STATE OF GEORGIA
DEPARTMENT OF NATURAL RESOURCES

REGISTRATION CERTIFICATE--*in vitro* TESTING WITH RADIOACTIVE MATERIAL UNDER GENERAL LICENSE

CERTIFICATE NUMBER
(To be completed by the Department)

Rule 391-3-17.02(6)(g) established a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to possess certain small quantities of radioactive materials for in-vitro clinical or laboratory tests not involving the internal or external administration of radioactive material or the radiation therefrom to human beings or animals. Possession of radioactive material under rule 391-3-17.02(6)(g) is not authorized until the physician, veterinarian, clinical laboratory, or hospital has filed this form and received from the Department a validated copy of this form with certification number.

COMPLETE FORM AND RETURN TO:

Georgia Department of Natural Resources
Radioactive Materials Program
4244 International Parkway, Suite 120
Atlanta, GA 30354

1. **FACILITY NAME, TELEPHONE NUMBER , AND ADDRESS** (include Zip Code)

2. **APPLICATION** (Check one box only)

I hereby apply for a certification pursuant to Rule 391-3-17.02(6)(g) for use of radioactive materials for :

☐ A. Myself, a duly licensed physician authorized to dispense drugs in the practice of medicine.

☐ B. The above named clinical laboratory.

☐ C. The above named hospital.

☐ D. The above named practice of veterinary medicine.

3. **If place of use is different from address listed above, give complete address**:

4. **CERTIFICATION**

I hereby certify that:

A. All information in this registration certificate is true and complete.

B. The registrant has appropriate radiation measuring instruments to carry out the tests for which radioactive material will be used under the general license of Rule 391-3-17.02(6)(g). The tests will be performed only by personnel competent in the use of the instruments and in the handling of the radioactive materials.

C. I understand that Georgia regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Department of Natural Resources- Radioactive Materials Program within 30 days from the effective date of such change.

D. I have read and understand the provisions of Rule 391-3-17.02(6)(g).; and I have retained the Rules and Regulations for Radioactive Materials, Chapter 391-3-17 in my files; and I understand that the registrant is required to comply within those provisions as to all radioactive material which he receives, acquires, possesses, uses, or transfers under the general license for which this Certificate is filed with the Georgia Department of Natural Resources.

PRINTED NAME AND TITLE OF APPLICANT	**SIGNATURE OF APPLICANT**	**DATE**

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE RULE 391-3-17.02(6)(g).

Rule 391-3-17.02(6)(g). General License for Use of Radioactive Material for Certain In-vitro Clinical or Laboratory Testing.

Note: The new drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specified diagnostic drugs in interstate commerce.

1. A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital to receive, acquire, possess, transfer, or use, for any of the following radioactive material, in accordance with the provisions of (6)(g) 2.,3.,4.,5., and 6., the following radioactive materials in prepackaged units for use in in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(i) Iodine-125, in units not exceeding ten microcuries (370 kBq) each.

(ii) Iodine-131, in units not exceeding ten microcuries (370 kBq) each.

(iii) Carbon-14, in units not exceeding ten microcuries (370 kBq) each.

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

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

(vi) Cobalt-57, in units not exceeding ten microcuries (370 kBq) each.

(vii) Selenium-75, in units not exceeding ten microcuries (370 kBq) each.

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

2. No person shall receive, acquire, possess, use, or transfer radioactive material pursuant to the general license established by (6)(g)1. until he has filed Department form, " Registration Certificate – In-Vitro Testing with Radioactive Material Under General License" with the Department and received from the Department a validated copy of this form with certification number assigned or until he has been authorized pursuant to (9)(e)3. to use radioactive material under the general license in (6)(g). The physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital shall furnish on the form the following information and such other information as may be required by that form:

(i) Name and address of the physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital;

(ii) The location of use; and

(iii) A statement that the physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in (6)(g)1. and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

3. A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by (6)(g)1. shall comply with the following:

(i) The general licensee shall not possess at any one time, pursuant to the general license in (6)(g)1., at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 200 microcuries (7.4 MBq).

(ii) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing the equivalent amount of radiation protection.

(iii) The general licensee shall use the radioactive material only as authorized by (6)(g)1.

(iv) 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, any Agreement State, or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in (6)(g)1.(viii) as required by Rule .03(13) of this Chapter.

4. The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to (6)(g)1.:

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to (11)(g) or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any Agreement State, or Licensing State which authorizes the manufacture and distribution of iodine-125, iodine-131,

carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under (6)(g) or its equivalent, and

(ii) Unless one of the following statements, as appropriate, or a 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:

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

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(NAME OF MANUFACTURER)

(I) This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, 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)

5. The physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital possessing or using radioactive material under the general license of (6)(g)1. 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.

6. Any person using radioactive material pursuant to the general license of (6)(g)1. is exempt from the requirements of Rules .03 and .07 of this Chapter with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in (6)(g)1.(viii) shall comply with the provisions of (13) and (15) of Rule .03 of this Chapter.) and (13)(B).