64E-5.201 Licensing of Radioactive Material.

(1) This part provides for the licensing of radioactive material. No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to this part or as otherwise provided in this part. Unless otherwise specified in the license or these rules, no licensee shall use radioactive materials:

(a) In or on human beings;

(b) In field applications where radioactive material is released to the environment;

(c) In products distributed to the public;

(d) In animals, plants, or their products which will be used for human consumption; or

(e) In plants or animals where their products are released to the environment.

(2) In addition to the requirements of this part, all licensees are subject to the requirements of Parts I, III, IX and XV. Licensees engaged in industrial radiographic operations are also subject to the requirements of Part IV, licensees using radionuclides in the healing arts are subject to the requirements of Part VI and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Part XI.

(3) The Procedures for Radioactive Materials Enforcement Actions, May 2000, which is available from the department and which is herein incorporated by reference, will be used to determine enforcement actions to be taken.

(4) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the law, or because of conditions revealed by such application or statement of fact on 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 the law or of the license, a rule, or an order of the Department.

Rulemaking Authority 404.051(4), 404.061(2), 404.20 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), 404.061(2), 404.081(1), 404.091, 404.141, 404.161, 404.162, 404.20(1) FS. History–New 7-17-85, Amended 8-25-91, 5-12-93, 5-15-96, Formerly 10D-91.301, Amended 10-8-00.

64E-5.202 Source Material - Exemptions.

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

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

(3) Any person is exempt from this part to the extent that such person receives, possesses, uses or transfers:

(a) Any quantities of thorium contained in:

1. Incandescent gas mantles;

2. Vacuum tubes;

3. Welding rods;

4. Electric lamps for illuminating purposes, provided that each lamp does not contain more than 50 milligrams of thorium;

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

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

7. Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;

(b) Source material contained in the following products:

1. Glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material;

2. Glassware containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, ceramic tile or other glass, or ceramic used in construction;

3. Glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983; or

4. Piezoelectric ceramic containing not more than 2 percent by weight source material;

(c) Photographic film, negatives, and prints containing uranium or thorium;

(d) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

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

1. The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 C.F.R. Part 40;

2. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: “DEPLETED URANIUM” or “CAUTION – RADIOACTIVE MATERIAL – URANIUM” if manufactured prior to December 31, 1969;

3. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: “UNAUTHORIZED ALTERATIONS PROHIBITED”, unless manufactured prior to December 31, 1969, and impressed with the legend “CAUTION – RADIOACTIVE MATERIAL – URANIUM”.

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

(f) 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 one-eighth inch (3.2 mm).

(g) Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either:

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

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

or other optical instruments;

(h) Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium; or

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

1. The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria or thorium dioxide; and

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

(4) The exemptions in this section do not authorize the manufacture of any of the products described.

Rulemaking Authority 404.051, 404.061, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), 404.141 FS. History–New 7-17-85, Amended 4-4-89, Formerly 10D-91.302.

64E-5.203 Radioactive Material Other Than Source Material - Exemptions.

(1) Exempt Concentrations.

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

2. A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license to the extent that this person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in Schedule A and introduced into the product or material by a licensee holding a specific license issued by the NRC 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) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under paragraph (1)(a), above, or equivalent regulations of the NRC, an Agreement State or Licensing State, except in accordance with a specific license issued by the NRC pursuant to 10 CFR section 32.11.

(2) Exempt Quantities.

(a) Except as provided in paragraphs (2)(b) through (d), below, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Schedule B.

(b) 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.

(c) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this section or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, pursuant to Section 32.18 of 10 C.F.R. Part 32, or by the Department, pursuant to subsection 64E-5.210(2), F.A.C., which license states that the radioactive material may be transferred by the licensee to persons exempt under this subsection or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

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

(e)1. Any person, who possesses radioactive material received or acquired before September 25, 1971, under the then existing general license issued to transfer, receive, acquire, own, possess, use and import quantities of radioactive materials listed in subparagraph 64E-5.203(2)(e)2., F.A.C., Table of General Licensed Quantities prior to September 25, 1971 below, or similar general license of a State, or provided that no person shall at any one time possess or use, pursuant to the general license provisions of this section, more than a total of ten such quantities.

2. Below is the Table of General Licensed Quantities prior to September 25, 1971:

	Radioactive material	Column No. I Not as a sealed source (microcuries)	Column No. III As a sealed source (microcuries)
a.	Antimony (Sb 124)	1	10
b.	Arsenic 76 (As 76)	10	10
c.	Arsenic 77 (As 77)	10	10
d.	Barium 140 – Lanthanum 140 (Ba La 140)	1	10
e.	Beryllium 7 (Be 7)	50	50
f.	Cadmium 109 – Silver 109 (Cd Ag 109)	10	10
g.	Calcium 45 (Ca 45)	10	10
h.	Carbon 14 (C 14)	50	50

i.	Cerium 144 – Praseodymium (Ce Pr 144)	1	10
j.	Cesium – Barium 137 (Cs Ba 137)	1	10
k.	Chlorine 36 (Cl 36)	1	10
l.	Chromium 51 (Cr 51)	50	50
m.	Cobalt 60 (Co 60)	1	10
n.	Copper 64 (Cu 64)	50	50
o.	Europium 154 (Eu 154)	1	10
p.	Fluorine 18 (F 18)	50	50
q.	Gallium 72 (Ga 72)	10	10
r.	Germanium 71 (Ge 71)	50	50
s.	Gold 198 (Au 198)	10	10
t.	Gold 199 (Au 199)	10	10
u.	Hydrogen 3 (Tritium) (H 3)	250	250
v.	Indium 114 (In 114)	1	10
w.	Iodine 131 (I-131)	10	10
x.	Iridium 192 (Ir 192)	10	10
y.	Iron 55 (Fe 55)	50	50
z.	Iron 59 (Fe 59)	1	10
aa.	Lanthanum 140 (La 140)	10	10
bb.	Manganese 52 (Mn 52)	1	10
cc.	Manganese 56 (Mn 56)	50	50
dd.	Molybdenum 99 (Mo 99)	10	10
ee.	Nickel 59 (Ni 59)	1	10
ff.	Nickel 63 (Ni 63)	1	10
gg.	Niobium 95 (Nb 95)	10	10
hh.	Palladium 109 (Pd 109)	10	10
ii.	Palladium 103 – Rhodium 103 (Pd-Rh 103)	50	50
jj.	Phosphorus 32 (P 32)	10	10
kk.	Polonium 210 (Po 210)	0.1	1
ll.	Potassium 42 (K 42)	10	10
mm.	Praseodymium 143 (Pr 143)	10	10
nn.	Promethium 147 (Pm 147)	10	10
oo.	Rhenium 186 (Re 186)	10	10
pp.	Rhodium 105 (Rh 105)	10	10
qq.	Rubidium 86 (Rb 86)	10	10
rr.	Ruthenium 106 – Rhodium 106 (Ru Rh 106)	1	10
ss.	Samarium 153 (Sm 153)	10	10
tt.	Scandium 46 (Sc 46)	1	10
uu.	Silver 105 (Ag 105)	1	10
vv.	Silver 111 (Ag 111)	10	10
ww.	Sodium 22 (Na 22)	10	10
xx.	Sodium 24 (Na 24)	10	10
yy.	Strontium 89 (Sr 89)	1	10
zz.	Strontium 89 – Yttrium 90 (Sr Y 90)	0.1	1
aaa.	Sulfur 35 (S 35)	50	50
bbb.	Tantalum 182 (Ta 182)	10	10
ccc.	Technetium 96 (Tc 96)	1	10
ddd.	Technetium 99 (Tc 99)	1	10
eee.	Tellurium 127 (Te 127)	10	10

fff.	Tellurium 129 (Te 129)	1	10
ggg.	Thallium 204 (Tl 204)	50	50
hhh.	Tin 112 (Sn 113)	10	10
iii.	Tungsten 185 (W 185)	10	10
jjj.	Vanadium 48 (V 48)	1	10
kkk.	Yttrium 90 (Y 90)	1	10
lll.	Yttrium 91 (Y 91)	1	10
mmm.	Zinc 65 (Zn 65)	10	10
nnn.	Beta or Gamma emitting radioactive material not listed above	1	10

(3) Exempt Items.

(a) Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, any person is exempt from these regulations to the extent that he receives, possesses, uses, transfers, owns or acquires the following products. 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:

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

a. Twenty-five millicuries (925 MBq) of tritium per timepiece;

b. Five millicuries (185 MBq) of tritium per hand;

c. Fifteen millicuries (555 MBq) of tritium per dial; bezels when used shall be considered as part of the dial;

d. One hundred microcuries (3.7 MBq) of promethium 147 per watch or two hundred microcuries (7.4 MBq) of promethium 147 per any other timepiece;

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

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

g. The radiation dose rate from hands and dials containing promethium 147 or radium 226 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(I) For wrist watches, 0.1 millirad (1 uGy) per hour at 10 centimeters from any surface;

(II) For pocket watches, 0.1 millirad (1 uGy) per hour at 1 centimeter from any surface. Radium shall not be used for pocket watches; and

(III) For any other timepiece, 0.2 millirad (2 uGy) per hour at 10 centimeters from any surface;

h. One microcurie (37 kBq) of radium 226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

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

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

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

5. Electron tubes, 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 shall not exceed 1 millirad (10 uGy) per hour at 1 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. One hundred fifty millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube.

b. One microcurie (37 kBq) of cobalt 60.

c. Five microcuries (185 kBq) of nickel 63.

d. Thirty microcuries (1.11 MBq) of krypton 85.

e. Five microcuries (185 kBq) of cesium 137.

f. Thirty microcuries (1.11 MBq) of promethium 147.

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

a. Each source contains no more than one exempt quantity set forth in Schedule B, and

b. Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source 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 Schedule B, provided that the sum of such fractions shall not exceed unity.

c. For americium 241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under this subparagraph.

(b) Self-Luminous Products Containing Radioactive Material.

1. Tritium, Krypton 85 or Promethium 147. Except for persons who manufacture, process or produce self-luminous products containing tritium, krypton 85 or promethium 147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires tritium, krypton 85 or promethium 147 in self-luminous products manufactured, or processed, produced, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 C.F.R. Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in this paragraph does not apply to tritium, krypton 85 or promethium 147 used in products for frivolous purposes or in toys or adornments.

2. Radium 226. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium 226 which were acquired prior to December 1980.

(c) Gas and Aerosol Detectors Containing Radioactive Material.

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from these regulations to the extent that such 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 detectors containing radioactive material shall have been manufactured, processed, produced, imported or initially transferred in accordance with a specific license issued by the NRC pursuant to Section 32.26 of 10 C.F.R. Part 32. 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.

2. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a State under comparable 10 CFR, section 32.26 authorizing distribution to persons exempt from regulatory requirements.

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

(a) Except as provided in paragraphs (b) and (c) of this section, any person is exempt from the requirements for a license set forth in these regulations if such person receives, possesses, uses, transfers, owns, or acquires capsules containing 1 microcurie (37 kBq) carbon 14 urea each, allowing for nominal variation that can occur during the manufacturing process, for in vivo diagnostic use for humans.

(b) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license as specified in these regulations.

(c) 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 as specified in 10 CFR Part 32, Sec. 32.21.

(d) Nothing in this section relieves a person from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

Rulemaking Authority 404.051, 404.061, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (10), 404.141 FS. History–New 7-17-85, Amended 4-4-89, Formerly 10D-91.303, Amended 10-8-00, Amended 12-26-13.

64E-5.204 Types of Licenses.

Licenses for radioactive materials are of two types: general and specific.

(1) Some general licenses provided in this part may be effective without the filing of applications with the department or the issuance of licensing documents to the particular persons, although the filing of a certificate with the department for general licenses pursuant to subsection 64E-5.206(7) or (8), F.A.C., shall be required of the particular general licensee prior to the receipt of radioactive material and the department requires registration of certain general licenses described in subsection 64E-5.206(4), F.A.C. The payment of a fee is also required by all persons possessing general licensed material described in paragraph (1)(c), below. The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.

(a) The annual registration fee set forth in this section for general licenses shall be payable every July 1, for as long as the license remains in effect.

(b) The annual fee for a general license set forth in Rule 64E-5.216, F.A.C., under reciprocal agreement shall be paid before the first entrance into the state and on each anniversary date thereafter, if applicable. Manufacturers, manufacturer's representatives, distributors, and waste treatment, storage or disposal companies servicing Florida radioactive materials license applicants or licensees are not exempt from this fee.

(c) Payment of the indicated annual fee pursuant to paragraph (1)(a), above, is required for the following types of devices held or activities performed under a general license:

1. Static elimination devices as described in paragraph 64E-5.206(1)(a), F.A.C.	$30.00 per unit
2. Measuring, gauging, and control devices as described in subsection 64E-5.206(4), F.A.C.	$30.00 per unit
3. *In Vivo* testing as described in subsection 64E-5.206(7), F.A.C.	$150.00 per license
4. *In Vitro* testing as described in subsection 64E-5.206(8), F.A.C.	$150.00 per license
5. Depleted uranium as described in subsection 64E-5.205(4), F.A.C.	$150.00 per license

(d) Those persons who hold a specific license from the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State and conduct activities under a reciprocal agreement with this State shall meet the requirements of subsection 64E-5.216(1), F.A.C., and pay the annual fee as specified in paragraph (2)(e), below.

(2) Specific licenses require the submission of an application to the Department and the issuance of a licensing document by the Department. The licensee is subject to all applicable portions of these regulations as well as any limitations specified in the licensing document. The licensee is subject to the payment of fees as authorized under Section 404.131, F.S., and as outlined below:

(a) The requirements of this part apply to a person who is an applicant for, or holder of a specific radioactive materials license issued pursuant to Subpart C, and for a special review of safety designs of sealed sources and devices, whether or not in conjunction with a license application on file or which may be filed.

(b) All communications concerning the requirements of this part should be addressed to or delivered in person to the Department of Health, Bureau of Radiation Control, 4052 Bald Cypress Way, Bin C21, Tallahassee, Florida 32399-1741.

(c) No additional fees shall be required for amendments to licenses.

(d) Payment of fees.

1. Application fees. Each application for a specific license for which a fee is prescribed shall be accompanied by a remittance in the full amount of the fee. No application will be processed prior to payment of the fee specified herein. The application fee is not refundable except in those cases where the Department has determined that a license is not required. The Department will consider any application abandoned if the Department does not receive a reply within 90 days to its most recent request for additional information. In such cases, the applicant must submit a new application with the application fee specified herein.

2. Annual fees. All current specific licenses that were in effect on January 1, 1979, are subject to payment of the annual fee prescribed herein and on every January 1, thereafter, as long as the license remains in effect. All specific licenses issued after January 1, 1979, are subject to payment of the annual fee specified in this section within 60 days of issuance of the license and on each anniversary date thereafter. The annual fee is not refundable except in those cases where the Department has determined that the fee is not required.

3. Method of payment. Checks, drafts or money orders for payment of fees shall be payable to DOH, Office of Radiation Control; and sent to: Department of Health, Bureau of Radiation Control, 4052 Bald Cypress Way, Bin C21, Tallahassee, Florida 32399-1741.

(e) Below is the schedule of fees for specific radioactive materials licenses:

	Application	Annual

	Fee	Fee
1. Source Material:		
a. Licenses for concentration of uranium from phosphate ores for the production of uranium as “yellow cake” or powdered solid;	$8,288	$14,330
b. Licenses for concentration of uranium from phosphate ores for the production of “green cake” or equivalent, moist or solid;	$4,522	$8,927
c. All other specific source material licenses excluding depleted uranium used as shielding and counterweights.	$653	$275
2. Special Nuclear Material (SNM):		
a. Licenses for use of SNM in sealed sources contained in devices used in measuring systems;	$784	$622
b. Licenses for use of SNM not sufficient to form a critical mass, except as in paragraph 2.a., above, and paragraphs 2.c. and 5.e., below;	$1,608	$2,333
c. Licenses for use of SNM to be used as calibration and reference sources.	$246	$131
3. Byproduct, naturally occurring or accelerator produced material:		
a. Licenses for processing or manufacturing for commercial distribution or industrial uses;	$3,508	$3,362
b. Licenses for processing or manufacturing and distribution of radiopharmaceuticals. This category includes radiopharmacies;	$3,072	$4,608
c. Licenses for industrial radiography performed only in an approved shielded radiography installation;	$1,870	$2,593
d. Licenses for industrial radiography performed only at the address indicated in the license, or at temporary job sites of the licensee;	$1,972	$3,188
e. Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials where the source is not removed from the shield and is less than 10,000 curies;	$726	$726
f.(I) Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials when the source is not removed from the shield and is greater than 10,000 curies and less than 100,000 curies, or where the source is less than 100,000 curies and is removed from the shield;	$1,697	$1,956
(II) Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials when the source is equal to or greater than 100,000 curies and less than 1,000,000 curies;	$4,391	$4,753
(III) Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials when the source is equal to or greater than 1,000,000 curies;	$11,736	$5,278
g. Licenses issued to distribute items containing radioactive materials to persons under a general license;	$1,972	$2,580
h. Fixed gauging devices;	$726	$1,159
i. Well logging;		
(I) Sealed sources or sub-surface tracer studies;	$1,362	$1,798
(II) Sub-surface tracer studies and sealed sources;	$1,723	$1,913
j. Nuclear laundry;	$3,840	$6,781
k. Industrial or medical research and development;	$1,421	$1,769
l.(I) Portable gauging devices;	$726	$1,159
(II) *In Vitro* and clinical laboratory**;**	$870	$1,102
(III) Academic;	$1,174	$1,405
(IV) Possession of uranium or thorium, or their decay products, as a result of mining or processing;	$1,174	$1,044
(V) All other specific licenses except as otherwise noted;	$870	$1,202
m. Licenses of broad scope;		
(I) Academic;	$3,840	$8,815
(II) Medical;	$3,840	$6,569
(III) Industrial or Research and Development;	$3,840	$5,482
n. Gas chromatography devices;	$521	$377
o. Reference or calibration sources equal to or less than 1 millicurie total;	$377	$158
p. Nuclear service licenses, such as, leak testing, instrument calibration, etc.	$622	$492
4. Waste disposal or processing:		

a. Commercial waste disposal or treatment facilities, including burial or incineration;	$331,010	$300,666
b. All other commercial facilities involving compaction, repackaging, storage or transfer;	$32,501	$29,965
c. Commercial treatment of radioactive materials for release to unrestricted areas.	$6,913	$6,882
5. Medical use:		
a.(I) Teletherapy or gamma stereotactic radiosurgery including gamma knife devices;	$1,838	$1,791
(II) High, medium, low or pulsed dose rate remote afterloader devices;	$1,697	$1,654
(III) High, medium, low or pulsed dose rate remote afterloader devices and gamma stereotactic radiosurgery including gamma knife devices or teletherapy devices;	$1,838	$1,791
b. Medical institutions, including hospitals, except category 5.a.(I), 5.a.(II), 5.a.(III), 5.e. and 5.f.;	$1,972	$2,290
c. Private practice physicians except category 5.a.(I), 5.a.(II), 5.a.(III), 5.d. and 5.f.;	$1,421	$1,608
d. Private practice physicians using only strontium 90 eye applicators, or materials authorized by Rule 64E-5.630, F.A.C., or materials authorized by Rule 64E-5.631, F.A.C.;	$726	$898
e. Nuclear powered pacemakers;	$521	$319
f.(I) Mobile nuclear medicine services.	$1,697	$1,950
(II) Mobile high, medium, low or pulsed dose rate remote afterloader device when the treatment is only performed on the mobile vehicle.	$2,970	$3,308
6. Civil defense.	$653	$985
7. Device, product, or sealed source safety evaluation:		
a. Safety evaluation of devices or products containing radioactive material, except reactor fuel devices, for commercial distribution or in accordance with the unique specifications of, and for use by, a single applicant; per device remaining in active status. Devices or products in inactive status more than 5 years must submit another application fee and be re-evaluated;	$4,500	$2,570
b. Safety evaluation of sealed sources containing radioactive material, for commercial distribution or in accordance with the unique specifications of, and for use by, a single applicant; per source remaining in active status. Sources in inactive status more than 5 years must submit another application fee and be re-evaluated.	$2,400	$2,900

Rulemaking Authority 404.051, 404.061, 404.131 FS. Law Implemented 404.031, 404.051, 404.061, 404.131, 404.141 FS. History–New 7-17-85, Amended 9-9-90, 8-25-91, 5-12-93, 11-6-94, Formerly 10D-91.304, Amended 5-18-98, 9-28-06, 8-16-07, 12-26-13.

64E-5.205 General Licenses - Source Material.

(1) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and State and local governmental agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any given time for research, development, educational, commercial or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any calendar year.

(2) Persons who receive, possess, use or transfer source material pursuant to the general license issued in (1), above, are exempt from the provisions of Parts III and IX to the extent that such receipt, possession, use or transfer is within the terms of such general license; provided, however, this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this part.

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

(4) Depleted Uranium in Industrial Products and Devices.

(a) A general license is hereby issued to receive, acquire, possess, use or transfer, in accordance with the provisions of (4)(b), (c), (d) and (e), below, 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.

(b) The general license in (4)(a), above, applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to Rule 64E-5.210, F.A.C., or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to general licensees of the U.S. Nuclear Regulatory Commission or an Agreement State.

(c)1. Persons who receive, acquire, possess or use depleted uranium pursuant to the general license established by (4)(a), above, shall submit the information requested on DOH Form 1619, entitled “General License for Depleted Uranium”, which is herein incorporated by reference effective 7-17-85, with the Department. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall submit a fee as required in paragraph 64E-5.204(1)(c), F.A.C.

2. The registrant possessing or using depleted uranium under the general license established by (4)(a), above, shall report in writing to the Department any changes in information furnished by him in the “Registration Certificate – Use of Depleted Uranium Under General License” form. The report shall be submitted within 30 days after the effective date of such change.

(d) A person who receives, acquires, possesses or uses depleted uranium pursuant to the general license established by (4)(a), above:

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

2. Shall not abandon such depleted uranium;

3. Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of Rule 64E-5.215, F.A.C. In the case where the transferee receives the depleted uranium pursuant to the general license established by (4)(a), above, the transferor shall furnish the transferee a copy of this regulation and a copy of the “Registration Certificate – Use of Depleted Uranium Under General License”. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission’s or Agreement State’s regulation equivalent to (4)(a), above, the transferor shall furnish the transferee a copy of this regulation and a copy of the “Registration Certificate – Use of Depleted Uranium Under General License” accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as in this regulation;

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

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

(e) Any person receiving, acquiring, possessing, using or transferring depleted uranium pursuant to the general license established by (4)(a), above, is exempt from the requirements of Parts III and IX with respect to the depleted uranium covered by that general license.

Rulemaking Authority 404.051, 404.061, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (6), (8), (9), (10), 404.061(2),

404.081(1), 404.141 FS. History–New 7-17-85, Formerly 10D-91.305.

64E-5.206 General Licenses – Radioactive Material Other Than Source Material.

(1) Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 C.F.R. Part 31. This general license is subject to the provisions of Rules 64E-5.103 through 64E-5.104, paragraph 64E-5.203(1)(b), Rules 64E-5.213, 64E-5.215, Part III, Part IX and Part XV, F.A.C.

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

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

(2) Reserved.

(3) Reserved.

(4) Certain Measuring, Gauging and Controlling Devices.

(a) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their businesses, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of paragraphs (4)(b), (c) and (d), below, 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.

(b)1. The general license in paragraph (4)(a), above, applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the Department pursuant to subsection 64E-5.210(4), F.A.C., or in accordance with the specifications contained in a specific license issued by the NRC, or an Agreement State, which authorizes distribution of devices to persons granted a general license by the NRC, or an Agreement State. Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in Section 179.21 of 21 C.F.R. Part 179. (Pursuant to Section 120.54(6), F.S., subparagraph 64E-5.206(4)(b)1., F.A.C., is substantively identical to 10 CFR 31.5(b)(1) published on 01/01/2007.)

2. The devices must have been received from one of the specific licenses described in subparagraph (b)1., above or through a transfer made under subparagraph 64E-5.206(4)(c)8., F.A.C.

(c) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in paragraph (4)(a), above;

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

2. Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified in the label. However,

a. Devices containing only krypton need not be tested for leakage of radioactive material; and

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

3. Shall assure that other testing, installation, servicing and removal from installation involving the radioactive material, its shielding or containment, are performed:

a. In accordance with the instructions provided by the labels, or

b. By a person holding an applicable specific license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities;

4. Shall maintain records showing compliance with the requirements of subparagraphs (4)(c)2. and 3., above. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing testing, installation, servicing and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by subparagraph (4)(c)2., above, shall be maintained for at least three years after

the next required leak test is performed or until the transfer or disposal of the sealed source. Records of tests of the on-off mechanism and indicator required by subparagraph (4)(c)2., above, shall be maintained for at least three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed. Records which are required by subparagraph (4)(c)3., above, shall be maintained for a period of at least 3 years from the date of the recorded event or until the transfer or disposal of the device; (Pursuant to Section 120.54(6), F.S., subparagraph 64E-5.206(4)(c)4., F.A.C., is substantively identical to 10 CFR 31.5(c)(4)i published on 01/01/2007.)

5. 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 0.005 microcurie (185 Bq) 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 U.S. Nuclear Regulatory Commission, 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 and, within 30 days, furnish to the Department a report containing a brief description of the event and the remedial action taken; and in the case of removable radioactive materials or failure of or damage to a source likely to result in contamination of the premises or the environment, a plan for ensuring the premises and environment are acceptable for unrestricted use using the criteria described in Rule 64E-5.222, F.A.C.

6. Shall not abandon the device containing radioactive material;

7. Except as provided in subparagraph (4)(c)8., below, shall transfer or dispose of the device containing radioactive material only by export as provided by subparagraph 15. below, transfer to a specific licensee of the Department, the NRC, or an Agreement State, whose specific license authorizes him to receive the device, and within 30 days after transfer of a device to a specific licensee or export, shall furnish to the Department a report containing identification of the device by manufacturer's or initial transferor's name and model number and serial number, the name, address, license number, where applicable, of the person receiving the device, and the date of the transfer;

8. Shall transfer the device by export as provided by paragraph 15 below, or to another general licensee only:

a. Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this section, a copy of Rules 64E-5.103, 64E-5.343, and 64E-5.344, F.A.C., and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Department the manufacturer's or initial transferor's name and model number and serial number of device transferred, the transferor's name and mailing address for the location of use, and the name, title and phone number of the responsible individual identified by the transferee in accordance with subparagraph 64E-5.206(4)(c)11., F.A.C., to have knowledge of and authority to take actions to ensure compliance with these regulations; or

b. 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; and

9. Shall comply with the provisions of Rules 64E-5.343 and 64E-5.344, F.A.C., for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of Parts III and IX.

10. Shall be required to obtain written Department authorization before transferring the device to any other specific license not specifically identified in subparagraph 64E-5.206(4)(c)7., F.A.C. A holder of a specific license may transfer a device for possession and use under its own specific license without prior approval if the specific license holder satisfies the following requirements:

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

b. Removes, alters, covers, or clearly and unambiguously augments the existing label otherwise required by subparagraph 64E-5.206(4)(c)1., F.A.C., so that the device is labeled in compliance with Rule 64E-5.325, F.A.C., provided the manufacturer, model number, and serial number is retained;

c. Obtains manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license such as leak testing procedures;

d. Reports the transfer under subparagraph 64E-5.206(4)(c)7., F.A.C.

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

12.a. Shall register, in accordance with sub-subparagraphs 64E-5.206(4)(c)12.b. and 64E-5.206(4)(c)12.c., F.A.C., all devices

except exit signs containing tritium. Each address for a location of use as described in sub-sub-subparagraph 64E-5.206(4)(c)12.c.(IV), F.A.C., represents a separate general license and requires a separate registration.

b. Shall annually register with the Department the possession of a device meeting the criteria in sub-subparagraph 64E-5.206(4)(c)12.a., F.A.C. Registration must be done by verifying, correcting or adding to the information provided in a request for registration received from the Department. The registration information must be submitted to the Department within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, the general licensee holding devices that meet the criteria of sub-subparagraph 64E-5.206(4)(c)12.a., F.A.C., is subject to the bankruptcy notification requirements in subsection 64E-5.213(3), F.A.C.

c. Shall provide the following information and any other information requested by the Department:

(I) Name and mailing address of the general licensee;

(II) For each device, the manufacturer's name or initial transferor name, model number, serial number, the radioisotope and activity as identified on the label;

(III) Name, title, and telephone number of the responsible person designated a representative of the general licensee under subparagraph 64E-5.206(4)(c)11., F.A.C.;

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

(V) Certification by the responsible representative of the general licensee that the information concerning the devices(s) has been verified through a physical inventory and checking the label information; and

(VI) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

d. Persons generally licensed by other Agreement States, Licensing States, or the U.S. Nuclear Regulatory Commission with respect to devices meeting the criteria in 10 CFR 31.5(c)(13)(i) are not subject to registration requirements if the devices are used in areas subject to the Department jurisdiction for less than 180 days in any calendar year. The Department will not request registration from such licensees.

13. Shall report to the Department changes in the general licensee name and the mailing address for each location of use within 30 days of the effective date of the change. For a portable device, a report of address change is required for a change in the device's primary place of storage.

14. Shall not hold devices that are not in use longer than 2 years. If the devices with shutters are not being used, the shutters must be locked in the closed position. The testing required by subparagraph 64E-5.206(4)(c)2., F.A.C., need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter trested before use. Devices kept in standby for future use are excluded from the two year time limit if the general licensee performs physical inventories at intervals not to exceed three months while they are in standby. (Pursuant to Section 120.54(6), Florida Statutes, subparagraph 64E-5.206(4)(c)14., F.A.C., is substantively identical to 10 CFR 31.5(c)(15) published on 01/01/2007.)

15. Shall not export the device containing radioactive material except in accordance with 10 C.F.R. Part 110;

16. Shall 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 that same time period, request a longer period to supply the information by providing the Department, a written justification for the request for extension of time. (Pursuant to Section 120.54(6), Florida Statutes, subparagraph 64E-5.206(4)(c)16., F.A.C., is substantively identical to 10 CFR 31.5(c)(11) published on 01/01/2007.)

(d) The general license in paragraph (4)(a), above, does not authorize the manufacture of devices containing radioactive material.

(e) The general license provided in paragraph (4)(a), above, is subject to the provisions of Rules 64E-5.103 through 64E-5.104, 64E-5.213, 64E-5.215, and Part XV, F.A.C.

(5) Luminous Safety Devices for Aircraft.

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

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

2. Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear

Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Department or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 C.F.R. Part 32.

(b) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in paragraph (5)(a), above, are exempt from the requirements of Parts III and IX except that they shall comply with the provisions of Rules 64E-5.343 and 64E-5.344, F.A.C.

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

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

(e) This general license is subject to the provisions of Rules 64E-5.103 through 64E-5.104, 64E-5.213, 64E-5.215, and Part XV, F.A.C.

(6) Calibration and Reference Sources.

(a) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of paragraphs (6)(d) and (e), below, americium 241 in the form of calibration or reference sources:

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

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

(b) A general license is hereby issued to own, receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of paragraphs (6)(d) and (e), below, to any person who holds a specific license issued by the Department which authorizes him to receive, possess, use and transfer radioactive material.

(c) A general license is hereby issued to own, receive, possess, use and transfer radium 226 in the form of calibration or reference sources in accordance with the provisions of paragraphs (6)(d) and (e), below, to any person who holds a specific license issued by the Department which authorizes him to receive, possess, use and transfer radioactive material.

(d) The general licenses in paragraph (6)(a), (b) and (c), above, apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 C.F.R. Part 32 or Section 70.39 of 10 C.F.R. Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Department, an Agreement State or Licensing State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 C.F.R. Part 32 or Section 70.39 of 10 C.F.R. Part 70.

(e) The general licenses provided in paragraphs (6)(a), (b) and (c), above, are subject to the provisions of Rules 64E-5.103 through 64E-5.104, 64E-5.213, 64E-5.215, Parts III, IX and XV, F.A.C. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

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

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

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

CAUTION – RADIOACTIVE MATERIAL – THIS SOURCE CONTAINS (AMERICIUM 241) (PLUTONIUM). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or importer

b. The receipt, possession, use and transfer of this source, model ___, serial no. ___, are subject to a general license and the regulations of a Licensing State. Do not remove this label.

CAUTION – RADIOACTIVE MATERIAL – THIS SOURCE CONTAINS RADIUM 226. DO NOT TOUCH RADIOACTIVE

PORTION OF THIS SOURCE.

_____

Name of manufacturer or importer

3. Shall not transfer, abandon or dispose of such source except by transfer to a person authorized by a license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive the source;

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

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

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

(7) Medical Diagnostic Uses.

(a) A general license shall be issued to any physician to receive, possess, transfer or use radioactive material set forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provision of (7)(b), (c) and (d), below, the radioactive material is in the form of capsules, disposable syringes or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with a specific license issued by the Department pursuant to subsection 64E-5.210(7), F.A.C., or by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State pursuant to equivalent regulations authorizing distribution to persons under a general license pursuant to this subsection or its equivalent:

1. Chromium 51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time;

2. Cobalt 57 for the measurement of intestinal absorption of cyanocobalamin;

3. Cobalt 58 for the measurement of intestinal absorption of cyanocobalamin;

4. Cobalt 60 for the measurement of intestinal absorption of cyanocobalamin;

5. Iodine 125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

6. Iodine 131 as sodium iodide for measurement of thyroid uptake; and

7. Iodine 131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume.

(b) No physician shall receive, possess, use or transfer radioactive material pursuant to the general license established by paragraph (7)(a), above, until he has submitted the original and one copy of the completed form DH 361, 10/12 and received from the Department a validated copy of this form with a certification number assigned. DH 361 10/12, entitled, “Certificate – Medical Use of Radioactive Material under General License,” is herein incorporated by reference and can be obtained from the internet at http://www.flrules.org/Gateway/reference.asp?No=Ref-03450 or at http://www.doh.state.fl.us/environment/radiation/matform.htm.

(c) A physician who receives, possesses or uses a pharmaceutical containing radioactive material pursuant to the general license established by paragraph (7)(a), above, shall comply with the following:

1. The physician shall not possess at any given time, pursuant to the general license in paragraph (7)(a), above, more than

a. Two hundred microcuries (7.4 MBq) of iodine 131,

b. Two hundred microcuries (7.4 MBq) of iodine 125,

c. Five microcuries (185 kBq) of cobalt 57,

d. Five microcuries (185 kBq) of cobalt 58,

e. Five microcuries (185 kBq) of cobalt 60,

f. Two hundred microcuries (7.4 MBq) of chromium 51;

2. The physician shall store the pharmaceutical in the original shipping container until administered, or in a container providing equivalent radiation protection;

3. The physician shall use the pharmaceutical only for the uses authorized by paragraph (7)(a), above;

4. The physician shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(d) The general licensed physician possessing or using radioactive material under the general license of paragraph (7)(a), above, shall report in duplicate to the Department any changes in the information furnished by him on Form 361. The report shall be submitted within 30 days after the effective date of such change.

(e) Any person using radioactive material pursuant to the general license of paragraph (7)(a), above, is exempt from the requirements of Parts III and IX with respect to the radioactive material covered by the general license.

(f) Manufacturers of radiopharmaceuticals which are under the general license in this subsection are required to affix a certain identifying label to the container, and in the leaflet or brochure which accompanies the radiopharmaceutical, pursuant to subsection 64E-5.210(7), F.A.C.

(8) General License for Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing.

(a) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of paragraphs (8)(b), (c), (d), (e) and (f), below, the following radioactive materials in prepackaged units for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

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

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

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

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

5. Mock Iodine 125 reference or calibration sources, in units not exceeding 0.05 microcuries (1.85 kBq) of iodine 129 and 0.005 microcuries (0.185 kBq) of americium 241 each.

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

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

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

(b) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by paragraph (8)(a), above, until he has submitted the original and one copy of the completed form DH 360 10/12, and received from the Department a validated copy of this form with a certification number assigned. DH 360 10/12 entitled, "Certificate – *In Vitro* Testing with Radioactive Material under General License" is herein incorporated by reference and can be obtained from the internet at http://www.flrules.org/Gateway/reference.asp?No=Ref-03451 or at http://www.doh.state.fl.us/environment/radiation/matform.htm.

(c) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by paragraph (8)(a), above, shall comply with the following:

1. The general licensee shall not possess at any given time, pursuant to the general license in paragraph (8)(a), above, at any single location of storage or use, a combined total amount of iodine 125, iodine 131, selenium 75, iron 59 or cobalt 57 in excess of 200 microcuries (7.4 MBq).

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

3. The general licensee shall use the radioactive material only for the uses authorized by paragraph (8)(a), above.

4. The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

5. The general licensee shall dispose of the mock iodine 125 reference or calibration sources described in paragraph (8)(a), above, as required by Rule 64E-5.328, F.A.C.

(d) The general licensee shall not receive, acquire, possess or use radioactive material pursuant to paragraph (8)(a), above:

1. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to subsection 64E-5.210(8), F.A.C., or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State which authorizes the manufacture and distribution of iodine 125, iodine 131, carbon 14, hydrogen 3 (tritium), iron 59, selenium 75, cobalt 57 or mock iodine 125 to persons under a general license described in this subsection or its equivalent, and

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

a. This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to

the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the U.S. Nuclear Regulatory 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

(e) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of paragraph (8)(a), above, shall report in writing to the Department any changes in the information furnished by him in the "Certificate – *In Vitro* Testing with Radioactive Material Under General License". The report shall be furnished within 30 days after the effective date of such change.

(f) Any person using radioactive material pursuant to the general license of paragraph (8)(a), above, is exempt from the requirements of Parts III and IX with respect to radioactive material covered by that general license, except that such persons using the mock iodine 125 described in subparagraph (8)(a)5., above, shall comply with the provisions of Rules 64E-5.328, 64E-5.343, and 64E-5.344, F.A.C.

(g) The New Drug provisions of the Federal Food, Drug and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

(9) Ice Detection Devices.

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

(b) Persons who own, receive, acquire, possess, use or transfer strontium 90 contained in ice detection devices pursuant to the general license in paragraph (9)(a), above:

1. Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of Rule 64E-5.328, F.A.C.;

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

3. Are exempt from the requirements of Parts III and IX except that such persons shall comply with the provisions of Rules 64E-5.328, 64E-5.343 and 64E-5.344, F.A.C.

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

(d) This general license is subject to the provisions of Rules 64E-5.103 through 64E-5.104, 64E-5.213, 64E-5.215 and Part XV, F.A.C.

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

Rulemaking Authority 404.051, 404.061, 404.071 FS. Law Implemented 404.022, 404.051(1), (4), (6), (8), (9), (10), (11), 404.061(2), 404.071(1), (3), 404.081(1), 404.141 FS. History–New 7-17-85, Amended 4-4-89, 1-1-94, Formerly 10D-91.306, Amended 9-28-06, 2-28-08, 12-26-13.

64E-5.207 Filing Application for Specific Licenses.

(1) An original and one copy of an application for specific licenses, license renewals, and license amendments shall be filed with the department on Application for Radioactive Materials License Non-Human Use, DH Form 1054 12/09 or Application for Radioactive Materials Human Use, DH Form 1322 12/09, which are herein incorporated by reference.

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

(3) An existing license shall not expire until final action by the department if a licensee has filed an application for renewal in proper form not less than 30 days before expiration of his existing license or for a new license authorizing the same activities.

(4) Applications for license amendments are not required to be submitted on DOH forms but shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

Rulemaking Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (6), (9), (10), (11), 404.061(2), 404.141 FS. History–New 7-17-85, Amended 4-4-89, 5-12-93, 5-15-96, Formerly 10D-91.307, Amended 2-11-10.

64E-5.208 General Requirements for the Issuance of Specific Licenses.

A license application for a new, amended, or renewed license will be approved if the department determines that:

(1) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these rules in such a manner as to minimize danger to public health and safety or property;

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

Rulemaking Authority 404.051, 404.061, 404.071, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (6), (10), (11), 404.061(2), 404.141 FS. History–New 7-17-85, Amended 5-12-93, 5-15-96, Formerly 10D-91.308.

64E-5.209 Special Requirements for Specific Licenses of Broad Scope.

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

(1) The different types of broad scope licenses are set forth below:

(a) 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.

(b) 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 Schedule D of this part, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule D, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(c) 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 Schedule D of this part, 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 Schedule D, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(2) An application for a Type A specific license of broad scope will be approved if:

(a) The applicant satisfies the general requirements specified in Rule 64E-5.208, F.A.C.;

(b) The applicant has engaged in more than one type of activity involving the use of radioactive material; and

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

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

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

3. The establishment of appropriate administrative procedures to assure:

a. Control of procurement and use of radioactive material;

b. 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 users, and the operating or handling procedures; and

c. Review, approval and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with (2)(c)3.b., above, prior to use of the radioactive material.

(3) An application for a Type B specific license of broad scope will be approved if:

(a) The applicant satisfies the general requirements specified in Rule 64E-5.208, F.A.C.; and

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

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

2. The establishment of appropriate administrative procedures to assure,

a. Control of procurement and use of radioactive material,

b. 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

c. Review, approval and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with (3)(b)2.b., above, prior to use of the radioactive material.

(4) An application for a Type C specific license of broad scope will be approved if:

(a) The applicant satisfies the general requirements specified in Rule 64E-5.208, F.A.C.;

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

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

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

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

(5) Specific licenses of broad scope are subject to the following conditions:

(a) Unless specifically authorized, persons licensed pursuant to this section shall not:

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

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

3. Conduct activities for which a specific license issued by the Department under Rule 64E-5.210 or 64E-5.211, F.A.C., is required; or

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

(b) Each Type A specific license of broad scope issued under this part 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.

(c) Each Type B specific license of broad scope issued under this part 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.

(d) Each Type C specific license of broad scope issued under this part 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 (4), above.

Rulemaking Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (6), (8), (9), (10), (11), 404.061(2), 404.071(1), (3), 404.081(1), 404.141 FS. History–New 7-17-85, Formerly 10D-91.310.

64E-5.210 Special Requirements for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices Which Contain Radioactive Material.

(1) Licensing the Distribution of Radioactive Material in Exempt Concentrations. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity or other product containing by-product material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the NRC, Washington, D.C. 20555. No person may introduce radioactive materials into a product or material knowing or having reason to believe that it will be transferred to persons exempt under subsection 64E-5.203(1), F.A.C., NRC or equivalent regulations of an Agreement State, except in accordance with a license issued by the NRC under 10 CFR section 32.11.

(2) Licensing the Distribution of Radioactive Material in Exempt Quantities. 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. No person may introduce radioactive materials into a product or material knowing or having reason to believe that it will be transferred to persons exempt under subsection 64E-5.203(1), F.A.C., NRC or equivalent regulations of an Agreement State, except in accordance with a license issued by the NRC under 10 CFR section 32.11.

(3) Licensing the Distribution of Radioactive Material in Exempt Items. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity or other product containing by-product material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the NRC, Washington, D.C. 20555. No person may introduce radioactive materials into a product or material knowing or having reason to believe that it will be transferred to persons exempt under subsection 64E-5.203(1), F.A.C., NRC or equivalent regulations of an Agreement State, except in accordance with a license issued by the NRC under 10 CFR section 32.11.

(4) Licensing the Manufacture and Distribution of Devices to General Licensees Under subsection 64E-5.206(4), F.A.C.

(a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons possessing a general license under subsection 64E-5.206(4), F.A.C., or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State will be approved if:

1. The applicant satisfies the general requirements of Rule 64E-5.208, F.A.C.;

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

a. The device can be safely operated by persons not having training in radiological protection,

b. 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 a dose in excess of 10 percent of the limits specified in Rule 64E-5.304, F.A.C., and

c. 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:

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

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

(III) Other organs – 50 rems (500 mSv); and

3. Each device bears a durable, legible, clearly visible label or labels approved by the Department which contain in a clearly identified and separate statement:

a. Instructions and precautions necessary to assure safe installation, operation and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information.

b. The requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity, and

c. The information called for in one of the following statements, as appropriate, in the same or substantially similar form. The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device:

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

CAUTION – RADIOACTIVE MATERIAL

_____

Name of manufacturer or distributor

(II) The receipt, possession, use and transfer of this device, model ___, serial no. ___, are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION – RADIOACTIVE MATERIAL

_____

Name of manufacturer or distributor

4. Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the radioisotope and quantity, the words "Caution Radioactive Materials," the radiation symbol described in Rule 64E-5.322, F.A.C., the name of the manufacturer or initial distributor.

5. Each device containing at least 10 millicuries (370 MBq) of cesium-137, 0.1 millicuries (3.7 MBq) of strontium-90, 1 millicurie (37 MBq) of cobalt-60, or 1 millicurie (37 MBq) of americium-241 or any other element with atomic numbers greater than 92, based on the activity indicated on the label, must bear a permanent label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words "Caution Radioactive Materials," and if practical, the radiation symbol described in Rule 64E-5.322, F.A.C. Example of a permanent label include labels that are embossed, etched, stamped or engraved to the source housing or device as applicable.

(b) In the event 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 which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Department will consider the following information:

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

(c) In the event the applicant desires that the general licensee under Rule 64E-5.206, F.A.C., or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the limits specified in Rule 64E-5.304, F.A.C.

(d) If a device containing radioactive material is transferred for use under the general license described in subsection 64E-5.206(4), F.A.C., each person that is licensed under subsection 64E-5.210(4), F.A.C., shall provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be

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

1. A copy of the general license contained in subsection 64E-5.206(4); subparagraphs 64E-5.206(4)(c)2., 3., and 4. or subparagraph 64E-5.206(4)(c)12., F.A.C., do not apply to the particular device, those paragraphs may be omitted;

2. A copy of Rules 64E-5.103, 64E-5.343, and 64E-5.344, F.A.C.;

3. A list of services that can only be performed by a specific licensee;

4. Information on acceptable disposal options including costs of disposal; and

5. An indication that department policy is to issue high civil penalties for improper disposal.

(e) If a device containing radioactive material is transferred for use under an equivalent general license of an Agreement State or the NRC, each person that is licensed under subsection 64E-5.210(4), F.A.C., shall provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to the initial transfer to the intermediate person. The required information includes the following:

1. A copy of the Agreement State or NRC equivalent to Rules 64E-5.103, 64E-5.343, and 64E-5.344, F.A.C. If a copy of the NRC regulations is provided to a prospective general licensee in lieu of the Agreement State's regulations, it shall be accompanied by a note explaining that the use of the device is regulated by the Agreement State. If certain parts of the regulations do not apply to the particular device, those regulations may be omitted;

2. A list of services that can only be performed by a specific licensee;

3. Information on acceptable disposal options including costs of disposal; and

4. The name or title, address, and phone number of the contact at the Agreement State regulatory agency or U.S. Nuclear Regulatory Commission, as applicable, from which additional information may be obtained.

(f) Each device that is transferred must meet the labeling requirements in subparagraphs 64E-5.210(4)(d)3. through 5., F.A.C.

(g) If a notification of bankruptcy has been made under subsection 64E-5.213(3), F.A.C., or the license is to be terminated, each person licensed under subsection 64E-5.210(4), F.A.C., shall provide, upon request, to the department, U.S. Nuclear Regulatory Commission and to any appropriate Agreement State, records of final disposition required under paragraph 64E-5.210(4)(j), F.A.C.

(h) Each person licensed under subsection 64E-5.210(4), F.A.C., shall comply with the following reporting and record keeping requirements.

1. Report all transfers of devices to persons for use under the general license described in subsection 64E-5.206(4), F.A.C., and all receipts of devices from persons licensed under subsection 64E-5.206(4), F.A.C., to the Department. This report must be submitted at intervals not to exceed 3 months and contain all of the information described in "Transfers of Industrial Devices Report 04/2007" which is herein incorporated by reference and is available at the address listed in paragraph 64E-5.204(2)(b), F.A.C., or can be obtained from the internet at http://www.flrules.org/Gateway/reference.asp?No=Ref-03452 or at http://www.doh.state.fl.us/environment/radiation/regs/64e-5tab.htm.

2. This report must be clear and legible and contain the following data:

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

b. The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

c. The date of transfer;

d. The type, model number, and serial number of the device transferred; and

e. The quantity and type of radioactive materials contained in the device.

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

4. For devices received from a subsection 64E-5.206(4), F.A.C., general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

5. If the licensee makes changes to the device possessed by a subsection 64E-5.206(4), F.A.C., general licensee, such that the

label must be changed to update required information, this report must identify the general licensee, the device, and the changes to information on the device label.

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

7. If no transfers have been made to or from persons generally licensed under subsection 64E-5.206(4), F.A.C., during the reporting period, the report must so indicate.

(i) Each person licensed under subsection 64E-5.210(4), F.A.C., shall comply with the following additional reporting and record keeping requirements for transfers and receipt of devices to Agreement States or the NRC.

1. Report all transfers of devices to persons for use under the general license in an Agreement State or the NRC, that are equivalent to subsection 64E-5.206(4), F.A.C., and all receipts of devices from persons licensed under a general license in Agreement State or the NRC jurisdiction to the responsible Agreement State or the NRC agency. This report must contain all of the information described in "Transfers of Industrial Devices Report 04/2007."

2. The report must be clear and legible and contain the following data:

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

b. The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

c. The date of transfer;

d. The type, model number, and serial number of the device transferred; and

e. The quantity and type of radioactive materials contained in the device.

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

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

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

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

7. If no transfers have been made to or from a particular Agreement State or the NRC during the reporting period, this information shall be reported to the responsible Agreement State or the NRC agency upon request of the agency.

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

(j) The persons shall maintain all information concerning transfers and receipts of devices that supports the reports required by subsection 64E-5.210(4), F.A.C. Records and reports described in subsection 64E-5.210(4), F.A.C., shall be maintained for inspection by the department for a period of 3 years following the date of the recorded event.

(5) Special Requirements for the Manufacture, Assembly or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble or repair luminous safety devices containing tritium or promethium 147 for use in aircraft, for distribution to general licensees under subsection 64E-5.206(5), F.A.C., will be approved if the requirements of Sections 32.53, 32.54, 32.55, 32.56 and 32.101 of 10 C.F.R., Part 32, or their equivalent and the general requirements specified in Rule 64E-5.208, F.A.C., are satisfied.

(6) Special Requirements for License to Manufacture Calibration Sources Containing Americium 241, Plutonium or Radium 226 for Distribution to Persons Generally Licensed Under subsection 64E-5.206(6), F.A.C. An application for a specific license to manufacture calibration and reference sources containing americium 241, plutonium or radium 226 to general licensees under subsection 64E-5.206(6), F.A.C., will be approved if the requirements of Sections 32.57, 32.58, 32.59 and 32.102 of 10 C.F.R., Part 32 and Section 70.39 of 10 C.F.R., Part 70, or their equivalent and the general requirements of Rule 64E-5.208, F.A.C., are satisfied.

(7) Manufacture and Distribution of Radioactive Material for Medical Use Under General License. In addition to requirements

set forth in Rule 64E-5.208, F.A.C., a specific license authorizing the distribution of radioactive material for use by physicians under the general license in subsection 64E-5.206(7), F.A.C., will be issued if:

(a) The applicant submits evidence that the radioactive material is to be manufactured, labeled and packaged in accordance with a new drug application which the Commissioner of Food and Drugs, Food and Drug Administration, has approved, or in accordance with a license for a biological product issued by the Secretary, U.S. Department of Health and Human Services; and

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

1. This radioactive drug may be received, possessed and used only by physicians licensed by the State of Florida to dispense drugs in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

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Name of Manufacturer

2. This radioactive drug may be received, possessed and used only by physicians licensed by the State of Florida to dispense drugs in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent of a Licensing State.

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Name of Manufacturer

(8) Manufacture and Distribution of Radioactive Material for Certain in *In Vitro* Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of subsection 64E-5.206(8), F.A.C., will be approved if:

(a) The applicant satisfies the general requirements specified in Rule 64E-5.208, F.A.C.

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

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

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

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

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

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

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

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

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

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

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

2. Displaying the radiation caution symbol described in subsection 64E-5.322(1), F.A.C., and the words, “CAUTION, RADIOACTIVE MATERIAL”, and “Not for Internal or External Use in Humans or Animals”.

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

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

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Name of manufacturer

2. 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.

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Name of manufacturer

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

(f) The applicant satisfies the requirements specified in paragraph 64E-5.210(10)(b), F.A.C.

(9) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to general licensees under subsection 64E-5.206(9), F.A.C., will be approved if:

(a) The applicant satisfies the general requirements of Rule 64E-5.208, F.A.C.; and

(b) The criteria of Sections 32.61, 32.62, and 32.103 of 10 C.F.R., Part 32, are met.

(10) Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Part VI for the uses listed in Rules 64E-5.626, 64E-5.627, 64E-5.630 and 64E-5.664, F.A.C., will be approved if:

(a) The applicant satisfies the general requirements specified in Rule 64E-5.208, F.A.C.;

(b) The applicant submits evidence that:

1. The applicant is registered or licensed with the U.S. Food and Drug Administration as a drug manufacturer; or

2. The applicant is registered or licensed as a drug manufacturer as specified in Chapter 499, Florida Statutes; or

3. The applicant has a nuclear pharmacy permit and only authorized nuclear pharmacists compound or dispense radiopharmaceuticals as specified in Section 465.0193, F.S.

(c) The applicant submits information on the radionuclide, chemical and physical form, the maximum activity per vial, syringe, generator, or other container of the radioactive drug, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by medical use licensees;

(d) The applicant satisfies the following labeling requirements:

1. The label affixed to each transport radiation shield of any material of a radioactive drug transferred for commercial distribution includes 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 the radioactive material at a specified date and time. The time can be omitted for radioactive drugs with a half life greater than 100 days.

2. A label affixed to each syringe, vial, or other container used to hold a radioactive drug transferred for commercial distribution includes the words “Caution, Radioactive Material” or “Danger, Radioactive Material” and an identifier that correlates the syringe, vial, or other container with the information on the transport radiation shield label; and

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

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

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

(f) An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radiopharmaceuticals containing for noncommercial transfer to licensees in its consortium licensed for medical pursuant to Part VI, or equivalent Agreement State, or NRC rules will be approved if:

1. The requirements of paragraphs 64E-5.210(10)(a), (b), and (e), F.A.C., are satisfied;

2. The information required of paragraphs 64E-5.210(10)(c) and (d), F.A.C., indicates the PET drugs to be noncommercially transferred to members of its consortium.

(11) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to Part VI for the uses listed in Rule 64E-5.627 or 64E-5.664, F.A.C., will be approved if:

(a) The applicant satisfies the general requirements specified in Rule 64E-5.208, F.A.C.;

(b) The applicant submits evidence that:

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

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

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

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

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

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

2. A statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the department pursuant to Part VI for uses listed in Rule 64E-5.627, F.A.C., or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. The labels, leaflets, or brochures required by this section are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(12) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use.

(a) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part VI for use as a calibration, transmission or reference source or for the uses listed in Rule 64E-5.631, 64E-5.634, 64E-5.664 or 64E-5.632, F.A.C., will be approved if:

1. The applicant satisfies the general requirements in Rule 64E-5.208, F.A.C.;

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

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 sources and devices as to their radioactive content, and

h. Instructions pertaining to radiation safety for handling and storing the source or device; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

3. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, date of assay, and a statement that the name of source or device is licensed by the department for distribution to persons licensed pursuant to Part VI or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, provided, that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;

(b) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than 6 months, he shall include in his 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; and

(c) In determining the acceptable interval for test of leakage of radioactive material, the Department will consider the following information:

1. Primary containment or source capsule,

2. Protection of primary containment,

3. Method of sealing containment,

4. Containment construction materials,

5. Form of contained radioactive material,

6. Maximum temperature withstood during prototype tests,

7. Maximum pressure withstood during prototype tests,

8. Maximum quantity of contained radioactive material,

9. Radiotoxicity of contained radioactive material, and

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

(13) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.

(a) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to subsection 64E-5.205(4), F.A.C., or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

1. The applicant satisfies the general requirements specified in Rule 64E-5.208, F.A.C.;

2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of 1 calendar quarter a radiation dose in excess of 10 percent of the limits specified in Subpart III A of these rules; and

3. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(b) In the case of an industrial product or device whose unique benefits have not been demonstrated, the Department will approve an application for a specific license under this subsection only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(c) Each person licensed pursuant to paragraph (13)(a), above, shall:

1. Maintain the level of quality control required by the license in the manufacture of the industrial product or device and in the installation of the depleted uranium into the product or device;

2. Label or mark each unit to:

a. Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium and the quantity of depleted uranium in each product or device; and

b. State that receipt, possession, use and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State;

3. 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”;

4.a. Furnish a copy of the general license described in subsection 64E-5.205(4), F.A.C., to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license described in subsection 64E-5.205(4), F.A.C., or

b. Furnish a copy of the general license certificate of the U.S. Nuclear Regulatory Commission’s or an Agreement State’s, or alternatively, furnish a copy of the general license described in subsection 64E-5.205(4), F.A.C., to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission

or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in subsection 64E-5.205(4), F.A.C.;

5. Report to the Department all transfers of industrial products or devices to persons for use under the general license described in subsection 64E-5.205(4), F.A.C. Such 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 submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the general licensee. If no transfers have been made to general licensees under subsection 64E-5.205(4), F.A.C., during the reporting period, the report shall so indicate;

6.a. Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 C.F.R., Part 40,

b. Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to subsection 64E-5.210(3), F.A.C., for use under a general license in that state's rules equivalent to subsection 64E-5.205(4), F.A.C.,

c. Such 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 agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the general licensee.

d. If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission, and

e. If no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon the request of that agency; and

7. Keep records showing the name, address and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in subsection 64E-5.205(4), F.A.C., or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of 2 years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred and compliance with the report requirements of this section.

(14) A licensee, manufacturer or an initial distributor of a sealed source or device containing a sealed source whose product contains exempt NARM or is intended for use under a general or specific license must submit a request for an evaluation of the sealed source or device containing a sealed source and obtain a registration from the Department.

(a) The request for review of a sealed source or device must be made in triplicate and include information about the design, manufacture, prototype testing, quality control and assurance program, labeling, leak testing and proposed uses. The licensee shall inform customers of current reasonable disposal options for the radioactive material.

(b) The request for review of a device must include information about installation, service and maintenance, operating and safety instructions, and its potential hazards. The information shall provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect public health, safety and property.

(c) The Department shall use criteria and standards sufficient to ensure that the radiation safety properties of the sealed source or device are adequate to protect public health, safety and property. Criteria and standards used by the Department in evaluating a sealed source or device include:

1. U.S. Department of Health and Human Services Publication FDA 81-8025 June 1981, Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM), which is herein incorporated by reference and can be obtained from the internet at https://www.flrules.org/gateway/reference.asp?No=Ref-03508 or at http://www.doh.state.fl.us/environment/radiation/matform.htm which is available from the department.

2. NRC Regulatory Guide 10.10 March 1987, Guide for the Preparation of Applications for Radiation Safety Evaluations and Registration of Devices Containing Byproduct Material, which is herein incorporated by reference and can be obtained from the internet at http://www.flrules.org/Gateway/reference.asp?No=Ref-03453 or at http://pbadupws.nrc.gov/docs/ML0037/ML003740220.pdf or at http://www.doh.state.fl.us/environment/radiation/.

3. NRC Regulatory Guide 10.11 June 1987, Guide for the Preparation of Applications for Radiation Safety Evaluations of Sealed Sources Containing Byproduct Material, which is herein incorporated by reference and can be obtained from the internet at http://www.flrules.org/Gateway/reference.asp?No=Ref-03454 or at http://pbadupws.nrc.gov/docs/ML0037/ML003740233.pdf or at http://www.doh.state.fl.us/environment/radiation/.

4. American National Standards Institute (ANSI) Standard, ANSI-HPS N43.8-2008, Classification of Industrial Ionizing Radiation Gauging Devices, which is herein incorporated by reference and can be obtained from the internet at http://hps.org/hpssc/documents/ansi_standards_order_form.pdf.

5. ANSI Standard, ANSI-HPS N43.4-2005, Classification of Radioactive Self-Luminous Light Sources, which is herein incorporated by reference and can be obtained from the internet at http://hps.org/hpssc/documents/ansi_standards_order_form.pdf.

6. ANSI Standard N432-1980, NBS Handbook 136, as issued in January 1981, Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography, which is herein incorporated by reference and can be obtained from the internet at http://www.flrules.org/Gateway/reference.asp?No=Ref-03455 or at http://pbadupws.nrc.gov/docs/ML0508/ML050840139.pdf or at http://www.doh.state.fl.us/environment/radiation/matform.htm which is available from the department.

7. ANSI Standard, ANSI-HPS N43.6-2007, Sealed Radioactive Sources Classification, which is herein incorporated by reference and can be obtained from the internet at http://hps.org/hpssc/documents/ansi_standards_order_form.pdf. The Ansi publications referenced in this rule section: ANSI-HPS N43.8-2008; ANSI-HPS N43.4-2005; ANSI-HPS N43.6-2007; are copyrighted materials. These materials are available for public inspection and examination at the Florida Department of State, Room 701, The Capitol, Tallahassee, Florida 32399-0250, and at the Florida Department of Health, Bureau of Radiation Control, 4042 Bald Cypress Way, Tallahassee, Florida 32399-1741.

(d) The licensee or applicant shall not distribute devices or products containing sealed sources unless the devices or sealed sources are manufactured and distributed in accordance with the registration and as authorized by a specific radioactive materials license issued by the department for such manufacture or distribution.

(e) The department shall not perform registration of devices or products containing sealed sources for persons outside the state.

(15) Each licensee who manufactures a nationally tracked source after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

Rulemaking Authority 404.051, 404.061, 404.071, 404.081 FS. Law Implemented 404.022, 404.051, 404.061, 404.081, 404.141 FS. History–New 7-17-85, Amended 8-25-91, 5-12-93, 1-1-94, 5-15-96, Formerly 10D-91.311, Amended 8-6-01, 9-28-06, 8-16-07, 2-28-08, 2-11-10, 12-26-13.

64E-5.211 Special Requirements for Issuance of Specific Licenses for Source Material Milling.

In addition to the requirements set forth in Rule 64E-5.208, F.A.C., a specific license for source material milling will be issued if the applicant submits to the Department an application as described herein and meets the other conditions specified below:

(1) An application for a license to receive title to, receive, possess and use source material for milling or by product material as defined in Part I shall address the following:

(a) Description of the proposed project or action;

(b) Area or site characteristics including geology, topography, hydrology and meteorology;

(c) Radiological and nonradiological impacts of the proposed project or action, including waterway and groundwater impacts;

(d) Environmental effects of accidents;

(e) Long-term impacts including decommissioning, decontamination and reclamation; and

(f) Site and project alternatives.

(2) The applicant shall not commence construction of the project until the Department has weighed the environmental, economic, technical and other benefits against the environmental costs and has concluded that the issuance of the license is appropriate.

(3) At least 1 full year prior to any major site construction, a preoperational monitoring program shall be conducted to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, an operational monitoring program shall be conducted to measure or evaluate compliance with applicable standards and regulations; to evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential longterm effects.

(4) Prior to issuance of the license, the applicant shall establish financial surety arrangements consistent with the requirements of Rule 64E-5.217, F.A.C.

(a) The amount of funds to be insured by financial surety arrangements shall be based on cost estimates which are furnished by the licensee and which the Department shall evaluate to determine that the cost estimates are reasonably comparable to other decontamination or decommissioning estimates in a plan for decontamination and decommissioning of mill buildings and the milling site to levels which would allow unrestricted use of these areas upon decommissioning, and the reclamation of tailings and waste disposal areas. The licensee shall submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and that evaluates alternatives for mitigating these impacts. In establishing specific surety arrangements, the licensee’s cost estimates shall take into account total costs that would be incurred if an independent contractor were hired to perform the decommissioning and reclamation work. In order to avoid unnecessary duplication and expense, the Department may accept financial sureties that have been consolidated with financial surety arrangements established to meet requirements of other Federal or state agencies or local governing bodies for such decommissioning, decontamination, reclamation and long-term site surveillance, provided such arrangements are considered adequate to satisfy these requirements and that portion of the surety which covers the decommissioning and reclamation of the mill, mill tailings site and associated areas, and the long-term funding charge are clearly identified. The licensee’s surety mechanism will be reviewed annually by the Department to assure that sufficient funds will be available for completion of the reclamation plan if the work had to be performed by an independent contractor. The amount of surety liability should be adjusted to recognize any increases or decreases resulting from inflation, changes in engineering plans, activities performed and any other conditions affecting costs. Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability shall be retained until final compliance with the reclamation plan is determined. This will yield a surety that is at least sufficient at all times to cover the costs of decommissioning, decontamination and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance could be provided with a surety instrument which is written for a specified period of time which must be automatically renewed unless the surety agent notifies the beneficiary, the Department and the licensee prior to the renewal date of their intention not to renew. In such a situation, the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief period of time to allow at least 60 days for the Department to collect.

(b) The total amount of funds for reclamation or long term surveillance and control shall be transferred to the United States if title and custody of such material and its disposal site is transferred to the United States upon termination of a license. Such funds include sums collected for long term surveillance and control. Such funds do not, however, include monies held as surety where no

default has occurred and the reclamation or other bonded activity has been performed.

(5) The applicant shall provide procedures describing the means employed to meet the following requirements during the operational phase of any project.

(a) Milling operations shall be conducted so that all effluent releases are below the limits of Part III and are as low as is reasonably achievable.

(b) The mill operator shall conduct daily inspections of any tailings or waste retention systems. Such inspections shall be conducted by a licensed engineer. Records of such inspections shall be maintained for review by the Department.

(c) The mill operator shall immediately notify the Department of the following:

1. Any failure in a tailings or waste retention system which results in a release of tailings or waste into unrestricted areas, and

2. Any unusual condition not contemplated in the design of the retention system which, if not corrected, could lead to failure of the system and result in a release of tailings or waste into unrestricted areas.

(6) Continued Surveillance Requirements for Source Material Mills Having Reclaimed Residues.

(a) The final disposition of tailings or wastes at source material milling sites should be such that the need for ongoing active maintenance is not necessary to preserve isolation. As a minimum, annual site inspections shall be conducted by the government agency retaining ultimate custody of the site where tailings or wastes are stored to confirm the integrity of the stabilized tailings or waste systems and to determine the need, if any, for maintenance and monitoring. Results of the inspection shall be reported to the U.S. Nuclear Regulatory Commission within 60 days following each inspection. The U.S. Nuclear Regulatory Commission may require more frequent site inspections, if, on the basis of a site-specific evaluation, such a need appears necessary due to the features of a particular tailings or waste disposal system.

(b) A minimum charge of $405,000 to cover the costs of long-term surveillance shall be paid by each mill operator to the Department prior to the termination of a uranium or thorium mill license. If site surveillance or control requirements at a particular site are determined, on the basis of a site-specific evaluation, to be significantly greater than those specified in (6)(a), above, additional funding requirements may be specified by the Department. The total charge to cover the cost of long-term surveillance shall be such that, with an assumed 1 percent annual real interest rate, the collected funds will yield interest in an amount sufficient to cover the annual costs of site surveillance. The charge will be assessed quarterly and will be reviewed annually by the Department to recognize or adjust for inflation.

Rulemaking Authority 404.051, 404.061, 404.0612, 404.071, 404.081, 404.111, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (7), (8), (11), 404.061(2), 404.0612, 404.071(1), 404.081(1), 404.111, 404.141 FS. History–New 7-17-85, Formerly 10D-91.312.

64E-5.212 Issuance of Specific Licenses.

(1) Upon a determination that an application meets the requirements of Chapter 404, Florida Statutes, and these regulations, the Department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

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

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

(b) Require reports and the keeping of records, and to provide for inspections of activities under the license; and

(c) Prevent loss or theft of material subject to this part.

(3) The department shall issue an expiration date authorizing each license to be valid for a period not to exceed 5 years from the last day of the issuance month. The department shall indicate the expiration date on each license. The licensee shall be granted a 90 day extension of the expiration date if written justification is submitted and approved by the department.

Rulemaking Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (8), 404.081(1), 404.141 FS. History–New 7-17-85, Amended 5-12-93, Formerly 10D-91.313.

64E-5.213 Specific Terms and Conditions of License.

(1) Each license issued pursuant to this part shall be subject to all the provisions of the applicable laws, now or hereafter in effect, and to all rules of the Department.

(2) No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control to any person unless the Department, after securing a completed specific license application and application fee from the transferee, has issued a proper license in accordance with the provisions of the Act.

(3)(a) Each specific or general licensee shall notify the Department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code (U.S.C.) by or against:

1. The licensee;

2. An entity, as that term is defined in 11 U.S.C. 101(14), controlling the licensee or listing the license or licensee as property of the estate; or

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

(b) This notification shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition for bankruptcy.

(4)(a) Each person licensed by the Department pursuant to this part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(b) Each person specifically licensed by the Department shall maintain a fixed facility located within the state of Florida.

(5) A separate license is required for the following:

(a) Each activity as designated by license category in paragraph 64E-5.204(2)(e), F.A.C.

(b) Facilities for which one or more of the following applies:

1. The facilities are not contiguous;

2. The facilities are not under a single radiation safety program; or

3. The facilities are not under the same management.

4. Temporary job sites lasting more than two years.

(c) Each facility operated by an out-of-state licensee under reciprocity as specified in Rule 64E-5.216, F.A.C., and does not meet the definition of a temporary job site.

(d) Each large irradiator as defined in Rule 64E-5.101, F.A.C.

(6) A separate license is not required for temporary job sites lasting less than two years or for each facility that is authorized under a broad scope license.

(7) A licensee shall notify the department in writing within 30 days after a radiation safety officer permanently discontinues performance of radiation safety officer duties.

(8) A licensee shall apply and receive a license amendment or Department approval:

(a) Before using radioactive material for a method or type or use not permitted by the license;

(b) Before permitting anyone to use radioactive material as an authorized user as authorized by the license;

(c) Before changing a radiation safety officer;

(d) Before ordering or receiving radioactive material in excess of the amount authorized on the license;

(e) Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and

(f) Before changing statements, representations, and procedures which are incorporated into the license.

(g) Identifying all sources or devices by manufacturer and model number as registered by the sealed source and device registry or for sources or devices not registered by the sealed source and device registry provide the information in subsection 64E-5.210(14), F.A.C.

Rulemaking Authority 404.051, 404.061 FS. Law Implemented 404.051(1), (4), 404.061(2), (3), 404.141 FS. History–New 7-17-85, Amended 4-4-89, 5-12-93, 8-29-94, Formerly 10D-91.314, Amended 5-18-98, 9-28-06, 2-11-10, 12-26-13.

64E-5.214 Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas.

(1) Except as provided in Part II, each specific license shall expire at the end of the specified day in the month and year stated therein. Each specific license revoked by the department expires at the end of the day on the date of the department's final order revoking the license or on the expiration date stated in the final order.

(2)(a) Each licensee shall notify the department in writing within 60 days of the occurrence of any of the following and either begin decommissioning its site or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release as specified in these rules or send a notice of a decommissioning plan within 12 months as specified in (4)(c) below and begin decommissioning upon approval of that plan.

1. The license has expired as specified in (1), above.

2. The licensee has ceased principal activities permanently at the entire site or in any separate building or outdoor area.

3. The licensee has conducted no principal activities under the license for 24 months.

4. The licensee has conducted no principal activities for 24 months in any separate building or outdoor area that contains residual radioactivity to the extent that the building or outdoor area is unsuitable for release as specified in these rules.

(b) The notification and request for termination of the license shall include the reports and information specified in (4)(a)4. and 5., below.

(3) No less than 30 days before the expiration date specified in the license, the licensee shall either:

(a) Submit an application for license renewal on the same form used for the initial application under Part II, or

(b) Notify the Department, in writing, if the licensee decides not to apply for license renewal.

(4)(a) If a licensee does not submit an application for license renewal under Part II, the licensee shall, on or before the expiration date specified in the license:

1. Terminate the use of radioactive material;

2. Remove residual radioactivity to the extent acceptable to the Department;

3. Properly dispose of the radioactive material;

4. Submit a properly completed DH Form 1059, which is herein incorporated by reference effective 7-17-85; and

5. Submit a radiation survey report to confirm the absence of radioactive materials or to establish the levels of residual radioactivity, unless the licensee demonstrates the absence of residual radioactivity in some other manner. The licensee shall, as appropriate:

a. For gamma radiation, report levels of radiation in units of microroentgens per hour at 10 centimeters and at 1 meter from surfaces.

b. For alpha and beta radiation, report levels of radioactivity in units of transformations per minute or microcuries per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete; and

c. Specify the instruments used and certify that each instrument is properly calibrated or tested.

(b)1. If no residual radioactivity attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable residual radioactivity was found.

2. Specific licenses including expired licenses will be terminated by written notice to the licensee when the department determines that:

a. Radioactive material has been properly disposed; and

b. A radiation survey has been performed which demonstrates that the premises are suitable for release for unrestricted use or satisfies the requirements specified in Rule 64E-5.221, 64E-5.222, 64E-5.223, or 64E-5.224, F.A.C.; or

c. Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release for unrestricted use or satisfies the requirements specified in Rule 64E-5.221, 64E-5.222, 64E-5.223 or 64E-5.224, F.A.C.; or

d. Department has received the following records, if requested:

(I) Disposal records specified in Rule 64E-5.330, subsections 64E-5.331(1)(a), (c), (2), (3), or paragraph 64E-5.336(2)(d), F.A.C.; and

(II) Records specified in subsection 64E-5.214(6), F.A.C.

(c)1. If detectable levels of residual radioactivity attributable to activities conducted under the license are found or licensee possesses other radioactive materials, the license continues in effect beyond the expiration date, if necessary, with respect to

possession of residual radioactivity present or possession of radioactive material, until the department notifies the licensee in writing that the license is terminated. During this time, the licensee is subject to the provisions of (5), below.

2. In addition to the information submitted under (4)(a)4. and 5., above, the licensee shall submit a plan for decommissioning if decommissioning procedures have not been approved previously by the department and could impact the health and safety of workers or the public as follows:

a. More than routine cleanup and maintenance is required;

b. Workers will be in areas with significantly increased surface contamination or radiation levels;

c. Procedures will result in significantly greater airborne concentrations of radioactive materials; or

d. Procedures will result in significantly greater releases of radioactive material to the environment.

3. Procedures which could potentially impact health, safety and the environment may not be performed until the decommissioning plan has been approved.

4. The proposed decommissioning plan must include:

a. A description of the planned decommissioning activities;

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

c. The time required to complete the decommissioning plan; and

d. A description of the planned final radiation survey.

5. The proposed decommissioning plan will be reviewed by the department and approved or additional information will be requested within 60 days.

6. Upon approval of the decommissioning plan by the department, the licensee shall complete decommissioning in accordance with the approved plan. As a final step in decommissioning, the licensee shall again submit the information required in (4)(a)5., above, of this section and shall certify the disposition of accumulated wastes from decommissioning.

7. If the information submitted as specified in (4)(a)5. or (4)(c)6. of this section does not adequately demonstrate that the premises are suitable for unrestricted use or does not satisfy the requirements specified in Rule 64E-5.221, 64E-5.222, 64E-5.223, or 64E-5.224, F.A.C., the department will inform the licensee of the appropriate further actions required for termination of the license.

(5) Each licensee who possesses radioactive material under (4)(c), above, following the expiration date specified in the license shall:

(a) Limit actions involving radioactive material to those related to decontamination, decommissioning, and other activities related to preparation for release for unrestricted use; and

(b) 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.

(6) Each licensee shall keep records of the decommissioning of the facility in an identified location until the license is terminated by the department. If records of relevant information are kept for other purposes, reference to these records and their location can be used. Records which must be kept include:

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

(b) Drawings of structures as originally built, of modifications, and of equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes which can be subject to contamination. Drawings and their location can be referenced if not on site. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(c) Except for areas containing only radioactive materials having half-lives of less than 65 days or sealed sources that either have not leaked or no contamination remains after any leak, a list contained in a single document and updated every 2 years, of the following:

1. All areas designated and formerly designated restricted areas as defined in Rule 64E-5.101, F.A.C.;

2. All areas outside of restricted areas that require documentation under paragraph 64E-5.214(6)(a), F.A.C.;

3. All areas outside of restricted areas where current and previous wastes have been buried as documented under Rule 64E-5.340, F.A.C.; and

4. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or satisfy the requirements specified in Rule 64E-5.221, 64E-5.222, 64E-5.223, or 64E-5.224, F.A.C.; and

(d) Records of the cost estimate performed for the performance bond required in Rule 64E-5.217, F.A.C., and records of the funding method used.

(7) Confirmatory or closeout surveys will be performed by the department according to the Closeout Inspection and Survey Procedures, November 1991, which are herein incorporated by reference and which are available from the department.

Rulemaking Authority 404.051(4), (6), (9), 404.061(2), 404.081 FS. Law Implemented 404.051(1), (4), (6), (9), 404.061(2), 404.081(1) FS. History– New 7-17-85, Amended 5-12-93, 8-14-96, Formerly 10D-91.315, Amended 5-18-98, 10-8-00, 12-19-01.

64E-5.215 Transfer of Material.

(1) No licensee shall transfer radioactive material except as authorized pursuant to this section.

(2) Except as otherwise provided in his license and subject to the provisions of (3) and (4), below, a licensee may transfer radioactive material:

(a) To the Department after receiving approval from the Department;

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

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

(d) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, a Licensing State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Department, an Agreement State or a Licensing State.

(3) Before transferring radioactive material to a specific licensee of the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, a Licensing State or to a general licensee who is required to register with the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form and quantity of radioactive material to be transferred.

(4) Any of the following methods for the verification required by (3), above, are applicable:

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

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

(c) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license to receive the type, form and quantity of radioactive material to be transferred, specifying the license number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within 10 days.

(d) The transferor may obtain other information compiled by a reporting service from official records of the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State regarding the identity of licensees and the scope and expiration dates of the licenses.

(e) When none of the methods of verification described in (4)(a) through (d), above, 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 for the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State that the transferee is licensed to receive the radioactive material.

(5) Shipment and transport of radioactive material shall be in accordance with the provisions of Part XV.

Rulemaking Authority 404.051, 404.061, 404.081, 404.141, 404.20 FS. Law Implemented 404.022, 404.051(1), (2), (4), (11), 404.061(2), 404.081(1), 404.20(1) FS. History–New 7-17-85, Formerly 10D-91.319.

64E-5.216 Reciprocal Recognition of Licenses for Byproduct, Source, Naturally Occurring and Accelerator Produced Radioactive Material, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

(1) Subject to these regulations, any person who holds a specific license from the NRC, or an Agreement State and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, will be granted a general license by the Department to conduct the activities authorized in such licensing document within the State of Florida, except for areas of exclusive federal jurisdiction, for a period not in excess of 180 consecutive days provided that:

(a) The out-of-state license document does not limit the performance of the function authorized by such document to specified installations or locations;

(b) The out-of-state licensee notifies the Department in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner;

(c) The out-of-state licensee complies with these applicable regulations and with all the terms and conditions of the licensing document, except any such terms and conditions that are inconsistent with these applicable regulations; and

(d) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this section except by transfer to a person who is specifically licensed by the Department, by the NRC, an Agreement State or a Licensing State to receive such material.

(e) Any licensee using or storing radioactive material at any location not listed on the license for a period in excess of 180 days in a calendar year, shall notify the department with the information listed in paragraph 64E-5.216(1)(b), F.A.C., prior to exceeding the 180 days.

(2) In addition to the provisions of subsection (1), above, any person who holds a specific license issued by the NRC, an agreement state, or a licensing state authorizing the holder to manufacture, transfer, install or service a device described in paragraph 64E-5.206(4)(a), F.A.C., within areas subject to the jurisdiction of the licensing body may be granted a general license by the Department to install, transfer, demonstrate or service such a device in this State provided that:

(a) Such person shall file 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 such report shall identify each general licensee to whom such device is transferred by name and address, the type of radioactive material contained in the device;

(b) The device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State;

(c) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that “Removal of this label is prohibited”; and

(d) The holder of the specific license shall furnish to each general licensee to whom he transfers such device, or on whose premises he installs such device, a copy of the general license contained in subsection 64E-5.206(4), F.A.C., or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

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

Rulemaking Authority 404.051(4), (11), 404.061(2) FS. Law Implemented 404.051(1), (2), (4), (6), (11), 404.061(2), 404.081(1) FS. History–New 7-17-85, Amended 4-4-89, Formerly 10D-91.321, Amended 10-8-00, 2-28-08, 2-11-10, 12-26-13.

64E-5.217 Bonding of Persons Licensed Pursuant to Subpart II C.

(1) Any applicant or licensee who is not exempt by the provisions of this subpart shall provide a performance bond.

(a) The bond shall be payable to the State of Florida and shall be in an amount determined by the department as sufficient to provide for the protection of the environment and the public health and safety in the event of abandonment, insolvency or other inability of the licensee to meet the requirements of the department. The department shall use (3), below, of this part to determine the amount of the bond required for each applicant or licensee. The mathematical product of the risk factors will be the amount of the required bond in dollars. In the event that an applicant or licensee feels that the amount of the bond determined by the use of the applicable risk factors is inappropriate, he may submit evidence to the department in support of a change to the bond amount. The department shall determine whether the evidence supports the requested change in the bond amount.

(b) An applicant or licensee may apply to the Department for exemption from the requirement of a bond if he can demonstrate that funds will accrue to the State of Florida which are sufficient to provide for the protection of the environment and the public health and safety in the event of abandonment, insolvency or other inability of the licensee to meet the requirements of the Department. If the Department does not grant the exemption from the requirement of a bond, the licensee may request a hearing in accordance with the provisions of Chapter 120, Florida Statutes.

(c) Licensees must provide the required bond within 90 days after being given notice by the Department of the requirements of a bond and its amount.

(d) The Department may re-evaluate, at any time, the adequacy of an existing bond or guaranty and may require an adjustment by either increasing or decreasing the amount of the bonding or guaranty required.

(e) A bond may be issued by a fidelity or surety company authorized to do business in the State of Florida or it may be a cash bond. The bond must initially provide for at least 24 months of coverage from the date of issuance and at no time thereafter shall the period of coverage be less than 12 months, for as long as the license remains in effect.

(f) The Department may order the bond to be forfeited if it finds any of the following:

1. The facility or site has been abandoned;

2. The licensee is insolvent; or

3. The licensee is unable to perform to the satisfaction of the Department.

(g) Upon determining that a bond shall be forfeited, the Department shall issue a notice to that effect.

(2) The following are exempt from the provisions of this subpart:

(a) Other governmental agencies;

(b) Educational institutions accredited by the Southern Association of Colleges and Schools and such other educational institutions as may be specifically exempted by the Department if the Department determines that such exemption will not endanger the public health, safety and welfare.

(c) Licensees of the State Licensing Board for the Healing Arts and those medical facilities possessing or using radioactive materials for medical purposes when supervised by such licensees.

(d) Any licensee whose mathematical product of the risk factors in (3), below, is less than 15,000.

(3) Risk factors for purposes of bonding:

Radioisotopes	Risk Factors	Physical Form	Factors
U-nat, U-235, U-238, and associated decay products	1	Non-encapsulated form	20
		Single encapsulated or source plated	3
Transuranics, Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227, Ac-225, I-129	50		
Th-nat, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-126, I-131, I-133			
I-125, H-3, C-14	5		
Half-Life of	Risk	Facility	Risk

Radioisotope	Factors	and Procedure	Factors
Greater than 6 years	30	Greater than 5000 ft.2	
6 months to 6 years	10	– High Risk	30
10 days to 6 months	5	– Low Risk	10
		500 to 5000 ft.2	
		– High Risk	10
		– Low Risk	5
		Less than 500 ft.2	
		– High Risk	5

Activity	Risk Factors	Activity	Risk Factors
Greater than 100,000 curies	2,000	License issued for storage only	3
10,000 to 100,000 curies	1,000		
1,000 to 10,000 curies	500		
100 to 1,000 curies	200		
10 to 100 curies	30		
1 to 10 curies	2		
License issued for manufacturing, benefication or processing of non-encapsulated radioactive materials	3	Sealed sources – not contained in a device with integral solid shielding	3

Rulemaking Authority 404.051, 404.061, 404.111, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), 404.061(2), 404.111, 404.141 FS. History–New 7-17-85, Amended 4-4-89, 5-12-93, Formerly 10D-91.322.

64E-5.218 Performance of Inspections.

(1) Radioactive material inspections may be announced or unannounced.

(2) Inspection procedures for all license categories will include the following:

(a) At the time of entrance to a facility, the department will inform the licensee management if available the purpose, extent, and approximate length of time required to complete the inspection;

(b) Consultation with workers in accordance with Rule 64E-5.905, F.A.C., may be performed;

(c) The department will review any or all records that are required to be maintained by these regulations or by license conditions;

(d) Radiation surveys will be performed to determine compliance with the regulations and license. The department's radiation detection and monitoring equipment will be operable and calibrated as required by these regulations;

(e) Upon completion of an inspection, the department will inform the licensee of the preliminary findings of the inspection prior to leaving the facility, if possible. Official notification of the inspection findings will be sent in writing to the licensee.

(3) The department will perform inspections to assure the radioactive materials are used only as specified in these regulations or in the license using instruments calibrated as specified in these regulations.

Rulemaking Authority 404.022, 404.042, 404.051, 404.061, 404.071, 404.081 FS. Law Implemented 404.022, 404.042, 404.051(1), (4), (6), (9), (10), 404.061(2), (3), 404.071(1), 404.081(1) FS. History–New 5-12-93, Formerly 10D-91.324.

64E-5.219 Emergency Planning.

(1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Rule 64E-5.220, F.A.C., must contain either:

(a) An evaluation showing that the maximum dose to a person off-site due to a release of radioactive materials would not exceed 1 rem (10 mSv) effective dose equivalent or 5 rem (50 mSv) to the thyroid; or

(b) An emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors can be used to support an evaluation submitted under (1)(a) of this section:

(a) The radioactive material is physically separated so that only a portion could be involved in an accident.

(b) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged.

(c) The release fraction in the respirable size range would be lower than the release fraction shown in Rule 64E-5.220, F.A.C., due to the chemical or physical form of the material.

(d) The solubility of the radioactive material would reduce the dose received.

(e) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Rule 64E-5.220, F.A.C.

(f) Operating restrictions or procedures would prevent a release fraction as large as that shown in Rule 64E-5.220, F.A.C.

(g) Other factors appropriate for the specific facility.

(3) Each application to possess source material in the form of uranium hexafluoride in excess of 50 kilograms in a single container or 1,000 kilograms total must contain either:

(a) An evaluation showing that the maximum intake of uranium by a member of the public due to a release would not exceed 2 milligrams; or

(b) An emergency plan for responding to the radiological hazards of an accidental release of source material and to any associated chemical hazards.

(4) One or more of the following factors can be used to support an evaluation submitted under (3)(a) of this section:

(a) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged.

(b) Facility design or engineered safety features in the facility would reduce the amount of the release.

(c) Other factors pertaining to the specific facility.

(5) Each application to possess special nuclear material in the form of uranium hexafluoride in excess of 50 kilograms in a single container or 1,000 kilograms total, or in excess of 2 curies (74 GBg) of plutonium in unsealed form or on foils or plated sources, must contain either:

(a) An evaluation showing that the maximum dose to a member of the public off-site due to a release of radioactive materials would not exceed 1 rem (10mSv) effective dose equivalent; or

(b) An emergency plan for responding to the radiological hazards of an accidental release of special nuclear material and to any associated chemical hazards.

(6) One or more of the following factors can be used to support an evaluation submitted under (5)(a) of this section:

(a) The radioactive material is physically separated so that only a portion could be involved in an accident.

(b) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged.

(c) In the case of fires or explosions, the release fraction would be lower than 0.001 due to the chemical or physical form of the material.

(d) The solubility of the material released would reduce the dose received.

(e) The facility design or engineered safety features in the facility would cause the release fraction to be lower than 0.001.

(f) Operating restrictions or procedures would prevent a release large enough to cause a member of the public off-site to receive a dose exceeding 1 rem (10mSv) effective dose equivalent.

(g) Other factors pertaining to the specific facility.

(7) An emergency plan responding to a release of radioactive material submitted under (1)(b), (3)(b) or (5)(b) of this section must include the following information:

(a) A brief description of the licensee’s facility and area near the site.

(b) An identification of each type of radioactive materials accident for which protective actions could be needed.

(c) A classification system for classifying accidents as alerts or site area emergencies.

(d) Identification of the means of detecting each type of accident in a timely manner.

(e) A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on site, and a description of the program for maintaining the equipment.

(f) A brief description of the methods and equipment to assess releases of radioactive materials.

(g) A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying off-site response organizations and the department and the responsibilities of licensee personnel for developing, maintaining, and updating the plan.

(h) A commitment to and a brief description of the means to promptly notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured on-site workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, or some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the department immediately after notification of the appropriate off-site response organizations and not later than 1 hour after the licensee declares an emergency.

(i) A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and the department.

(j) A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency, including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(k) A brief description of the means of restoring the facility to a safe condition after an incident.

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

(m) A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant’s activities at the proposed place of use of the radioactive material.

(8) The licensee shall allow the off-site response organizations expected to respond in case of an accident 60 days to comment on the licensee’s emergency plan before submitting it to the department. The licensee shall provide any comments received within the 60 days to the department with the emergency plan.

Rulemaking Authority 404.022, 404.042, 404.051, 404.061, 404.071, 404.081 FS. Law Implemented 404.022, 404.042, 404.051(1), (4), (6), (9), (10), 404.061(2), (3), 404.071(1), 404.081(1) FS. History–New 5-12-93, Formerly 10D-91.326.

64E-5.220 Radioactive Quantities.

(1) Listed below are the quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release as required in Rule 64E-5.219, F.A.C.:

Material	Release Fraction	Curies
Actinium 228	.001	4,000
Americium 241	.001	2
Americium 242	.001	2
Americium 243	.001	2
Antimony 124	.01	4,000
Antimony 126	.01	6,000
Barium 133	.01	10,000
Barium 140	.01	30,000
Bismuth 207	.01	5,000
Bismuth 210	.01	600
Cadmium 109	.01	1,000
Cadmium 113	.01	80
Calcium 45	.01	20,000
Californium 252	.001	9
Carbon 14	.01 (non CO_2)	50,000
Cerium 141	.01	10,000
Cerium 144	.01	300
Cesium 134	.01	2,000
Cesium 137	.01	3,000
Chlorine 36	.5	100
Chromium 51	.01	300,000
Cobalt 60	.001	5,000
Copper 64	.01	200,000
Curium 242	.001	60
Curium 243	.001	3
Curium 244	.001	4
Curium 245	.001	2
Europium 152	.01	500
Europium 154	.01	400
Europium 155	.01	3,000
Gadolinium 153	.01	5,000
Germanium 68	.01	2,000
Gold 198	.01	30,000
Hafnium 172	.01	400
Hafnium 181	.01	7,000
Holmium 166m	.01	100
Hydrogen 3	.5	20,000
Iodine 125	.5	10
Iodine 131	.5	10
Indium 114m	.01	1,000
Iridium 192	.001	40,000
Iron 55	.01	40,000
Iron 59	.01	7,000
Krypton 85	1.0	6,000,000
Lead 210	.01	8

Manganese 56	.01	60,000
Mercury 203	.01	10,000
Molybdenum 99	.01	30,000
Neptunium 237	.001	2
Nickel 63	.01	20,000
Niobium 94	.01	300
Phosphorus 32	.5	100
Phosphorus 33	.5	1,000
Polonium 210	.01	10
Potassium 42	.01	9,000
Promethium 145	.01	4,000
Promethium 147	.01	4,000
Radium 226	.001	100
Ruthenium 106	.01	200
Samarium 151	.01	4,000
Scandium 46	.01	3,000
Selenium 75	.01	10,000
Silver 110m	.01	1,000
Sodium 22	.01	9,000
Sodium 24	.01	10,000
Strontium 89	.01	3,000
Strontium 90	.01	90
Sulfur 35	.5	900
Technetium 99	.01	10,000
Technetium 99m	.01	400,000
Tellurium 127m	.01	5,000
Tellurium 129m	.01	5,000
Terbium 160	.01	4,000
Thulium 170	.01	4,000
Tin 113	.01	10,000
Tin 123	.01	3,000
Tin 126	.01	1,000
Titanium 44	.01	100
Vanadium 48	.01	7,000
Xenon 133	1.0	900,000
Yttrium 91	.01	2,000
Zinc 65	.01	5,000
Zirconium 93	.01	400
Zirconium 95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma	.001	10,000
Any other alpha emitter	.001	2

Contaminated equipment, alpha	.0001	20
Packaged waste, alpha	.0001	20

(2) For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in this section exceeds one.

(3) Waste packaged in Type B containers as specified in Rule 64E-5.101, F.A.C., does not require an emergency plan.

Rulemaking Authority 404.022, 404.042, 404.051, 404.061, 404.071, 404.081 FS. Law Implemented 404.022, 404.042, 404.051(1), (4), (6), (9), (10), 404.061(2), (3), 404.071(1), 404.081(1) FS. History–New 5-12-93, Formerly 10D-91.327.

64E-5.221 Radiological Criteria for License Termination.

The criteria in this subpart apply to the decommissioning of facilities licensed under this chapter but do not apply to uranium and thorium recovery facilities as specified in Rule 64E-5.211, F.A.C., or to sites which previously have submitted and received department approval of a license termination plan or decommissioning plan as specified in subsection 64E-5.214(2), F.A.C.

(1) After a site has been decommissioned and the license terminated in accordance with the criteria in this subpart, the department will require additional cleanup only if based on new information or if it determines that the criteria of this subpart were not met and residual activity remaining at the site could result in significant threat to public health and safety.

(2) When calculating total effective dose equivalent to the average member of the critical group, the licensee shall determine the peak annual total effective dose equivalent expected within the first 1,000 years after decommissioning.

Rulemaking Authority 404.051(4), (6), (9), 404.061(2), 404.081 FS. Law Implemented 404.051(1), (4), (6), (9), 404.061(2), 404.081(1) FS. History– New 12-19-01.

64E-5.222 Radiological Criteria for Unrestricted Use.

A site is acceptable for unrestricted use if the total effective dose equivalent to an average member of the critical group from the residual radioactivity that is distinguishable from background radiation does not exceed 25 millirem (0.25 mSv) per year including radioactivity from groundwater sources of drinking water and the residual radioactivity levels are as low as reasonably achievable. Determination of the ALARA levels must take into account any detriments such as deaths from transportation accidents potentially expected to result from decontamination and waste disposal.

Rulemaking Authority 404.051(4), (6), (9), 404.061(2), 404.081 FS. Law Implemented 404.051(1), (4), (6), (9), 404.061(2), 404.081(1) FS. History– New 12-19-01.

64E-5.223 Criteria for License Termination Under Restricted Conditions.

A site is acceptable for license termination under restricted conditions if it meets the criteria below.

(1) The residual levels associated with restricted conditions are ALARA or the licensee can demonstrate that further reductions in residual radioactivity to comply with the provisions of Rule 64E-5.222, F.A.C., would result in an increase in public or environmental harm. Determination of the ALARA levels must take into account any detriments such as traffic accidents potentially expected to result from decontamination and waste disposal.

(2) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 millirem (0.25 mSv) per year.

(3) The licensee has provided sufficient financial assurance to enable an independent third party including a governmental custodian of a site to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

(a) Funds sufficient to pay decommissioning costs placed into an account segregated from the licensee’s assets and outside the licensee’s administrative control before the start of decommissioning operations; or

(b) A bond as specified in Rule 64E-5.217, F.A.C., or

(c) An arrangement deemed acceptable by the governmental entity that is assuming custody and ownership of a site.

(4) The licensee has submitted a decommissioning or license termination plan as specified in subsection 64E-5.214(2), F.A.C., to the department indicating the licensee's intent to decommission in accordance with this part and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the license termination or decommissioning plan how the advice of individuals and institutions in the community who could be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

(a) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters:

1. Whether provisions for institutional controls proposed by the licensee:

a. Will provide reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 millirem (0.25 mSv) per year;

b. Will be enforceable; and

c. Will not impose undue burdens on the local community or other affected parties.

2. Whether the licensee has provided sufficient financial assurance to enable an independent third party including a governmental custodian of a site to assume and carry out responsibilities for any necessary control and maintenance of the site.

(b) In seeking advice on the issues identified in (a), above, the licensee shall provide for:

1. Participation by representatives of a broad cross section of community interests who could be affected by the decommissioning;

2. An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

3. A publicly available summary of the results of all such discussions including a description of the individual viewpoints of the participants on the issues and the extent of agreement or disagreement among the participants on the issues.

(5) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect there is reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed 100 millirem (1 mSv) per year.

Rulemaking Authority 404.051(4), (6), (9), 404.061(2), 404.081 FS. Law Implemented 404.051(1), (2), (3), (4), (6), (9), 404.061(2), 404.081(1) FS. History–New 12-19-01.

64E-5.224 Alternate Criteria for License Termination.

The department will terminate a license using alternate criteria greater than the dose criterion of Rule 64E-5.222, subsection 64E-5.223(2), and sub-subparagraph 64E-5.223(4)(a)1.a., F.A.C., if the licensee:

(1) Provides assurance that public health and safety would continue to be protected and that it is unlikely that the total effective dose equivalent from all combined man-made sources other than medical sources would be more than 100 millirem per year (1 millisievert per year) by submitting an analysis of possible sources of exposure;

(2) Has employed restrictions to the extent practical on site use according to the provisions of Rule 64E-5.223, F.A.C., in minimizing exposures at the site;

(3) Reduces doses to ALARA levels considering any detriments such as traffic accidents potentially expected to result from decontamination and waste disposal; and

(4) Has submitted a decommissioning or license termination plan to the department indicating the licensee's intent to decommission as specified in subsection 64E-5.214(2), F.A.C., and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the license termination or decommissioning plan how the advice of individuals and institutions in the community who could be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

(a) Participation by representatives of a broad cross section of community interests who could be affected by the decommissioning;

(b) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(c) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement on the issues.

(5) The use of alternate criteria to terminate a license requires the approval of the department after consideration of any comments provided by the U. S. Environmental Protection Agency and any public comments submitted as specified in Rule 64E-5.225, F.A.C.

Rulemaking Authority 404.051(4), (6), (9), 404.061(2), 404.081 FS. Law Implemented 404.051(1), (2), (4), (6), (9), 404.061(2), 404.081(1) FS. History–New 12-19-01.

64E-5.225 Public Notification and Public Participation.

Upon the receipt of a license termination or decommissioning plan or a proposal for release of a site as specified in Rule 64E-5.223 or 64E-5.224**,** F.A.C., and the total effective dose equivalent will exceed 50 millirem (0.5 mSv), the department shall:

(1) Notify and solicit comments from:

(a) Local and other state governments in the vicinity of the site and any Indian Nation or other indigenous people that could be affected by the decommissioning; and

(b) The U. S. Environmental Protection Agency if the licensee proposes to release a site as specified in Rule 64E-5.224**,** F.A.C.

(2) Publish a notice in the Florida Administrative Weekly to solicit comments from affected parties.

Rulemaking Authority 404.051(4), (6), (9), 404.061(2), 404.081 FS. Law Implemented 404.051(1), (2), (4), (6), (9), 404.061(2), 404.081(1) FS. History–New 12-19-01.

64E-5.226 Minimizing Contamination.

After the effective date of this rule, applicants for licenses other than renewals shall describe in the application how facility design and procedures for operation will minimize contamination of the facility and the environment to the extent practical, facilitate eventual decommissioning, and minimize the generation of radioactive waste to the extent practical.

Rulemaking Authority 404.051(4), (6), (9), 404.061(2), 404.081 FS. Law Implemented 404.051(1), (4), (6), (9), 404.061(2), 404.081(1) FS. History– New 12-19-01.