NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH

CERTIFICATE - IN VITRO TESTING WITH RADIOACTIVE MATERIAL UNDER GENERAL LICENSE

180 NAC 3-008.09 establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals 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 180 NAC 3-008.09 is not authorized until the physician, veterinarian, clinical laboratory, or hospital has filed Form NRH-17 and received from the Department a validated copy of Form NRH-17 with a certification number.

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 180 NAC 3-008.09

3-008.09 General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing

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 stated tests, in accordance with the provisions of 180 NAC 3-008.09, items 2. through 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:

    a. Iodine-125, iodine-131, selenium-75, cobalt-57, and carbon-14 in units not exceeding 370 kBq (10 microcuries) each.
    b. Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 microcuries) each.
    c. Iron-59, in units not exceeding 740 kBq (20 microcuries) each.
    d. Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 1.85 Bq (0.005 microcurie) of americium-241 each.

2. No person receives, acquires, possesses, uses or transfers radioactive material pursuant to the general license established by 180 NAC 3-008.09, item 1. until s/he has filed Department Form NRH-17, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the Department and received from the Department a validated copy of Department Form NRH-17 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital must furnish on Department Form NRH-17 the following information and such other information as may be required by that form:

    a. Name and address of the physician, veterinarian, clinical laboratory or hospital;
    b. The location of use; and
    c. 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 180 NAC 3-008.09, item 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 180 NAC 3-008.09, item 1. must comply with the following:

    a. The general licensee must not possess at any one time, pursuant to the general license in 180 NAC 3-008.09, item 1. at any one location of storage or use a total amount of iodine-125, iodine-131, iron-59, cobalt-57 and/or selenium-75 in excess of 7.4 MBq (200 microcuries).

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

    c. The general licensee must use the radioactive material only for the uses authorized by 180 NAC 3-008.09, item 1.

    d. The general licensee must 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, 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 must dispose of the Mock Iodine-125 reference or calibration sources described in 180 NAC 3-008.09, item 1.d. as required by 180 NAC 4-039 and 4-040.

4. The general licensee must not receive, acquire, possess, or use radioactive material pursuant to 180 NAC 3-008.09, item 1.:

    a. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 180 NAC 3-014.08 or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement 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 180 NAC 3-008.09 or its' equivalent, and

    b. Unless the following statement, or 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 must 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 in which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
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 180 NAC 3-008.09, item 1. must report in writing to the Department, any changes in the information furnished by him/her in the "Certificate - In Vitro Testing with Radioactive Material Under General License", Department Form NRH-17. The report must be furnished within 30 days after the effective date of such change.

6. Any person using radioactive material pursuant to the general license of 180 NAC 3-008.09, item 1. is exempt from the requirements of 180 NAC 4 and 180 NAC 10 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 180 NAC 3-008.09 item 1.d. must comply with the provisions of 180 NAC 4-039, 4-057, and 4-058.

Department of Health & Human Services
DHHS
NEBRASKA

INSTRUCTIONS

Submit this form in duplicate to the Department of Health and Human Services, Division of Public Health , Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, Nebraska 68509-5026.

A certification number will be assigned and a validated copy of NRH-17 will be returned.

(Print or Type)

1. Licensee Information

Legal Name: (Physician, Veterinarian, Clinical Laboratory or Hospital) _____

Address: _____

_____

City, State and Zip+4 _____

Person Authorized to sign binding documents for the Licensee _____

2. I hereby apply for a Certificate Number pursuant to 180 NAC 3-008.09 for use of radioactive materials for:

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

☐ b. The above named clinical laboratory.

☐ c. The above named hospital.

3. If place of use is different from address in Item 1, please give complete address:

4. CITIZENSHIP ATTESTATION

☐ It is not necessary to complete the Attestation part of this application below if the application is for a corporation or other separate legal entity. **Explain why:** (For example: This application is for a corporation, partnership, etc.) _____ _____ **OR**

☐ **If the entity is owned by an individual, complete the United States Citizenship Attestation Form below.**

UNITED STATES CITIZENSHIP ATTESTATION FORM

For the purpose of complying with Neb. Rev Stat. §§. 4-108 through 4-114, I attest as follows:

□ I am a citizen of the United States OR

□ I am a qualified alien under the Federal Immigration and Nationality Act, my Immigration status and alien number are as follows: _____ and I am providing a copy of my USCIS documentation.

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

Name (type or print first, middle, last)	Signature	Date

5. Certification:

I certify that:

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

b. Appropriate radiation measuring instruments are available to carry out the tests for which radioactive material will be used under the general license of 180 NAC 3-008.09. 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 Department regulations require that any change in the information furnished on this certificate be reported to the Department within 30 days from the date of such change.

d. I have read and understand the provisions of 180 NAC 3-008.09 of the Department regulations; and I understand that compliance with those provisions is required as to all radioactive material which is received, acquired, possessed, used, or transferred under the general license for which this certification number is filed with the Department.

_____

(Signature of Person listed in Item 1.) (Date)

4. To be completed by the Department:

Certification Number _____ ***Date*** _____

Radioactive Materials Program Manager _____