RC FORM 512
(6/2022)

ARKANSAS DEPARTMENT OF HEALTH
RADIATION CONTROL SECTION

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

IVGL - _____
(to be assigned by ADH)

RH-402.k. of the ASBH Rules for Control of Sources of Ionizing Radiation 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 under RH-402.k. is not authorized until the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine, has filed RC FORM 512 and received from the Department a validated copy of RC FORM 512 with a registration number, or until authorized pursuant to RH-8013. to use radioactive material under the general license in RH-402.k. Note: Possession of radioactive material in excess of the limits in RH-402.k. requires a specific license.

Submit RC Form 512 to the following address: **Arkansas Department of Health, Radiation Control Section, General License Registration Program, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867**. Please print or type all entries, unless otherwise indicated.

I hereby apply for a general license registration number pursuant to RH-402.k. for use of radioactive material for:

- ○ Myself, a duly licensed physician authorized to dispense drugs in the practice of medicine in the State of Arkansas.
- ○ The clinical laboratory named below.
- ○ The hospital named below.
- ○ Myself, a veterinarian duly licensed in the practice of veterinary medicine in the State of Arkansas.

APPLICANT FILING FORM –

Name:	Address:
Telephone number:	City, state, zip:

PLACE OF USE IF DIFFERENT FROM ABOVE –

Name:	Address:
Telephone number:	City, state, zip:

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 in RH-402.k. The tests will be performed only be personnel competent in the use of the instruments and in the handling of the radioactive materials.

C. I have read and understand the provisions of RH-402.k.; and I understand that the registrant is required to comply with those provisions as to all radioactive material which he receives, acquires, possesses, uses, or transfers under the general license for which this registration certificate is filed with the ADH, Radiation Control Section.

D. I understand that Department regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Radiation Control Section within thirty (30) days after the effective date of such change.

Name:	Signature:
Title:	Date:

WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. RH-106. REQUIRES THAT SUBMISSIONS TO THE DEPARTMENT BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECTS. ANY PERSON WHO VIOLATES RH-107.a.1. OR a.2. MAY BE SUBJECT TO ENFORCEMENT ACTION IN ACCORDANCE WITH RH-700.

RH-402. General Licenses – Radioactive Material Other Than Source Material.

k. Use of radioactive material for certain *in vitro* clinical or laboratory testing.

1. 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 RH-402.k.2., 3., 4., 5. and 6. of this paragraph k., the following radioactive materials in prepackaged units:

   A. Carbon-14, in units not exceeding ten (10) microcuries each 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.

   B. Cobalt-57, in units not exceeding ten (10) microcuries each 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.

   C. Hydrogen-3 (Tritium), in units not exceeding fifty (50) microcuries each 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.

   D. Iodine-125, in units not exceeding ten (10) microcuries each 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.

   E. Iodine-131, in units not exceeding ten (10) microcuries each 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.

   F. Iron-59, in units not exceeding twenty (20) microcuries each 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.

   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 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.

   H. Selenium-75, in units not exceeding ten (10) microcuries each 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.

2. No person shall receive, acquire, possess, use, or transfer radioactive material pursuant to the general license established by RH-402.k.1. until the individual has filed Department form "Registration Certificate - *In Vitro* Testing with Radioactive Material under General License" with the General License Registration Program, Radiation Control Section, Arkansas Department of Health and received from the Department a validated copy of this form with registration number assigned or until he has been authorized pursuant to RH-8013. to use radioactive material under the general license in RH-402.k. The registrant shall furnish on the above form the following information and such other information as may be required by that form:

   A. Name and address of the registrant;

   B. The location of use; and

   C. A statement that the registrant has appropriate radiation measuring instruments to carry out *in vitro* clinical or laboratory tests with radioactive materials as authorized under the general license in RH-402.k., and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive materials.

3. A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by RH-402.k.1. shall comply with the following:

   A. The general licensee shall not possess at any one (1) time, pursuant to the general license established by RH-402.k.1. 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 200 microcuries.

   B. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

   C. The general licensee shall use the radioactive material only for the uses authorized by RH-402.k.1.

   D. The general licensee shall not transfer the radioactive material except by transfer to a person authorized to receive it pursuant to a license issued by the Department, the U.S. Nuclear Regulatory Commission, or any Agreement State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

   E. The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in RH-402.k.1.G. as required by RH-1400.

4. The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to RH-402.k.1.:

   A. Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement State that authorizes 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 under RH-402.k.1.

   B. 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:

      "**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)"

5. The registrant possessing or using radioactive material under the general license of RH-402.k.1. shall report in writing to the Radiation Control Section Chief, any changes in the information furnished by him in the Department form "Registration Certificate - *In Vitro* Testing with Radioactive Material under General License." The report shall be furnished within thirty (30) days after the effective date of such change.

6. Any person using radioactive material pursuant to the general license of RH-402.k.1. is exempt from the requirements of Section 3, "Standards for Protection Against Radiation," with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in RH-402.k.1.G. shall comply with the provisions of RH-1400., RH-1501., and RH-1502.