Illinois Emergency Management Agency
Division of Nuclear Safety
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Springfield, IL 62704-4462
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IL 473-342 (05/09) This state agency is requesting information that is necessary to establish compliance with the Radiation Protection Act of 1990 (420 ILCS 40/1-40/45). Failure to provide requested information may result in further administrative or compliance action.
https://iema.illinois.gov/nrs/radsafety/licensees.html

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

A general license authorizing physicians, veterinarians, laboratories, or hospitals to possess certain small quantities of C-14, Co-57, H-3, I-125, Mock I-125, I-131, Fe-59, and Se-75 for specified *in vitro* clinical or laboratory testing is established in 32 Ill. Adm. Code 330.220(e). Possession of radioactive material under Section 330.220(e) is not authorized until the applicant has filed this form and received from the Agency a validated copy with certification number assigned, or until authorized pursuant to Section 330.260(c)(3) to use radioactive material under the general license in Section 330.220(e).. This regulation appears on the back of this form.

If larger quantities or other forms of radioactive material than those specified in the general license of Section 330.220(e) are required, the applicant should file an application for a specific radioactive material license. Copies of application and certification forms may be obtained at https://iema.illinois.gov/nrs.html or by contacting the Radioactive Materials Branch at the email or phone above.

Instructions

Submit this form to the Agency address above. A certification number will be assigned, and a validated copy of this form will be returned. Populate the information below and leave the right-hand box empty.

The following information is provided in accordance with 32 Ill. Adm. Code 330.220(e).

LEAVE THE BOX BELOW BLANK. THIS INFORMATION WILL BE SUPPLIED BY THE AGENCY.

_____ _____
License Number **Expiration date**

_____
Authorizing Agency Signature

PHYSICIAN/VETERINARIAN/FACILITY NAME: _____

COMPANY ADDRESS: _____

LOCATION OF USE (If different from above): _____

TELEPHONE: _____ CELL: _____ EMAIL: _____

I hereby certify that:

1. All information in this certificate is true and complete.
2. I have appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests in which I will use radioactive material under the general license of Section 330.220(e) and I am competent in the uses of such instruments.
3. I understand that Agency regulations require that any change in the information furnished on this certificate be reported to the Agency within 30 days from the date of such change.
4. I have read and understand the provisions of Sections 330.220(e) of Agency regulations reprinted on the reverse side of this form; and I understand that I am required to comply with those provisions as to all radioactive material which I receive, possess, use, or transfer under the general license for which this certificate is filed with the Agency.

Contact Person: _____ By: _____
(Applicant's or Certifying Official's Signature)

Date: _____ _____
(Print or type Name)

_____
(Print or type Title)

Section 330.220(e) General License for Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing.

AGENCY NOTE: The New Drug provisions of the Federal Food, Drug and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

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 subsections (e)(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) Carbon-14, in units not exceeding 10 microcuries (370 kBq) each.
   B) Cobalt-57, in units not exceeding 10 microcuries (370 kBq) each.
   C) Hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.
   D) Iodine-125, in units not exceeding 10 microcuries (370 kBq) each.
   E) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.
   F) Iodine-131, in units not exceeding 10 microcuries (370 kBq) each.
   G) Iron-59, in units not exceeding 20 microcuries (740 kBq) each.
   H) Selenium-75, in units not exceeding 10 microcuries (370 kBq) each.
2. No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by subsection (e)(1) until he or she has filed the Agency form entitled "Certificate – In Vitro Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of the form with certification number assigned. No person shall transfer a validated copy of the form to another person without prior written consent of the Agency. The following information shall be furnished to the Agency on the form entitled "Certificate – In Vitro Testing with Radioactive Material Under General License"::
   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, 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 subsection (e)(1) and that the 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 subsection (e)(1) shall comply with the following:
   A) The general licensee shall not possess at any one time, pursuant to the general license in subsection (e)(1), 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 MBq (200 μCi).
   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 subsection (e)(1).
   D) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, 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.
   E) The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in subsection (e)(1)(E) as required by 32 Ill. Adm. Code 340.1010(a).
4. The general licensee shall not receive, acquire, possess or use radioactive material pursuant to subsection (e)(1):
   A) Except as prepackaged units that are labeled in accordance with the provisions of an applicable specific license issued pursuant to Section 330.280(g) or in accordance with the provisions of a specific license issued by NRC or an Agreement State that 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 this subsection (e) or its equivalent; and
   B) Unless one of the following statements, as appropriate, or a statement that contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

      This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, 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 or Importer

5. The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of subsection (e)(1) shall report in writing to the Agency, any changes in the information furnished by the licensee in the "Certificate – In Vitro Testing with Radioactive Material Under General License", Agency Form KLM.006. The report shall be furnished within 30 days after the effective date of the change.
6. Any person using radioactive material pursuant to the general license of subsection (e)(1) is exempt from the requirements of 32 Ill. Adm. Code 400 and 340, with respect to byproduct materials covered by that general license, except that such persons using the Mock Iodine-125 described in subsection (e)(1)(E) shall comply with the provisions of Sections 340.1010, 340.1210, and 340.1220.