

**DEPARTMENT OF THE ENVIRONMENT**

RADIOLOGICAL HEALTH PROGRAM  
1800 WASHINGTON BLVD.  
BALTIMORE, MARYLAND 21230

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

Paragraph C.22(i) of Part C of the Maryland Regulations for Control of Ionizing Radiation 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 C.22(i) is not authorized until the physician, veterinarians, clinical laboratory, or hospital has filed Form MDE-211 and received from the Department a validated copy of MDE-211 with certification number.

**INSTRUCTIONS**

Submit this form in Duplicate to the Maryland State Department of the Environment, Radiological Health Program, 1800 Washington Blvd., Baltimore, Maryland 21230.

A certification number will be assigned and a validated copy Form MDE 211 will be returned.

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1. Please print or type in the space to the left, below, the name and address (including ZIP Code) of the physician, veterinarians, clinical laboratory, or hospital for whom or for which this form is filed. Include name of county.

3. To be completed by the Department  
Certification No.

Expiration Date:

2. I hereby apply for a certification pursuant to C.22(i) of Part C for use of radioactive material for (Please check one):

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

b. The above-named clinical laboratory.

(Leave this space blank-number to be assigned  
Department.)

c. The above-named hospital.

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

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5. Certification:

I hereby certify that:

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

b. Appropriate radiation measuring instruments are available to carry out the test for which radioactive material will be used under the general license of C.22 (i) of Part C. 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 to 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 Paragraph C.22(i) of Part C; 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 Certificate is filed with the Department.

Date \_\_\_\_\_ By \_\_\_\_\_

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(Print name and title of position of person filing form)

## CONDITIONS AND LIMITATIONS OF GENERAL LICENSE C.22(I)

### C.22 (i) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing

(1) A general license, valid for no longer than 3 years, is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated test, in accordance with the provisions of C.22 (i) (2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration or radioactive material, or the radiation therefrom, to human beings or animals

- (i) Carbon-14, in units not exceeding 10 microcuries (370 kBq)
- (ii) Cobalt-57, in units not exceeding 10 microcuries (370 kBq) each
- (iii) Hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.
- (iv) Iodine-125, in units not exceeding 10 microcuries (370 kBq) each
- (v) Mock Iodine-125 reference or calibrations sources, in units not exceeding 0.05. microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (1.85 Bq) of americium-241 each.
- (vi) Iodine-131, in units not exceeding 10 microcuries (370 kBq) each.
- (vii) Iron-59, in units not exceeding 20 microcuries (740 kBq)
- (viii) 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 C.22 (i) (1) until he has filed Agency Form MDE-211, "Certificate In Vitro Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of Agency Form MDE 211 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on Agency Form MDE 211 the following information and such other information as may be required by that form:

- (i) Name and address of the physician, veterinarian, clinical laboratory or hospital ;
- (ii) the location of use; and
- (iii) 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 C.22 (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 C.22 (i) (1) shall comply with the following:

- (i) The general licensee shall not possess at any one time, pursuant to the general license in C.22 (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).
- (ii) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
- (iii) The general licensee shall use the radioactive material only for the uses authorized by C.22 (i) (1).
- (iv) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to 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
- (v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in C.22(i) (1) (v) as required by D.1001 of these regulations.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to C.22 (i) (1):

- (i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to C.28(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 with 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 C.22 (i) or its equivalent, and
- (ii) 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:
  - (a) 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

- (b) 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 C.22 (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", Agency Form MDE-211. 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 C.22 (i) (1) is exempt from the requirements of Parts D and J of these regulations with respect to radioactive material covered by that general license, except that such person shall comply with the provisions of D.1202, and D.1201, and D.1207 of these regulations.

**Note:** If larger quantities or other forms of radioactive material than those specified in general license of Part C Section C.22(i) are required, an "Application for Radioactive Material License", should be filed to obtain a specified radioactive material license. Copies of application and certification forms may be obtained from the Maryland State Department of the Environment, Radiological Health Program 1800 Washington Blvd., Baltimore MD 21230 or [http://www.mde.state.md.us/Programs/AirPrograms/Radiological\\_Health/radioactive\\_forms/index.asp](http://www.mde.state.md.us/Programs/AirPrograms/Radiological_Health/radioactive_forms/index.asp).