FLORIDA DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL
RADIOACTIVE MATERIALS SECTION
4052 BALD CYPRESS WAY, BIN #C21
TALLAHASSEE, FLORIDA 32399-1741

CERTIFICATE – *IN VITRO* TESTING WITH RADIOACTIVE MATERIAL UNDER GENERAL LICENSE

Subsection 64E-5.206(8), Florida Administrative Code (F.A.C.), establishes a general license authorizing physicians, veterinarians, clinical laboratories and hospitals to possess certain small quantities of radioactive material for in vitro clinical or laboratory tests not involving the internal or external administration of the radioactive material or the radiation therefrom to human beings or animals. Possession of radioactive material under 64E-5.206(8), F.A.C., is not authorized until the physician, veterinarian, clinical laboratory, or hospital has filed Department of Health (DOH) form, DH 360 and received from DOH a validated copy of DH 360 with certification number.

INSTRUCTIONS: Submit the original and one copy of this form to the **Department of Health, Bureau of Radiation Control, 4052 Bald Cypress Way, Bin C21, Tallahassee, Florida 32399-1741**. A certification number will be assigned and a validated copy of this form will be returned. Please print or type the name and address (including ZIP Code), of the physician, veterinarian, clinical laboratory or hospital for whom or for which this form is filed:

1.

NAME:_____

ADDRESS:_____

_____

PHONE: (_____)_____

If place of use is different from address above, please give complete address:

ADDRESS:_____

_____

2. I hereby apply for certification pursuant to 64E-5.206(8), F.A.C., for use of radioactive material for:

a. _____Myself, a duly licensed physician authorized to dispense drugs in the practice of medicine.
b. _____Myself, a duly licensed veterinarian.
c. _____The above-named clinical laboratory.
d. _____The above-named hospital.

3. Enclosed is my payment of: $_____.

4. CERTIFICATION: I HEREBY CERTIFY THAT:

a) Appropriate radiation measuring instruments are available to carry out the tests for which radioactive material will be used under the general license of 64E-5.206(8). F.A.C. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the radioactive material.

b) I understand that DOH regulations require that any change in the information furnished on this certificate be reported to DOH within 30 days from the date of such change.

c) I have read and understand the provisions of Subsection 64E-5.206(8), F.A.C.; and I understand that I am required to comply with those provisions as to all radioactive material which I receive, possess, use, or transfer under the general license for which this Certificate is filed with DOH.

d) All information in this certificate is true and complete.

Date:_____ By:_____
(Print Name and Title of Person Filing Form.)

Certification No.: Expires On:

_____

GENERAL LICENSE FOR USE OF RADIOACTIVE MATERIALS FOR CERTAIN *IN VITRO* CLINICAL OR LABORATORY TESTING 64E-5.206(8)

(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 (8)(a), above until he has submitted the original and one copy of the information requested on form DH 360 10/12, entitled "Certificate – *In Vitro* Testing with Radioactive Material under General License" with the Department and received from the Department a validated copy of the "Certificate – *In Vitro* Testing with Radioactive Material under General License" with a certification number assigned which is herein incorporated by reference and available 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.