demonstrate that individuals who will prepare the radioactive drugs for medical use meet the requirements of s. DHS 157.68.

6. The applicant shall submit information that he or she will do all of the following:

a. Possess and use instrumentation to measure the radioactivity of the 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 drugs prior to transfer for commercial distribution or noncommercial transfer to medical use licensees in a consortium.

b. 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.

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

d. Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m or strontium-82/rubidium-82 generator, test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, according to s. DHS 157.63 (3), and retain a record of each measurement under s. DHS 157.71 (14). The licensee shall report the results of any test that exceeds the permissible concentration listed in s. DHS 157.63 (3) (a) at the time of generator elution, in accordance with s. DHS 157.72 (4).

7. A licensee shall satisfy the labeling requirements in subd. 4.

8. Nothing in this paragraph relieves a licensee or registrant from complying with applicable FDA, other federal and state requirements governing radioactive drugs.

(j) *Manufacture and distribution of sources or devices containing radioactive material for medical use.* The department shall approve an application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed under subch. VI for use as a calibration, transmission or reference source or for the uses listed in ss. DHS 157.65 (1), 157.66 (1), 157.67 (1) and 157.70 if all of the following conditions are satisfied:

1. The applicant satisfies the general requirements in sub. (2).

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

a. The radioactive material contained, its chemical and physical form and amount.

b. Details of design and construction of the source or device.

c. 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.

d. For devices containing radioactive material, the radiation profile of a prototype device.

e. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests.

f. Procedures and standards for calibrating sources and devices.

g. Legend and methods for labeling the radioactive content of sources and devices.

h. Instructions for handling and storing the source or device from the radiation safety standpoint. The instructions shall 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 that 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 source or device is licensed by the department for distribution to persons licensed under subch. VI and s. DHS 157.62 (4) or under equivalent licenses of the NRC, an agreement state or a licensing state.

4. If the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than 6 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. In determining the acceptable interval for the test for leakage of radioactive material, the applicant shall submit all of the following information:

a. Primary containment of the source capsule.

b. Protection of primary containment.

c. Method of sealing containment.

d. Containment construction materials.

e. Form of contained radioactive material.

f. Maximum temperature withstood during prototype tests.

g. Maximum pressure withstood during prototype tests.

h. Maximum quantity of contained radioactive material.

i. Radiotoxicity of contained radioactive material.

j. Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

5. The source or device has been registered in the sealed source and device registry.

(k) *Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.* 1. The department shall approve an application for a specific license to manufacture industrial products and devices containing depleted uranium for use under s. DHS 157.11 (1) (c) or equivalent regulations of the NRC or an agreement state under the following conditions:

a. The applicant satisfies the general requirements specified in sub. (2).

b. 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 year a radiation dose in excess of 10% of the annual limits specified in s. DHS 157.22 (1).

c. 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 department shall approve an application for a specific license under this paragraph only if the department determines that the product or device combines a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

3. The department may deny any application for a specific license under this paragraph if the end use or uses of the industrial product or device cannot be reasonably foreseen.

4. A person licensed under subd. 1. shall do all of the following:

a. 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.

b. Label or mark each unit to identify the manufacturer or initial transferor of the product or device and the number of the license under which the product or device was manufactured or initially transferred, 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 NRC or an agreement state.

c. Assure 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".

d. Furnish a copy of the general license contained in s. DHS 157.11 (1) (c) and a copy of the “Certificate — Use of Depleted Uranium Under General License" to each person to whom he or she transfers depleted uranium in a product or device; or furnish a copy of the general license contained in the NRC’s or agreement state’s regulation equivalent to s. DHS 157.11 (1) (c) and a copy of the NRC’s or agreement state’s certificate with a note explaining that use of the product or device is regulated by the NRC or an agreement state under requirements substantially the same as those in s. DHS 157.11 (1) (c).

e. Report to the department all transfers of industrial products or devices to persons for use under the general license in s. DHS 157.11 (1) (c). The report shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the department 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 filed with the department 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 s. DHS 157.11 (1) (c) during the reporting period, the report shall so indicate.

f. Report to the NRC all transfers of industrial products or devices to persons for use under the NRC general license in 10 CFR 40.25.

g. Report to the responsible state agency all transfers of devices manufactured and distributed under this paragraph for use under a general license in that state’s regulations equivalent to s. DHS 157.11 (1) (c).

h. The report required in subd. 4. f. and g. shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the department 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 filed with the department within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person.

i. If no transfers have been made to NRC licensees during the reporting period, the report shall so indicate.

j. If no transfers have been made to general licensees within this state or another particular agreement state during the reporting period, this information shall be reported to the department or the responsible agency in another agreement state, upon the request of that agency.

k. Keep records showing the name, address and point of contact for each general licensee to whom he or she transfers depleted uranium in industrial products or devices for use under the general license provided in s. DHS 157.11 (1) (c) or equivalent regulations of the NRC or an agreement state. The records shall be maintained for a period of 3 years from the date of each transfer respectively 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 this section.

(4m) SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO INITIALLY TRANSFER SOURCE MATERIAL TO A PERSON. (a) The department shall approve an application for a specific license to initially transfer source material if all the following conditions are satisfied:

1. The applicant satisfies the general requirements in s. DHS 157.13 (2).

2. The applicant submits adequate information on, and the department approves the methods to be used for quality control, labeling, and providing safety instructions to recipients, based upon adequate information submitted by the applicant.

(b) Each person licensed under par. (a) 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.”

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

(d) Each person licensed under par. (a) shall provide all of the following information to each person to whom source material is transferred for use under s. DHS 157.11 (1), or equivalent regulations of the NRC or another agreement state, before the source material is transferred to the person for the first time in each calendar year:

1. A copy of ss. DHS 157.11 (1) and 157.13 (4m) or relevant equivalent regulations of the NRC or another agreement state.

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

(e) Each person licensed under s. DHS 157.13 (4m) a. shall report transfers as follows:

1. File a report with the department for each general licensee under s. DHS 157.11 (1) or equivalent NRC or another agreement state provisions to whom greater than 50 grams (0.11 lbs) of source material has been transferred in a single calendar quarter. The report shall include the following information:

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

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

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

2. For material shipped to another state, file a report with each applicable responsible state agency or the NRC that identifies all persons, operating under provisions equivalent to s. DHS 157.11 (1), to whom greater than 50 grams (0.11 lbs) 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 applicable responsible state agency, or NRC, being reported to:

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

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

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

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 s. DHS 157.11 (1) or equivalent NRC or another agreement state provision during the current period, a report shall be submitted to the department and applicable responsible state agency or the NRC. If no transfers have been made to general licensees in a particular state during the reporting period, this information shall be reported to the responsible state agency or the NRC upon request.

(f) Each person licensed under par. (a) shall maintain all information that supports the reports required by this subsection concerning each transfer to a general licensee for a period of one year after the event is included in a report.

(5) SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE FOR MEDICAL USE OF RADIOACTIVE MATERIAL. (a) *License application.* The department shall approve an application for a specific license for medical use of radioactive material if all of the following conditions are satisfied:

1. The applicant satisfies the general requirements specified in sub. (2).

2. The applicant submits procedures required by s. DHS 157.67, as applicable.

3. In addition to the requirements in this paragraph and par. (b), an application for a license or amendment for medical use of radioactive material as described in s. DHS 157.70 shall also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in ss. DHS 157.59 to 157.62, identification of and commitment to follow the applicable radiation safety program requirements in ss. DHS 157.63 (1) to 157.67 (1) that are appropriate for the specific s. DHS 157.70 medical use, as well as any specific information on each of the following:~~In addition to the requirements in this paragraph and par. (b), an application for a license or amendment for medical use of radioactive material as described in s. DHS 157.70 shall also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in ss. DHS 157.59 to 157.62, as well as any specific information on each of the following:~~

a. Radiation safety precautions and instructions.

b. Training and experience of proposed users.

c. Methodology for measurement of dosages or doses to be administered to patients or human research subjects.

d. Calibration, maintenance and repair of instruments and equipment necessary for radiation safety.

4. An applicant for a license for mobile services shall assure that release of individuals or human research subjects to whom radioactive drugs or implants containing radioactive material are administered will be released under s. DHS 157.62 (8).

5. The applicant or licensee shall provide any other information requested by the department in its review of the application.

(b) *License amendment.* An application for a license amendment shall meet all of the following requirements:

1. A licensee shall apply for and must receive a license amendment before the licensee does any of the following:

a. Receives or uses radioactive material for a type of use that is permitted under this subchapter, but that is not authorized on the licensee's current license issued under this subchapter.

b. Permits anyone to work as an authorized user, authorized nuclear pharmacist, ophthalmic physicist, or authorized medical physicist under the license, except an individual who is certified by a specialty board appropriate to the intended use of radioactive material and recognized by the NRC; or is named as an authorized user, authorized nuclear pharmacist, ophthalmic physicist, or authorized medical physicist on a department, NRC or other agreement state license, or on a permit issued by a licensee who is authorized by a Type A license of broad scope to permit the medical use of radioactive material.~~Permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except an individual who is certified by a specialty board appropriate to the intended use of radioactive material and recognized by the NRC; or is named as an authorized user, authorized nuclear pharmacist or authorized medical physicist on a department, NRC or other agreement state license, or on a permit issued by a licensee who is authorized by a Type A license of broad scope to permit the medical use of radioactive material.~~

c. Changes radiation safety officers, except as provided in s. DHS 157.61 (1) (c).

d. Permits anyone to work as an associate radiation safety officer, or before the radiation safety officer assigns duties and tasks to an associate radiation safety officer that differ from those for which the associate radiation safety officer is authorized on the

license.~~Permits anyone to work as an associate radiation safety officer, or before the radiation safety officer assigns duties and tasks to an associate radiation safety officer that differ from those for which this individual is authorized on the license.~~

~~d~~c. Receives radioactive material in excess of the amount or in a different form or receives a different radionuclide than is authorized on the license

~~e~~f. Adds to or changes the areas identified in the application or on the license, except for areas where radioactive material is used only under ss. DHS 157.63 (1) and (2).

~~f~~g. Changes the address~~(es)~~ of use identified on the application or on the license.~~Changes the address or addresses of use identified in the application or on the license.~~

h. Revises procedures required by ss. DHS 157.67 (4) and (10) to (12), as applicable, where such revision reduces radiation safety.

i. Receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

2. An application for a license amendment shall include procedures required by s. DHS 157.67, as applicable.

(c) *Notifications.* A licensee shall make all of the following notifications:

1. Provide to the department a copy of the board certification ~~and the written attestation, signed by a preceptor~~, the NRC or agreement state license, ~~or~~ or other equivalent permit or license for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, an ophthalmic physicist, or an authorized medical physicist under par. (b) 1. b. For individuals permitted to work under par. (b) 1. b., within the same 30 day time frame, the licensee shall also provide, as appropriate, verification of completion of all the following:~~Provide to the department a copy of the board certification and the written attestation, signed by a preceptor, the NRC or agreement state license or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under par. (b) 1. b. For individuals permitted to work under par. (b) 1. b., within the same 30 day time frame, the licensee shall also provide, as appropriate, verification of completion of all the following:~~

a. Any additional case experience required in s. DHS 157.64 (4) (b) 2. g. for an authorized user under s. DHS 157.64 (1).

b. Training in device operation, safety procedures, and clinical use for the type of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type of use for which the individual is seeking authorization as an authorized user under s. DHS 157.67 (1).

c. Training for the type of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type of use for which the individual is seeking authorization as an authorized medical physicist.

2. Notify the department in writing no later than 30 days after any of the following occurs:

a. An authorized user, an authorized nuclear pharmacist, a radiation safety officer, an associate radiation safety officer, an authorized medical physicist, or an ophthalmic physicist permanently discontinues performance of duties under the license or has a name change.~~An authorized user, an authorized nuclear pharmacist, a radiation safety officer or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change.~~

b. The licensee's mailing address changes.

c. The licensee's name changes but the name change does not constitute a transfer of control of the license.

d. The licensee has added to or changed the areas where radioactive material is used under ss. DHS 157.63 (1) or (2) if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from a PET radionuclide/PET radioactive drug production area.~~The licensee has added to or changed the areas where radioactive material is used under s. DHS 157.63 (1) and (2).~~

e. The licensee permits an individual qualified to be a radiation safety officer under ss. DHS 157.61 (7) and (11) to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with s. DHS 157.61 (1) (c).

f. The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in par. (b) 1. i. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

(d) *Exemptions for Type A broad scope licensees.* ~~1.~~ A licensee possessing a Type A specific license of broad scope for medical use is exempt from all of the following requirements:

~~a~~1. The provisions of par. (a) 3. regarding the need to file an amendment to the license for medical uses of radioactive material as described in s. DHS 157.70.

~~b~~2. The provisions of par. (b) 1. b.

~~c~~3. The provisions of par. (b) 1. f. regarding additions to or changes in the areas of use only at the addresses identified in the application or on the license.~~The provisions of par. (b) 1. e. regarding additions to or changes in the areas of use only at the addresses specified in the license.~~

~~d~~4. The provisions of par. (c) 1.

~~e~~5. The provisions of par. (c) 2. a. for an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, or an ophthalmic physicist.~~The provisions of par. (c) 2. a. for an authorized user, an authorized nuclear pharmacist or an authorized medical physicist.~~

~~f~~6. The provisions of s. DHS 157.61 (6) (a).

(6) SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO CONDUCT INDUSTRIAL RADIOGRAPHY OPERATIONS. The department shall approve an application for a specific license to conduct radiography using radioactive materials if all the following conditions are satisfied:

(a) The applicant satisfies the general requirements specified in sub. (2).

(b) The applicant has an adequate program for training radiographers and radiographer's assistants that meets the requirements of s. DHS 157.44 (3).

(c) 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.

(d) The applicant submits written operating and emergency procedures that meet the requirements of s. DHS 157.44 (4).

(e) 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 6 months that meets the requirements of s. DHS 157.44 (3) (e).

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

(g) The applicant submits the qualifications of the individual designated as the radiation safety officer.

(h) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium shielding, the applicant shall describe the procedures for performing the test. The description shall include all of the following:

1. Methods of collecting the samples.
2. Qualifications of the individual who analyzes the samples.
3. Instruments to be used.
4. Methods of analyzing the samples.

(i) The applicant verifies that calibration of survey meters and alarming rate meters is performed according to the requirements of ss. DHS 157.38 and 157.44 (6) (g) 4., respectively.

(j) The applicant identifies and describes the location or locations of all field stations and permanent radiographic installations.

(k) The applicant identifies the location or locations where all records required by this and other subchapters will be maintained.

(L) If a license application includes underwater radiography, a description of all of the following:

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.
3. Methods for gas-tight encapsulation of equipment.

(m) If an application includes offshore platform or lay-barge radiography, a description of all of the following:

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

(n) The applicant describes the program for inspection and maintenance of radiographic exposure devices and storage containers to ensure proper functioning of components important to safety.

(7) SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO CONDUCT IRRADIATOR OPERATIONS. (a) The department shall approve an application for a specific license for the use of radioactive material in an irradiator if all the following conditions are satisfied:

1. The applicant satisfies the general requirements in sub. (2).
2. The applicant submits an adequate program for training irradiator operators that includes all of the following:

a. Classroom training.

b. On-the-job or simulator training.

c. Safety reviews.

d. The method employed by the applicant to test each operator's understanding of the department's regulations and licensing requirements and the irradiator operating, safety and emergency procedures.

e. Minimum training and experience of personnel who may provide training.

3. The applicant submits an outline of the written operating and emergency procedures that describes the radiation safety aspects of the procedures.

4. The applicant submits a description of the overall organizational structure for managing the irradiator, including the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have radiation safety responsibilities or authorities, and who within the management structure has the authority to stop unsafe operations. The applicant shall also describe the training and experience required for the position of radiation safety officer.

5. The applicant includes a description of the access control systems required by s. DHS 157.73 (2), radiation monitors required by s. DHS 157.73 (5), the method of detecting leaking sources required by s. DHS 157.73 (16) including the sensitivity of the method and a diagram of the facility showing the locations of all required interlocks and radiation monitors.

6. If the applicant intends to perform leak testing, the applicant shall establish procedures for performing leak testing of dry-source-storage sealed sources and submit a description of these procedures to the department. The description shall include all the following:

a. Methods of collecting the leak test samples.

b. Qualifications of the individual who collects the samples.

c. Instruments to be used.

d. Methods of analyzing the samples.

7. If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading shall only be done by a person specifically authorized by the department, the NRC or another agreement state to load or unload irradiator sources. The information in this subdivision shall also be indicated on the application.

8. The applicant describes the inspection and maintenance checks, including the frequency of the checks required by s. DHS 157.73 (17).

(b) A license issued under par. (a) is subject to all of the following conditions:

1. The applicant may not begin construction of a new irradiator prior to the submission to the department of both an application for a specific license for the irradiator and the fee required by s. DHS 157.10 (3). As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site, but does not include engineering and other design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license by the department.

2. Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this subsection. The department shall approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates the likely provision of an adequate level of safety for workers and the public.

3. Each license will be issued with the condition that the licensee will, at any time before expiration of the license, upon the department's request, submit a written statement to enable the department to determine whether the license should be modified, suspended or revoked.

(8) SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO CONDUCT WELL LOGGING. The department shall approve an application for a specific license for the use of radioactive material in well logging if all the following conditions are satisfied:

(a) The applicant satisfies the general requirements specified in sub. (2).

(b) The applicant submits an adequate program for training well logging supervisors and well logging assistants that includes all the following:

1. Initial training.

2. On-the-job training.

3. Annual safety reviews provided by the licensee.

4. Means by which the applicant will demonstrate the well logging supervisor's knowledge and understanding of and ability to comply with the department's rules and licensing requirements and the applicant's operating and emergency procedures.

5. Means by which the applicant will demonstrate the well logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

(c) The applicant submits to the department written operating and emergency procedures as described in s. DHS 157.53 (2) or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

(d) The applicant establishes and submits to the department the applicant's program for annual inspections, at intervals not to exceed 13 months, of the job performance of each well logging supervisor to ensure that the department's rules, license requirements, and the applicant's operating and emergency procedures are followed. The applicant's inspection records shall be retained for 3 years after each annual internal inspection.

(e) The applicant submits a description of its overall organizational structure as it applies to the radiation safety responsibilities in wire-line services or subsurface tracer studies, including specified delegations of authority and responsibility.

(f) If an applicant wants to perform leak testing of sealed sources, the applicant identifies 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 establishes procedures to be followed and submits a description of these procedures to the department. The description shall include all the following:

1. Instruments to be used.

2. Methods of performing the analysis.

3. Pertinent experience of the person who will analyze the wipe samples.

(9) ISSUANCE OF SPECIFIC LICENSES. (a) If the department determines that an application meets the applicable requirements, the department shall issue a specific license within 180 days of filing of a complete application authorizing the proposed activity in such form and containing such conditions and limitations as the department deems appropriate or necessary.

(b) The department may incorporate in any license at the time of issuance or thereafter, any additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this section as the department deems appropriate or necessary.

(10) SPECIFIC TERMS AND CONDITIONS OF LICENSES. (a) A license issued under this section shall be subject to all the provisions of ss. 254.31 to 254.45, Stats., this chapter and orders of the department.

(b) 1. No license issued or granted under this section and no right to possess or utilize radioactive material granted by any license issued under this subsection may 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 department, after securing full information, finds that the transfer complies with the applicable provisions of the statutes, rules and orders of the department, and gives its consent in writing.

2. An application for transfer of license shall include all the following:

a. The identity and technical and financial qualifications of the proposed transferee.

b. Financial assurance for decommissioning information, as applicable, required by s. DHS 157.15.

(c) A person licensed by the department under this section shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(e) A licensee shall notify the department in writing within 10 days following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 of the United States Code by or against any one of the following:

1. The licensee.

2. An entity defined in 11 USC 101(15) controlling the licensee or listing the license or licensee as property of the estate.

3. An affiliate defined in 11 USC 101(2) of the licensee.

Note: Title 11 of the U.S. Code deals with bankruptcy.

(f) The notification specified in par. (e) shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

(11) EXPIRATION AND TERMINATION OF LICENSES AND DECOMMISSIONING OF SITES AND SEPARATE BUILDING OR OUTDOOR AREAS. (a) Except as provided in sub. (12) (b), a specific license shall expire at the end of the specified day in the month and year stated in the license. If an application for license renewal has been filed at least 30 days prior to the expiration date stated in the existing license and the department denies the renewal application, the license shall expire on the date as stated in the determination of denial. If an application for license renewal is filed less than 30 days from the expiration date stated in the existing license, the department may deny the renewal application and the license shall expire on the expiration date stated in the license.

(b) A specific license revoked by the department expires at the end of the day on the date of the department's final determination, or on the expiration date stated in the determination, or as otherwise provided by department order.

(c) A specific license remains valid, with respect to possession of radioactive material, until the department notifies the licensee in writing that the license is terminated. While the license is valid, the licensee shall do all of the following:

1. Limit actions involving radioactive material to those related to decommissioning and other activities related to preparation for release for unrestricted use.

2. Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the department notifies the licensee in writing that the license is terminated.

(d) A licensee shall do all of the following:

1. Notify the department within 60 days of any of the following:

a. Expiration of the license pursuant to par. (a) or (b).

b. The licensee's deciding to permanently cease principal activities 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 department requirements.

c. The absence of conduct of any principal activities under the license for a period of 24 months.

d. The absence of conduct of any principal activities for a period of 24 months 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 department requirements.

2. If any separate building or outdoor area contains stored radioactive material or residual radioactivity so that the building or outdoor area is unsuitable for release, do one of the following:

a. Begin decommissioning its site, separate building or outdoor area if a decommissioning plan has been previously approved by the department.

b. Submit a decommissioning plan within 12 months if required by par. (f) and begin decommissioning upon approval of that plan.

(e) Concurrent with the notification required by par. (d), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to s. DHS 157.15 in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance shall be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to par. (f) 4. Following approval of the decommissioning plan and with the department's approval, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site.

(f) A licensee shall submit a decommissioning plan to the department if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site, separate building or outdoor area have not been previously approved by the department and the procedures and activities may adversely effect the health and safety of workers or the public. The

procedures may not be carried out prior to the department's approval of the decommissioning plan. Examples of applicable procedures and activities include any of the following cases:

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

2. Procedures by which workers 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 materials than are present during operation.

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

(g) The department may approve an alternate schedule for submittal of a decommissioning plan required pursuant to par. (d) if the department determines that the alternative 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.

(h) The proposed decommissioning plan for the site or separate building or outdoor area shall include all of the following elements:

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

2. A description of planned decommissioning activities.

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

4. A description of the planned final radiation survey.

5. An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

6. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, a justification for the delay based on the criteria in par. (i).

(i) The department shall approve the proposed decommissioning plan if the information in the plan demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be ensured.

(j) Except as provided in par. (h), a licensee shall complete decommissioning of the site or separate building or outdoor area no later than 24 months following the initiation of decommissioning. When decommissioning involves the entire site, a licensee shall request license termination no later than 24 months following the initiation of decommissioning.

(k) The department may approve a request for an alternative schedule for completion of decommissioning of the site, separate building or outdoor area, and license termination if appropriate, if the department determines that the alternative is warranted after consideration of all the following:

1. Whether it is technically feasible to complete decommissioning within the allotted 24-month period.

2. Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period.

3. Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay.

4. Whether a significant reduction in radiation exposure to workers may be achieved by allowing short-lived radionuclides to decay.

5. Other site-specific factors which the department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, court decisions, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(L) As the final step in decommissioning, a licensee shall do all the following:

1. Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed department form for disposition of radioactive materials or equivalent information.

Note: The form may be obtained by writing the Department at: Department of Health Services, Radiation Protection Section, PO Box 2659, Madison WI 53701-2659; or by downloading from the Department website at: http://dhs.wisconsin.gov/radiation/Index.htm.

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 s. DHS 157.33.

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

4. Specify the survey instruments used and certify that each instrument is properly calibrated and tested.

Note: Submit reports to the Department at: Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701-2659.

(m) The department shall terminate a specific license, including an expired license, by written notice to the licensee when the department determines all of the following have occurred:

1. Radioactive material has been properly disposed of.

2. Reasonable effort has been made to eliminate residual radioactive contamination, if present.

3. The licensee has filed with the department sufficient information, including a radiation survey, to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in s. DHS 157.33.

4. The licensee has submitted records required under s. DHS 157.13 (18) (b) and (d) to the department.

(12) RENEWAL OF LICENSES. (a) An application for renewal of a specific license shall be filed under sub. (1).

(b) If a licensee, not less than 30 days prior to expiration of his or her existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, the license may not expire until final action by the department.

Note: A license renewal form may be obtained by writing the Department at: Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701-2659; or by downloading from the Department website at: http://dhs.wisconsin.gov/radiation/Index.htm.

(13) AMENDMENT OF LICENSES AT REQUEST OF LICENSEE. An application for amendment of a license shall be filed under sub. (1) and shall specify the respects in which the licensee desires the license to be amended and the grounds for the amendment. The licensee shall include the appropriate fee specified in s. DHS 157.10 (3) with the amendment application.

Note: A specific license application form is not required for an amendment request.

(14) DEPARTMENT ACTION ON APPLICATIONS TO RENEW OR AMEND. In considering an application by a licensee to renew or amend the license, the department shall apply the criteria set forth in subs. (2), (3) and (4) and in subchs. IV, V and VI, as applicable.

(15) TRANSFER OF MATERIAL. (a) No licensee may transfer radioactive material except as authorized under this subsection.

(b) Except as otherwise provided in its license and subject to the provisions of pars. (c) and (d), a licensee may transfer radioactive material to any of the following:

1. The department only after receiving prior approval from the department.

2. The U.S. department of energy.

3. Any person exempt from these regulations to the extent permitted under the exemption.

4. Any person authorized to receive radioactive material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the department, the NRC, any agreement state, any licensing state or to any person otherwise authorized to receive radioactive material by the federal government or any agency thereof, the department, an agreement state or a licensing state.

5. Any person as otherwise authorized by the department in writing.

6. The agency in another state that regulates radioactive material under 42 USC 5801.

(c) Before transferring radioactive material to a specific licensee of the department, the NRC, an agreement state or a licensing state, or to a general licensee who is required to register with the department, the NRC, an agreement state or a licensing state prior to receipt of the radioactive material, a 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) A licensee transferring radioactive materials as described in par. (c) may use any of the following methods for verification:

1. The transferor may possess and read a copy of the transferee's specific license or registration certificate that is currently in force.

2. The transferor may possess a written statement, from the transferee, certifying 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 an oral statement 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 statement is confirmed in writing within 10 days.

4. The transferor may obtain other information compiled by a reporting service from official records of the department, the NRC, 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 subds. 1. to 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 department, the NRC, 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 under the provisions of subch. XIII.

(16) MODIFICATION, SUSPENSION AND REVOCATION OF LICENSES. (a) The terms and conditions of a license shall be subject to amendment, revision or modification by the department. The department may suspend, revoke or modify the license due to amendments to ss. 254.31 to 254.45, Stats., this chapter or orders issued by the department.

(b) The department may revoke, suspend or modify any license or reciprocal recognition of an out-of-state license, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of ss. 254.31 to 254.45, Stats., 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 department 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 ss. 254.31 to 254.45, Stats., this chapter or orders issued by the department or voluntary application for amendment, revision or modification submitted by the licensee.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, the department may not modify, suspend or revoke a license unless, prior to such action, the department notifies the licensee, in writing, of the facts or

conduct that warrant the action and the licensee has been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(d) A person who considers himself or herself affected by a department denial of license application or amendment, license revocation, or license suspension may submit to the department a written request for hearing about the license action. A written request for hearing on a license action shall be received by the department within 10 days after receipt of a notice of the department's decision to deny license application or renewal or revoke or suspend a license. The hearing request shall include the information required in s. DHS 157.90 (3).

Note: Hearing requests shall be sent to: Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison, WI 53701-2659. Certified mail may be sent to: Department of Health Services, Radiation Protection Section, 1 West Wilson St, Room 150, Madison, WI 53702-0007.

(17) EVENT REPORTING. (a) *Events that must be reported immediately.* A licensee shall notify the department by telephone as soon as possible but not later than 4 hours after the discovery of an event, such as a fire, explosion or toxic gas release, which prevents immediate protective actions necessary to avoid exposures to radiation, radioactive materials or releases of licensed radioactive material that could exceed regulatory limits established in this chapter.

(b) *Events that must be reported within 24 hours.* A licensee shall notify the department within 24 hours by telephone, facsimile, or in person after the discovery of any of the following events involving licensed material:

1. An unplanned contamination event that meets all of the following criteria:

a. Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area.

b. Involves a quantity of material greater than 5 times the lowest annual limit on intake specified in ch. DHS 157 Appendix E for the material.

c. Restricts access to the area for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

2. An event in which equipment is disabled or fails to function as designed under any of the following circumstances:

a. The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident.

b. The equipment is required to be available and operable when it is disabled or fails to function.

c. No redundant equipment is available and operable to perform the required safety function.

3. An event that requires unplanned medical treatment of an individual with spreadable radioactive contamination on the individual's clothing or body.

4. A fire or explosion damaging any licensed material or any device, container or equipment containing licensed material under any of the following circumstances:

a. The quantity of material involved is greater than 5 times the lowest annual limit on intake specified in ch. DHS 157 Appendix E for the material limits.

b. The damage affects the integrity of the licensed material or its container.

Note: Submit report to the Department via telephone at (608) 267-4797 or via facsimile at (608) 267-3695.

(c) *Content and submission of reports.* 1. Reports required to be submitted to the department under pars. (a) and (b) shall, to the extent that the information is available, include all the following information:

a. The caller's name and call back telephone number.

b. A description of the event, including the date and time of its occurrence.

c. The exact location of the event.

d. The isotopes, quantities, and chemical and physical form of the licensed material involved in the event.

e. Any personnel radiation exposure data available.

2. A licensee who makes a report required by par. (a) or (b) shall submit a written report within 30 days of the initial telephone or facsimile report containing all of the following information:

a. A description of the event, including the probable cause and the manufacturer and model number, if applicable, of any equipment that failed or malfunctioned.

b. The exact location of the event.

c. The isotopes, quantities, and chemical and physical form of the licensed material involved.

d. The date and time of the event.

e. Corrective actions taken or planned and the results of any evaluations or assessments.

f. The extent to which individuals were exposed to radiation or to radioactive materials without identification of individuals by name.

Note: Submit written reports to the Department at: Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701-2659.

(18) RECEIPT, TRANSFER AND DISPOSAL RECORDS. (a) *Record retention.* A licensee shall retain records required by s. DHS 157.06 (1) or by license condition. If a retention period is not otherwise specified by this chapter or license condition, the record shall be retained until the department terminates each license.

(b) *Transfer of records to the department.* Prior to license termination, a licensee authorized to possess radioactive material, in an unsealed form, with a half-life greater than 120 days, shall forward to the department all records of disposal of licensed material made under s. DHS 157.30 (2) to (5), including burials authorized before January 28, 1981, and the results of measurements and calculations required by s. DHS 157.31 (3).

(c) *Transfer of records to new licensee.* 1. If licensed activities are transferred or assigned in accordance with s. DHS 157.13 (10) (b), each licensee authorized to possess radioactive material in unsealed form, with a half-life greater than 120 days, shall transfer the following records to the new licensee:

a. Records of disposal of licensed material made under s. DHS 157.30 (2) to (5), including burials authorized before January 28, 1981.

b. Records of the results of measurements and calculations required by s. DHS 157.31 (3).

2. The new licensee shall be responsible for maintaining the records required in subd. 1. until the license is terminated.

(d) *Transfer of records of decommissioning activities.* A licensee shall forward the records required by s. DHS 157.15 (7) to the department prior to license termination.

(19) SERIALIZATION OF NATIONALLY TRACKED SOURCES. A licensee who manufactures a nationally tracked source shall assign a unique serial number to each nationally tracked source. Serial numbers shall be composed only of alpha-numeric characters.

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter; CR 06-021: cr. (1) (i), (4) (d) 1. f. and g., (5) (c) 1. a. to c., am. (4) (c), (d) 1. (intro.) and d., 5. i., and (i) 1., (8) (intro.), (11) (d) 2. (intro.) and (17) (b) 1. (intro.), r. and recr. (4) (i) 5., renum. (5) (c) 1. to be (5) (c) 1. (intro.) and am., r. (10) (d), Register October 2006 No. 610, eff. 11-1-06; CR 09-062: cr. (1) (j), (4) (i) 2. e., 6. d. and (19), am. (4) (a) 1. (intro.), (g) 2. b., d., e., (i) (title), (intro.), 2. a., 4. a., b., 6. a. and (j) (intro.) Register April 2010 No. 652, eff. 5-1-10; correction to numbering of (4) (i) 6. d. made under s. 13.92 (4) (b) 1., Stats., Register April 2010 No. 652; **CR 16-078: am. (1) (h) (intro.), 1., cr. (1) (h) 3. to 5., am. (1) (i), cr. (4) (d) 1. h., am. (4) (e), (f), (h) 2., cr. (4) (j) 5., (4m), renum. (10) (b) to (10 (b) 1., cr. (10) (b) 2., am. (10) (e) 2. Register January 2018 No. 745, eff. 2-1-18; correction in (1) (g), (2) (f), (3) (b) 2., 3., (4) (a) 1. b., (d) 1. h., (4m) (e) (intro.), (10) (b) 2. a., (17) (b) 1. b., 4. a. made under s. 35.17, Stats., Register January 2018 No. 745.**

DHS 157.14 **Reciprocity. (1)** RECOGNITION OF LICENSES ISSUED BY THE NRC OR OTHER STATES. The department shall reciprocally recognize radioactive material licenses issued by the NRC or a state agency in another state under the conditions set forth in this section.

(2) LICENSES OF BYPRODUCT, SOURCE AND SPECIAL NUCLEAR MATERIAL IN QUANTITIES NOT SUFFICIENT TO FORM A CRITICAL MASS. (a) Subject to this chapter, any person who holds a specific license from the NRC or another 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 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 any year provided that all of the following occur:

1. The licensing document does not limit the activity authorized by the document to specified installations or locations.

2. The out-of-state licensee notifies the department in writing at least 3 days prior to engaging in the activity. The notification shall indicate the exact location of use, start date, time period, names, documentation of training, in-state address of the individual performing the activity, radiation sources to be used within the state, operating and emergency procedures and shall be accompanied by a copy of the pertinent licensing document. The out-of-state licensee shall also notify the department of any changes in the work location, schedule, radioactive material or work activities. If, for a specific case, the 3-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon written application to the department, obtain permission to proceed sooner. The department may waive the requirement for filing additional written notifications during the remainder of the year following the receipt of the initial notification from a person engaging in activities under the general license granted under this paragraph.

Note: The form may be obtained by writing the department at: Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701-2659; or by downloading from the department website at: http://dhs.wisconsin.gov/radiation/Index.htm.

3. The out-of-state licensee complies with this chapter and with all the terms and conditions of the licensing document, except any terms and conditions that may be inconsistent with this chapter.

4. The out-of-state licensee supplies any other information as required by the department.

5. The out-of-state licensee does not transfer or dispose of radioactive material possessed or used under the general license granted under this paragraph except by transfer to a person who is either specifically licensed by the department, the NRC or another agreement state to receive the material, or is exempt from the requirements for a license for the material under s. DHS 157.09 (2) (a).

6. The out-of-state licensee pays the fee prescribed in s. DHS 157.10 (3).

(b) Any person who holds a specific license issued by the NRC or another agreement state authorizing the holder to manufacture, transfer, install or service a device described in s. DHS 157.11 (2) (b) within areas subject to the jurisdiction of the licensing body is granted a general license to install, transfer, demonstrate or service the device in this state provided that all of the following occur:

1. The person files a report with the department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each report shall identify each general licensee to whom the device is transferred by name and address, the type and model number 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 under applicable provisions of the specific license issued to the person by the NRC or an agreement state.

3. The person provides assurance that any labels required to be affixed to the device under regulations of the authority that licensed manufacture of the device bear the following statement: “Removal of this label is prohibited."

4. The holder of the specific license furnishes to each general licensee to whom the device is transferred or on whose premises the device is installed a copy of the general license contained in s. DHS 157.11 (2) (b) or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(c) The department may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by the NRC or an agreement state or any product distributed under the licensing document upon determining that the action is necessary to prevent undue hazard to public health and safety or property.

(3) LICENSES OF NARM. (a) Subject to this chapter, any person who holds a specific license for NARM from a licensing 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 granted a general license to conduct the activities authorized within this state for a period not in excess of 180 days in any year provided that all of the following occur:

1. The licensing document does not limit the authorized activity to specified installations or locations.

2. The out-of-state licensee notifies the department in writing at least 3 days prior to engaging in such activity. The 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. If, for a specific situation, the 3-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon written application to the department, obtain permission to proceed sooner.

Note: The department may waive the 3-day notification requirement when the activities of the out-of-state licensee are routinely scheduled at the same location in the state.

3. The out-of-state licensee complies with this chapter and with all the terms and conditions of the licensing document except any terms and conditions that may be inconsistent with this chapter.

4. The out-of-state licensee supplies any other information as required by the department.

5. The out-of-state licensee does not transfer or dispose of radioactive material possessed or used under the general license granted in this paragraph except by transfer to a person who is either specifically licensed by the department or by another licensing state to receive radioactive material, or exempt from the requirements for a license for radioactive material under s. DHS 157.09 (1).

6. The out-of-state licensee pays the fee prescribed in s. DHS 157.10 (3).

(b) Notwithstanding the provisions of par. (a), any person who holds a specific license issued by a licensing state authorizing the holder to manufacture, transfer, install or service a device described in s. DHS 157.11 (2) (b) within areas subject to the jurisdiction of the licensing body is granted a general license to install, transfer, demonstrate or service the device in this state provided that all of the following conditions are met:

1. The person files a report with the department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each report shall identify each general licensee to whom the 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 under applicable provisions of the specific license issued to the person by a licensing state.

3. The person assures that any labels required to be affixed to the device under regulations of the authority that licensed manufacture of the device bears the following statement: “Removal of this label is prohibited."

4. The holder of the specific license furnishes to each general licensee to whom the holder transfers the device or on whose premises the holder installs the device a copy of the general license contained in s. DHS 157.11 (2) (b) or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(c) The department may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by a licensing state or any product distributed under the licensing document upon determining that the action is necessary to prevent undue hazard to public health and safety or property.

(4) JURISDICTIONAL STATUS. (a) A licensee shall determine the jurisdictional status of a temporary job-site before radioactive materials may be used at a job site at any federal facility within the state. If the jurisdictional status is unknown, the licensee shall contact the federal agency that controls the site to determine if the job site is under exclusive federal jurisdiction.

(b) A licensee shall obtain authorization from another agreement state or the NRC before radioactive material may be used at a temporary job site in another state. Authorization may be obtained either by applying for reciprocity or a specific license from that state or the NRC.

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter; CR 06-021: am. (2) (a) 5. and (b) (intro.), Register October 2006 No. 610, eff. 11-1-06.

DHS 157.15 Financial assurance and records for decommissioning. (1) FINANCIAL ASSURANCE REQUIREMENT FOR A SPECIFIC LICENSE.

(a) *Unsealed radioactive material, sealed sources or plated foils.* A person applying for a specific license authorizing the possession and use of unsealed radioactive material, sealed sources or plated foils shall submit a decommissioning funding plan as described in sub. (5) with the license application for any of the following types of materials:

1. Unsealed radioactive material with a half-life greater than 120 days and in quantities greater than 10^5 times the applicable quantities listed in ch. DHS 157 Appendix I.

2. Unsealed radioactive material with a half-life greater than 120 days involving a combination of isotopes with R divided by 10^5 being greater than one, where R is defined as the sum of the ratios of the quantity of each isotope to the applicable value in ch. DHS 157 Appendix I.

3. Sealed sources or plated foils with a half-life greater than 120 days and in quantities greater than 10^{12} times the applicable quantities listed in ch. DHS 157 Appendix I.

4. Sealed sources or plated foils with a half-life greater than 120 days involving a combination of isotopes with R divided by 10^{12} being greater than one, where R is defined as the sum of the ratios of the quantity of each isotope to the applicable value in ch. DHS 157 Appendix I.

(b) Other radioactive material. A person applying for a specific license authorizing the possession and use of radioactive material not covered by par. (a) with a half-life greater than 120 days and in quantities specified in sub. (4) shall do either of the following:

1. Submit a decommissioning funding plan as described in sub. (5).

2. Submit a written certification, signed by the chief financial officer or other individual designated by management to represent the licensee, that financial assurance has been provided in the amount prescribed in sub. (4) using one of the methods described in sub. (5) and a signed original of the financial instrument obtained to satisfy the requirements of sub. (6). The written certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued by the department but before receipt of radioactive material by the applicant. If the applicant defers execution of the financial instrument until after the license has been issued, the applicant shall submit to the department a signed original of the financial instrument obtained before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the department, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of sub. (6).

(2) EXEMPTIONS. The following are exempt from the requirements of this section:

(a) A state, local or other government agency, except for a government agency licensed to handle or process radioactive waste.

(b) A person authorized to possess only radioactive materials with a half-life of 65 days or less.

(c) Other persons exempted by the department based on a review of the license application.

(3) IMPLEMENTATION. (a) A person who possesses a specific license authorizing the possession and use of radioactive material issued on or after the effective date of August 1, 2002, which is of a type described in sub. (1), shall provide financial assurance for decommissioning under this section.

(b) A person who possesses a specific license issued before the effective date of August 1, 2002, shall do one of the following:

1. For a license authorizing the use of radioactive material meeting the criteria of sub. (1) (a), submit a decommissioning funding plan as described in sub. (5) and a certification of financial assurance for at least $1,125,000, under the criteria in sub. (4), with any application for license renewal.

2. For a license authorizing the use of radioactive material meeting the criteria of sub. (1) (b), submit a decommissioning funding plan as described in sub. (5) or a certification of financial assurance for decommissioning according to the criteria of sub. (4) with any application for license renewal.

(c) The term of the financial assurance shall be from the issuance or renewal of the license until the department terminates the license.

(d) A licensee's financial assurance arrangements may be reviewed ~~annually~~ by the department to recognize any increases or decreases resulting from inflation or deflation, changes in engineering plans, activities performed or any other condition affecting costs for decommissioning to ensure that sufficient funding is available to cover liability that remains until license termination.

(4) REQUIRED AMOUNTS FOR FINANCIAL ASSURANCE. (a) A licensee shall provide the following minimum amounts of financial assurance for decommissioning, unless otherwise specified by the department:

1. One million one hundred twenty-five thousand dollars if the quantity of material is greater than 10^4 but less than or equal to 10^5 times the applicable quantities of ch. DHS 157 Appendix I in unsealed form. For a combination of isotopes, R divided by 10^4 is greater than one but R divided by 10^5 is less than or equal to one.

2. Two hundred twenty-five thousand dollars if the quantity of material is greater than 10^3 but less than or equal to 10^4 times the applicable quantities of ch. DHS 157 Appendix I in unsealed form. For a combination of isotopes, R divided by 10^3 is greater than one but R divided by 10^4 is less than or equal to one.

3. One hundred thirteen thousand dollars if the quantity of material is greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of ch. DHS 157 Appendix I in sealed sources or plated foils. For a combination of isotopes, R divided by 10^{10} is greater than one but R divided by 10^{12} is less than or equal to one.

(b) The department may eliminate, reduce or raise the required amount of financial assurance under par. (a) for an individual applicant or licensee based on the cost estimate for decommissioning included in the decommissioning funding plan required under sub. (5) (a).

(5) DECOMMISSIONING FUNDING PLAN. (a) A decommissioning funding plan shall be submitted to the department for review and approval and shall include all the following information:

1. A detailed cost estimate for decommissioning in an amount reflecting all of the following:

a. Probable extent of contamination through the use or possession of radioactive material at the facility or site and the projected cost of removal of the contamination to a level specified by the department. The evaluation shall encompass probable contaminating events associated with the licensee's or applicant's operation and shall be based on factors such as quantity, half-life, radiation hazard, toxicity and chemical and physical forms.

b. The extent of possible offsite property damage caused by operation of the facility or site.

c. The cost of removal and disposal of radiation sources that are or would be generated, stored, processed or otherwise present at the licensed facility or site.

d. The costs involved in reclaiming the property on which the facility or site is located and all other properties contaminated by radioactive material authorized under the license.

e. The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination.

f. The cost of an independent contractor to perform all decommissioning activities including an adequate contingency factor.

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

3. A description of the method for assuring funds for decommissioning according to sub. (6), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility.

(b) The decommissioning funding plan shall also contain the licensee's certification that financial assurance has been provided in the amount of the cost estimate for decommissioning and that a signed original of the financial instrument obtained to satisfy the requirements of sub. (6) has been submitted and accepted, unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning.

(c) At intervals not to exceed 3 years, the licensee shall resubmit the decommissioning funding plan to the department with adjustments as necessary to account for changes in costs and extent of contamination. The amount of financial assurance shall not be decreased until the updated decommissioning funding plan is approved. The licensee shall update the information submitted with the original or previously approved decommissioning funding plan, and shall specifically consider the effect of all 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 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.
8. Use of a settling pond.

(6) FINANCIAL ASSURANCE OPTIONS. A licensee may use any of the following methods to provide financial assurance for decommissioning:

(a) *Prepayment.* Prepayment is the deposit prior to operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets in an amount 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.

(b) *Surety method, insurance or other guarantee.* Payment of future decommissioning costs shall be guaranteed by a surety method, insurance or other guarantee. A surety method may be in the form of a surety bond, letter of credit or line of credit. Self insurance, or any method which essentially constitutes self-insurance, may not be used as a method of providing financial assurance. Any surety method or insurance used to provide financial assurance for decommissioning must meet all of the following criteria:

1. The surety method or insurance shall be open-ended or, if written for a specified term, renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the department, the beneficiary and the licensee of its intention not to renew. The surety method or insurance shall 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 department within 30 days after receipt of notification of cancellation.

2. The surety method or insurance shall be payable to a trust established for decommissioning costs. The department shall approve the trustee and the trust.

Note: An acceptable trustee includes the State of Wisconsin or an entity having the authority to act as a trustee and whose trust operations are regulated and examined by a state or federal government agency.

3. The surety method or insurance shall remain in effect until the department terminates the license.

(c) *External sinking fund.* An external sinking fund may be used 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 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 shall meet the requirements of par. (b).

(d) *Statement of intent.* A state or local government licensee exempt under sub. (2) shall submit a written statement of intent containing a cost estimate for decommissioning or an amount based on sub. (4). The cost estimate shall indicate that funds for decommissioning will be obtained when necessary.

(7) RECORDS. (a) A licensee shall keep the following records of information related to decommissioning of a facility in an identified location until the site is released for unrestricted use:

1. Records of spills or other unusual occurrences involving the spread of radioactive contamination in and around the facility, equipment or site. The records may be limited to instances where contamination remains after any cleanup procedures or when there is reasonable likelihood that radioactive contaminants may have spread to inaccessible areas or into porous materials such as concrete. The records shall 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 or stored, and of locations of possible inaccessible contamination such as buried pipes that may contain radioactive contaminants. If required drawings are referenced, each relevant document does not need to be indexed individually. If drawings are not available,

a licensee shall substitute appropriate records of available information concerning the areas and locations of inaccessible contamination.

Note: As-built architectural and engineering drawings need to reflect the final details of the structures and equipment as they were constructed.

3. Except for areas containing only sealed sources that have not leaked or where no contamination remains after a leak, or radioactive materials with half-lives of less than 65 days, a list containing all the following:

a. All areas currently and formerly designated as restricted areas.

b. All areas outside of restricted areas that require documentation under subd. 1.

c. All areas outside of restricted areas where current and previous wastes have been buried as documented under s. DHS 157.31 (9).

d. All areas outside of restricted areas that contain radioactive material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in s. DHS 157.13 (11) (d) or apply for approval for disposal under s. DHS 157.30 (2).

4. Records of the cost estimate performed for the decommissioning funding plan or the amount certified for decommissioning and records of the funding method used for assuring funds.

(b) A licensee shall keep the records in par. (a) until the site is decommissioned and approved by the department for unrestricted use.

(c) Prior to a licensed activity being transferred to another licensee under s. DHS 157.13 (10) (b), the original licensee shall transfer all records under par. (a) to the new licensee. The new licensee shall be responsible for maintaining the records until their license is terminated by the department.

(d) The list under par. (a) 3. shall be updated every 2 years.

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter; CR 06-021: am. (1) (a) (intro.), (b) 2., (3) (b) 1., (4) (a) 1. to 3., (5) (a) 3. and (7) (a) 3. (intro.), cr. (1) (a) 3. and 4., Register October 2006 No. 610, eff. 11-1-06; **CR 16-078: am. (1) (a) 2., 4., (5) (a) (intro.), 1. (intro.), cr. (5) (a) 1. e., f., r. and recr. (5) (a) 2., am. (5) (a) 3., (b), cr. (5) (c) Register January 2018 No. 745, eff. 2-1-18; correction in (1) (a) 1. to 4., (4) (a) 1. to 3. made under s. 35.17, Stats., Register January 2018 No. 745.**