In-Vitro Testing With Radioactive Material Form

(Please read accompanying instructions before completing this form)

Rule 3701:l-46-11 of the Administrative Code, establishes a general license authorizing physicians, clinical laboratories, hospitals, and veterinarians in the practice of veterinary medicine 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 in Ohio under this rule is not authorized until the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine, has filed this form or its equivalent and received from the Director of Health a validated copy of the form with a registration number.

1. Name of Applicant
(*Person or firm proposing to conduct the activities described below)*

2. Type of Application

I hereby apply for a license number per Rule 3701:1-46-11 of the Administrative Code, for use of radioactive material for:

- ❑ My self, a duly licensed physician authorized to dispense drugs in the practice of medicine
- ❑ The clinical laboratory named in item 1
- ❑ The hospital named in item 1
- ❑ Veterinarian in the practice of veterinary medicine

3. Address of Applicant
(Mailing address or other location where licensee may be located)

4. License No. (*Leave blank if initial registration — number will be assigned by Bureau of Radiation Protection)*

5. Telephone
(Include Area Code)
( )

6. Fax
(Include Area Code)
( )

If place of use is different from address listed above, give complete physical address (No P.O. boxes, please)

Instructions

Submit this form in duplicate to:
Ohio Department of Health, Bureau of Radiation Protection
246 North High Street, Columbus, Ohio 43215
Attn: Materials Licensing

Tax ID No.

7. Certification *(Must be completed by applicant)*

I, THE UNDERSIGNED, HEREBY CERTIFY THAT:

a. All information in this report is true and complete.

b. The registrant has appropriate radiation measuring instruments to carry out the tests for which radioactive material will be used per the general license Rule 3701:1-46-11 of the Administrative Code. 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 Ohio Department of Health regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Bureau of Radiation Protection within 30 days from the effective date of such change.

d. I have read and understand the provisions of the applicable regulations (Rule 3701:1-46-11 of the Administrative Code); and I understand that the registrant is required to comply with those provisions as to all radioactive material which they receive, acquire, possess, use, or transfer under the general license for which this registration certificate is filed with the Bureau of Radiation Protection.

Printed or Typed Name and Title of Applicant	Signature	Date

I THE APPLICANT AND ANY OFFICIAL EXECUTING THIS APPLICATION ON BEHALF OF THE APPLICANT NAMED ABOVE CERTIFIES THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH CHAPTER 3748 OF THE OHIO REVISED CODE AND RULES PROMULGATED THEREUNDER, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS OR ATTACHMENTS CONTAINED HEREIN, ARE TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

CONDITIONS AND LIMITATIONS OF *IN-VITRO* TESTING GENERAL LICENSE

The basis for the regulation and the authority to grant a general license for *in-vitro* testing is summarized below, per Ohio Administrative Code 3701:1-46-11, which states in part, as follows:

GENERAL LICENSE FOR USE OF RADIO ACTIVE 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 rule, the following by product by product or accelerator produced materials in prepackaged units:

(1) Iodine-125, in units not exceeding three hundred-seventy kilobecquerels (ten microcuries) each for use in *in-vitro* clinical or laboratory tests not involving internal or external administration of by product or accelerator produced material, or the radiation therefrom, to human beings or animals.

(2) Iodine-131, in units not exceeding three hundred-seventy kilobecquerels (ten microcuries) each for use in *in-vitro* clinical or laboratory tests not involving internal or external administration of by product material, or the radiation therefrom, to human beings or animals.

(3) Carbon-14, in units not exceeding three hundred-seventy kilobecquerels (ten microcuries) each for use in *in-vitro* clinical or laboratory tests not involving internal or external administration of by product material, or the radiation therefrom, to human beings or animals.

(4) Hydrogen-3 (tritium), in units not exceeding 1.85 megabecquerels (fifty microcuries) each for use in *in-vitro* clinical or laboratory tests not involving internal or external administration of by product material, or the radiation therefrom, to human beings or animals.

(5) Iron-59, in units not exceeding seven hundred-forty kilobecquerels (twenty microcuries) each for use in *in-vitro* clinical or laboratory tests not involving internal or external administration of by product material, or the radiation therefrom, to human beings, or animals.

(6) Selenium-75, in units not exceeding three hundred-seventy kilobecquerels (ten microcuries) each for use in *in-vitro* clinical or laboratory tests not involving internal or external administration of by product material, or the radiation therefrom, to human beings or animals.

(7) Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kilobecquerels (.05 microcuries) of Iodine-129 and one hundred-eighty-five becquerels (.005 microcuries) of Americium-241 each for use in *in-vitro* clinical or laboratory tests not involving internal or external administration of by product material, or the radiation therefrom, to human beings or animals.

(8) Cobalt-57, in units not exceeding three hundred seventy kilobecquerels (ten microcuries) each for use in *in-vitro* clinical or laboratory tests not involving internal or external administration of accelerator produced material, or the radiation therefrom, to human beings or animals.

(B) A person shall not receive, acquire, possess, use, or transfer by product or accelerator produced material under the general license established by paragraph (A) of this rule unless that person:

(1) Has filed the radioactive materials In Vitro testing form with the director; or

(2) Has a license that authorizes the medical use of radio active produced material that was issued under rules for medical uses of radioactive material.

(C) A person who receives, acquires, possesses, or uses [of by product or accelerator produced material pursuant to the general license established by (A) of this rule shall comply with the following:

(1) The general licensee shall not possess at any one time, pursuant to the general license in paragraph (A) of this rule, 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 7.4 megabecquerels (two hundred microcuries).

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

(3) The general licensee shall use the by product or accelerator produced material only for the uses authorized by paragraph (A) of this rule.

(4) The general licensee shall not transfer the by product or accelerator produced material except by transfer to a person authorized to receive it by a license pursuant to this chapter, from the United States nuclear regulatory commission, from an agreement state, or a NARM licensing state, or transfer the by product or accelerator produced 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 rule as required by rule 3701:l-38-19 of the Administrative Code.

(D) The general licensee shall not receive, acquire, possess, or use by product or accelerator produced material pursuant to paragraph (A) of this rule:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of rule 3701:1-46-42 of this chapter or in accordance with the provisions of a specific license Issued by the nuclear regulatory commission or an agreement state that authorizes manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, mock iodine-125, or a NARM licensing state that authorizes manufacture and distribution of cobalt-57 for distribution to persons generally licensed by the nuclear regulatory commission or an agreement state or NARM licensing state.

(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:

(a) 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 United States 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 licensee possessing or using by product or accelerator produced materials under the general license of paragraph (A) of this rule shall report in writing to the director any changes in the information furnished by the licensee in the radioactive materials *in-vitro* testing form. The report shall be furnished within thirty days after the effective date of such change.

(F) Any person using by product or accelerator produced material pursuant to the general license of paragraph (A) of this rule is exempt from the requirements of chapter 3701:1-38 of the Administrative Code with respect to byproduct or accelerator produced materials covered by that general license, except that such persons using the mock iodine-125 described in paragraph (A)(7) of this rule shall comply with the provisions of paragraph (A) of rule 3701:1-38-19 of the administrative code and paragraphs (A) and (B) of rule 3701:138-21 of the Administrative Code.