NJRAD Form-483 (Revised November 16, 2010)

REGISTRATION CERTIFICATE
In vitro Testing with Byproduct under General License

INSTRUCTIONS
In the box below, print or type the name, address (including ZIP Code), and telephone number of the registrant physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine for whom or for which this registration form is filed
Submit this form to:

NJ Department of Environmental Protection
Bureau of Environmental Radiation
Mail Code 25-01, PO Box 420,
Trenton, NJ 08625-0420

New Jersey Department of Environmental Protection
Bureau of Environmental Radiation
Radioactive Materials Program
Mail Code 25-01, P.O. Box 420
Trenton, NJ 08625-0420
Tel. (609) 984-5557
Fax. (609) 633-2210
Website: http://www.agreementstate.nj.gov

REGISTRATION NUMBER:

NJ Department of Environmental Protection
Bureau of Environmental Radiation
Radioactive Materials Program

(If this is an initial registration, leave this space blank and a number will be assigned by DEP. If this is a change of information from a previously registered general licnese, include your registration number.)

Name and current mailing address of registrant:

Telephone: _____

Email: _____

Physical Location of Use (if different from above):
Address:

I hereby apply for a registration number pursuant to NJAC 7:28-52.1 for use of byproduct materials for (check all that apply):

- ☐ Myself, a duly licensed physician authorized to disperse drugs in the practice of medicine.
- ☐ The above-named clinical laboratory.
- ☐ The above named hospital.
- ☐ Veterinarian in the practice of veterinary medicine

A letter to the NJ DEP Bureau of Environmental Radiation, Mail Code 25-01, PO Box 420, Trenton, NJ 08625-0420 may be used to report any change of information furnished by a registrant as required by §31.11(e). If larger quantities or other forms of byproduct material than those specified in the general license of 10 CFR 31.11 are required, file NJRAD Form 313,"Application for Radioactive Material License," to obtain a specific byproduct material license. Copies of application and registration forms may be obtained from the NJ DEP Bureau of Environmental Radiation, Mail Code 25-01, PO Box 420, Trenton, NJ 08625-0420 or may be downloaded from our website at http://www.agreementstate.nj.gov

NJAC 7:28-52.1 establishes a general license authorizing physicians, clinical laboratories, hospitals, and veterinarians in the practice of veterinary medicine to possess certain small quantities of byproduct material for *in vitro* clinical or laboratory tests not involving the internal or external administration of the byproduct material or the radiation therefrom to human beings or animals. Possession of byproduct material under NJAC 7:28-52.1 (10 CFR 31.11 adopted by reference) is not authorized until the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine, has filed DEP NJRAD Form 483 and received from the Department a validated copy of NJRAD Form 483 with a registration number.

I hereby certify that:

- All information in this registration certificate is true and complete.
- The registrant has appropriate radiation measuring instruments to carry out the tests for which byproduct material will be used under the general license of NJAC 7:28-52.1 (10 CFR 31.11). The tests will be performed only by personnel competent in the use of the instruments and in the handling of the byproduct materials.
- I understand that Department regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Supervisor, Diffuse NARM, Source and Special Nuclear Materials, General Licensing & Decommissioning Section within 30 days from the effective date of such change.
- I have read and understand the provisions of NJAC 7:28-52 of DEP regulations [10 CFR 31 (reprinted on the back of this form)]; and
- I understand that the registrant is required to comply with those provisions as to all byproduct material which he receives, acquires, possesses, uses, or transfers under the general license for which this Registration Certificate is filed with the NJ Department of Environmental Protection.

Name of Certifying Official:

Title of Certifying Official :

Signature: **Date:**

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE N.J.A.C. 7:28-52 (10 CFR 31.11)

§ 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

(a) 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 stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:

(1) Iodine-125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(2) Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(3) Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(4) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(5) Iron-59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings, or animals.

(6) Selenium-75, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(7) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(8) Cobalt-57, in units not exceeding 0.37 megabecquerel (10 microcuries) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(b) A person shall not receive, acquire, possess, use, or transfer byproduct material under the general license established by paragraph (a) of this section unless that person:

(1) Has filed NJRAD Form 483, "Registration Certificate—In Vitro Testing with Byproduct Material Under General License," with the Radioactive Materials Program, and has received from the Department a validated copy of NJRAD Form 483 with a registration number assigned; or

(2) Has a license that authorizes the medical use of byproduct material that was issued under part 35 of this chapter.

(c) A person who receives, acquires, possesses, or uses byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:

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

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

(3) The general licensee shall use the byproduct material only for the uses authorized by paragraph (a) of this section.

(4) The general licensee shall not transfer the byproduct material except by transfer to a person authorized to receive it by a license pursuant to this chapter or from an Agreement State, nor transfer the byproduct 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 (a)(7) of this section as required by N.J.A.C. 7:28-6.

(d) The general licensee shall not receive, acquire, possess, or use byproduct material pursuant to paragraph (a) of this section:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of § 32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State, or before November 30, 2007, and the provisions of a specific license issued by a State with comparable provisions to § 32.71 that authorize manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, cobalt-57, or Mock Iodine-125 for distribution to persons generally licensed by the Agreement State or the State with comparable provisions to § 32.71.

(2) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, 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 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.

_____

(Name of Manufacturer)

(e) The radioactive material registrant possessing or using byproduct materials under the general license of paragraph (a) of this section shall report in writing to the Director, Office of Federal and State Materials and Environmental Management Programs, any changes in the information furnished by him in the "Registration Certificate—In Vitro Testing With Byproduct Material Under General License." Form NJRAD Form 483. The report shall be furnished within 30 days after the effective date of such change.

(f) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements N.J.A.C. 7:28-6.1 and N.J.A.C. 7:28-50.1 with respect to byproduct materials covered by that general license, except that such persons using the Mock Iodine-125 described in paragraph (a)(7) of this section shall comply with the provisions of N.J.A.C. 7:28-6.1