July 9, 2015

Pamela Henderson, Deputy Director
Division of Material Safety, State, Tribal
and Rulemaking Programs
U.S. Nuclear Regulatory Commission
Sent only via e-mail to AgreementStateRegs.Resource@NRC.gov

Dear Ms. Henderson:

Enclosed is a copy of the final revisions to the Florida Radiation Hazard Regulations Florida Administrative Code Rule 64E-5.206 addressing the issue identified in NRC's March 6, 2015 letter to Cynthia Becker (enclosed) regarding changes needed to complete RATS 2012-1. We have highlighted the changes made to this rule which may also be found at https://www.flrules.org/gateway/RuleNo.asp?title=CONTROL OF RADIATION HAZARDS&ID=64E-5.206.

We believe that this revision satisfies the RATS 2012-1 compatibility category established in the (FSME) Procedure SA-200.

Please contact me if you have any questions or need further clarification. My phone number is (850) 245-4043 or you may reach me by e-mail at Mike.Stephens@FLHealth.gov.

Sincerely,

Michael N. Stephens
Environmental Program Health Consultant
Bureau of Radiation Control
www.floridahealth.gov/prevention-safety-and-wellness/radiation-control/index.html

Enclosures: 64E-5.206, FAC Final Rule
NRC March 6, 2015 Letter

cc: Cindy Becker, Chief Bureau of Radiation Control
Charles Hamilton, Administrator, Radioactive Materials Section
Donna Janda, NRC RASO Region I Donna.Janda@nrc.gov

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 21 C.F.R. Part 179, section 179.21, April 1, 2013 edition, and is herein incorporated by reference and may be obtained from the internet at http://www.flrules.org/Gateway/reference.asp?No=Ref-05471 or at http://www.gpo.gov/fdsys/pkg/CFR-2013-title21-vol3/pdf/CFR-2013-title21-vol3-part179-subpartB.pdf.

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- and/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.

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.

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.

(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.

(11) Certain Items and Self-Luminous Products Containing Radium-226.

(a) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of subsections 64E-5.206(11)(b), (c), and (d), F.A.C., radium-226 contained in the following products manufactured prior to November 30, 2007.

1. Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanatory jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

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

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

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

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

(b) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in paragraph 64E-5.206(11)(a), F.A.C., of this section are exempt from the provisions of Parts III and IX, to the extent that the receipt, possession, use, or transfer of radioactive materials is within the terms of the general license. This exemption shall not apply to any such person specifically licensed under Chapter 64E-5, F.A.C.

(c) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in subsection 64E-5.206(11)(a), F.A.C., must also comply with the following requirements:

1. Shall notify the Department should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Department within 30 days;

2. Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to Rule 64E-5.328, F.A.C., or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the Department;

3. Shall not export products containing radium-226 except in accordance with 10 C.F. R. Part 110, 1-1-14 edition which is herein incorporated by reference and can be obtained from the internet at http://www.flrules.org/Gateway/reference.asp?No=Ref-05472 or at http://www.gpo.gov/fdsys/pkg/CFR-2014-title10-vol2/pdf/CFR-2014-title10-vol2-part110.pdf;

4. Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under Part III, or equivalent regulations of an Agreement State or the NRC, as otherwise approved by the Department.

5. 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.

(d) Except for disassembly and repair of timepieces described in subparagraph 64E-5.206(11)(a)2., F.A.C., the general license in paragraph 64E-5.206(11)(a), F.A.C., does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226.

Rulemaking Authority 404.051, 404.061, 404.071 FS. Law Implemented 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, 7-1-15.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 6, 2015

Ms. Cynthia L. Becker, Chief
Bureau of Radiation Control
Florida Department of Health
4052 Bald Cypress Way, Bin C21
Tallahassee, FL 32399-1741

Dear Ms. Becker:

We have reviewed the final revision to the Florida regulations F.A.C. Chapter 64E-5, received by our office on January 27, 2015. These regulations were reviewed by comparison to the equivalent U.S. Nuclear Regulatory Commission (NRC) rules and the requirements of the two amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Mike Stephens on March 3, 2015.

As a result of our review, we have one comment that has been identified in the enclosure. Please note that we have limited our review to regulations required for compatibility and/or health and safety. We have determined that if these regulations are revised, incorporating our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements."

We request that when you revise your regulations to address our comment, a copy of the "as published" regulations be provided to us for review. As requested in NMSS Procedure SA-201, "Review of State Regulatory Requirements," please highlight the location of any changes made by Florida, in response to our comment, and provide a copy to Division of Material Safety, State, Tribal, and Rulemaking Programs, NMSS. The SRS Data Sheet summarizes our knowledge of the status of other Florida regulations, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the NMSS Web site: http://nrc-stp.ornl.gov/rulemaking.html.

If you have any questions regarding the comment, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact Michelle Beardsley, State Regulation Review Coordinator, at (610) 337-9642 (Michelle.Beardsley@nrc.gov) or David Spackman at (301) 415-6389 (David.Spackman@nrc.gov).

Sincerely,

/RA/

Pamela J. Henderson, Deputy Director
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Enclosures:
1. Compatibility Comment
2. Florida SRS Data Sheet

DISTRIBUTION: SP05
DIR RF (15-06)
Monica Ford, RSAO
Bob Gallaghar, Acting RSAO
Florida File

OFFICE	ASPB	ASPB	OGC	ASPB:BC	MSTR:DD
NAME	DSpackman	Via e-mail MBeardsley	CEngland for MSpencer	CEinberg	PHenderson
DATE	2/ /15	2/09/15	2/27/15	3/3/15	3/6/15

ML15040A577 **OFFICIAL RECORD COPY** **Package ML15028A080**

COMPATIBILITY COMMENT ON FLORIDA FINAL REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	64E-5.206(4)(c).2.b	31.5(c)(2)(ii)	2012-1	C	**Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere** Florida's regulation uses the word "or" in place of NRC's use of the phrase "and/or." in section 64E-5.206(4)(c).2.b. Florida should change 64E-5.206(4)(c).2.b to read "…of other beta- and/or gamma-emitting material…" because the current regulation is less restrictive than 31.5(c)(2)(ii). Florida needs to make the above change to 64E-5.206(4)(c).2.b in order to meet the Compatibility Category C designation assigned to 10 CFR 31.5.