CERTIFICATE OF IN VITRO TESTING WITH RADIOACTIVE MATERIAL UNDER GENERAL LICENSE

The Commonwealth of Massachusetts
Department Of Public Health
Division of Radiation Control
250 Washington St., Boston, MA 02108
Tel: 617-624-5757

INSTRUCTIONS: 105 CMR Section 120.122(I) (see Enclosure 1) of Radiation Control Regulations 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 Section 120.122(I) is not authorized until the physician, veterinarian, clinical laboratory, or hospital has filed form MDRC 120.100-2 and received from the Department a validated copy of form MDRC 120.100-2 with certification number. Submit this form to DRCRadMaterials@mass.gov. A certification number will be assigned and a validated copy of form MDRC 120.100-2 will be returned.

CERTIFICATE NUMBER: (Leave blank, to be completed by Agency) _____

VALIDATION: (Leave blank, to be completed by Agency) _____ _____
DIRECTOR SIGNATURE DATE

1. Please print the name and address (including zip code) of the physician, veterinarian, clinical laboratory, or hospital for whom or for which this form is filed:

   NAME: _____

   ADDRESS: _____

2. I, the undersigned, hereby apply for a certification pursuant to section 120.122(I) for use of radioactive material for:

   ☐ a. Myself, a duly licensed physician [authorized to dispense drugs] in the practice of medicine.

   ☐ b. Myself, a duly licensed veterinarian.

   ☐ c. The aforementioned clinical laboratory.

   ☐ d. The aforementioned hospital.

3. If different location(s) of use from the address provided in Item 1, please provide complete address(es):

   ADDRESS 1: _____

   ADDRESS 2: _____

   ADDRESS 3: _____

   ADDRESS 4: _____

4. CERTIFICATION: I, the undersigned, hereby certify that:
   a. All information in this certification 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 section 120.122(I). The tests will be performed only by personnel competent in the use of the instruments and in the handling of the radioactive material.
   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 effective date of such change.
   d. I have read and understand the provisions of 120.122(I); 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 Certificate is filed with the Department.

_____ _____
NAME OF INDIVIDUAL FILING FORM SIGNATURE OF INDIVIDUAL FILING FORM

_____ _____
TITLE OF INDIVIDUAL FILING FORM DATE

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE SECTION 105 CMR 120.122 (I)

120.122 (I): General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.[4]

(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 105 CMR 120.122(I)(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 ten microcuries (370 kBq) each.

(b) Cobalt-57, in units not exceeding ten 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 ten 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 ten microcuries (370 kBq) each.

(g) Iron-59, in units not exceeding 20 microcuries (740 kBq) each.

(h) Selenium-75, in units not exceeding ten microcuries (370 kBq) each.

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 105 CMR 120.122(I)(1) until he has filed form MDRC 120.100-2, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of form MDRC 120.100-2 with certification number assigned, or, has a license that authorizes the medical use of radioactive material that was issued under 105 CMR 120.500. The physician, veterinarian, clinical laboratory or hospital shall furnish on form MDRC 120.100-2 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, 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 105 CMR 120.122(I)(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 105 CMR 120.122(I)(1) shall comply with the following:

(a) The general licensee shall not possess at any one time, pursuant to the general license in 105 CMR 120.122(I)(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 200 microcuries (7.4 MBq).

(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 105 CMR 120.122(I)(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, the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing 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 105 CMR 120.122(I)(1)(e) as required by 105 CMR 120.251.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 105 CMR 120.122(I)(1):

(a) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 105 CMR 120.128(H) or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing 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 105 CMR 120.122(I) or its equivalent; and

(b) unless one of the following statements, as appropriate, or a substantially similar statement which 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 which accompanies the package:

1. 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.

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Name of Manufacturer

2. 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 a Licensing State.

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Name of Manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 105 CMR 120.122(I)(1) shall report in writing to the Agency, any changes in the information furnished by him in the "Certificate - In Vitro Testing with Radioactive Material Under General License", form MDRC 120.100-2. The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of 105 CMR 120.122(I)(1) is exempt from the requirements of 105 CMR 120.200 and 120.750 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 105 CMR 120.122(I)(1)(e) shall comply with the provisions of 105 CMR 120.251, 120.281 and 120.282.