Minnesota Department of Health
Radiation Control
625 Robert Street North
P.O. Box 64975
St. Paul, Minnesota 55164-0975
Telephone: (651) 201-4545 **Fax: (651) 201-4606**

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

Instructions

Complete all items of the application. Submit original to the Radiation Control Unit of the Minnesota Department of Health (MDH). Retain a copy for your files. Possession of Radioactive Material is not authorized under Chapter 4731 until a validated copy of this certificate with a certificate number is received from MDH.

ITEM 1. NAME AND MAILING ADDRESS OF APPLICANT:	**ITEM 2. PHYSICAL ADDRESS WHERE RADIOACTIVE MATERIAL WILL BE USED, IF DIFFERENT THAN IN ITEM 1.** *(Do Not Use P.O. Box)*
TELEPHONE NUMBER *(Include area code):*	

RADIOACTIVE MATERIAL

ITEM 4. Please check all that apply *Chapter 4731)* (Attach additional pages if necessary):

- ☐ Carbon-14, in units not exceeding 370 kBq (10 microcuries) each.
- ☐ Cobalt-57, in units not exceeding 370 kBq (10 microcuries) each.
- ☐ Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 microcuries) each.
- ☐ Iodine-125, in units not exceeding 370 kBq (10 microcuries) each.
- ☐ Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (0.05 microcurie) of Iodine-129 and 185 Bq (0.005 microcurie) of Americium-241 each.
- ☐ Iodine-131, in units not exceeding 370 bKq (10 microcuries) each.
- ☐ Iron-59, in units not exceeding 740 kBq (20 microcuries) each.
- ☐ Selenium-75, in units not exceeding 370 kBq (10 microcuries) each.

CERTIFICATION *(To be completed by an individual authorized to make binding commitments on behalf of the applicant.)*

4731.3245 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 incidental to the tests to human beings or animals.

Possession of radioactive material under 4731.3245 is not authorized until the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine, has filed MDH form and received a validated copy from MDH with a registration number.

I hereby apply for a registration number for use of byproduct materials for:

- ☐ 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.

I understand that the Minnesota Department of Health requires that any change in the furnished information be reported within 30 days of the effective date of such change.

The registrant has appropriate radiation measuring instruments to carry out the tests for which byproduct material will be used under this general license. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the byproduct materials.

Certification

I have read and understand the provisions of 4731.3245 (reprinted and attached to this form); and I understand that the registrant is required to comply with those provisions as to all radioactive material which is received, acquired, possessed, used, or transferred under the general license for which this Registration Certificate is filed.

I herby certify that this application was prepared in conformance with Chapter 4731.3245 and that all information contained herein, including any supplements hereto, is true and correct to the best of my knowledge and belief.

Name of Applicant:	Title:
Signature of Applicant:	Date:

FOR MDH USE ONLY

Certificate Number:	**Expiration Date:**

4731.3245 GENERAL LICENSE; IN VITRO CLINICAL OR LABORATORY TESTING USE.

Subpart 1. License issued. A physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital is issued a general license to receive, acquire, possess, transfer, or use, according to this part, 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:

A. iodine-125, in units not exceeding ten microcuries each;
B. iodine-131, in units not exceeding ten microcuries each;
C. carbon-14, in units not exceeding ten microcuries each;
D. hydrogen-3 (tritium), in units not exceeding 50 microcuries each;
E. iron-59, in units not exceeding 20 microcuries each;
F. selenium-75, in units not exceeding ten microcuries each;
G. 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; and
H. cobalt-57, in units not exceeding ten microcuries each.

Subp. 2. License requirements. A person must not receive, acquire, possess, use, or transfer radioactive material under the general license issued under subpart 1 unless the person:

A. has filed a registration certificate in vitro testing with radioactive material under general license form, as prescribed by the commissioner, with the commissioner and received from the commissioner a validated copy of the form with a registration number assigned; or
B. has a license that authorizes the medical use of radioactive material issued under parts 4731.4400 to 4731.4527.

Subp. 3. Additional requirements. A person who receives, acquires, possesses, or uses radioactive material under the general license issued under subpart 1 must:

A. not possess at any one time, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, or cobalt-57 in excess of 200 microcuries (7.4 MBq);
B. store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection;
C. use the radioactive material only for the uses authorized under subpart 1;
D. not transfer the radioactive material, except by transfer to a person who is authorized to receive it under a license issued by the commissioner, the NRC, or an agreement state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier; and
E. dispose of the mock iodine-125 reference or calibration sources described in subpart 1, item G, as required under part 4731.2400.

Subp. 4. Limitation. A general licensee under this part must not receive, acquire, possess, or use radioactive material:

A. except as prepackaged units that are labeled according to:
   (1) a specific license issued under part 4731.3390; or
   (2) a specific license issued by the NRC or an agreement state that authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, mock iodine-125, or cobalt-57 to persons generally licensed by the NRC or an agreement state; and
B. unless the following statement, or a substantially similar statement that contains the information called for, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

> "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 rules of and a general license issued by the Nuclear Regulatory Commission or a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

(Name of manufacturer)"

Subp. 5. Changes in registration. A registrant possessing or using radioactive material under the general license issued under subpart 1 must report in writing to the commissioner any changes in the information provided in the form under subpart 2, item A. The report must be furnished within 30 days after the effective date of the change.

Subp. 6. Exemptions. A person using radioactive material under the general license issued under subpart 1 is exempt from parts 4731.1000 to 4731.2950 and Code of Federal Regulations, title 10, part 21, with respect to radioactive material covered by the general license, except that persons using mock iodine-125 under subpart 1, item G, must comply with parts 4731.2400, 4731.2600, and 4731.2610.