Form AEC-483
(4-68)
10 CFR 31

U.S. ATOMIC ENERGY COMMISSION

REGISTRATION CERTIFICATE—IN VITRO TESTING WITH BYPRODUCT MATERIAL UNDER GENERAL LICENSE

Form Approved
Budget Bureau No.
38-R0160

Section 31.11 of 10 CFR 31 establishes a general license authorizing physicians, clinical laboratories, and hospitals to possess certain small quantities of byproduct material for *in vitro* clinical or laboratory tests not involving the internal or external administration of the byproduct material or the radiation therefrom to human beings or animals. Possession of byproduct material under 10 CFR 31.11 is not authorized until the physician, clinical laboratory, or hospital has filed Form AEC-483 and received from the Commission a validated copy of Form AEC-483 with registration number.

INSTRUCTIONS

Submit this form in triplicate to: United States Atomic Energy Commission, Washington, D.C. 20545, Attention: Director, Division of Materials Licensing. *A registration number will be assigned and a validated copy of Form AEC-483 will be returned.*

1. Please print or type within the shaded area, below, the name and address (including ZIP Code) of the registrant physician, clinical laboratory, or hospital for whom or for which this registration form is filed.

Thomas J. Liddy, M.D.
Roche Clinical Laboratories
1 Fairfield Crescent
West Caldwell, New Jersey 07006

2. I hereby apply for a registration number pursuant to § 31.11, 10 CFR 31 for use of byproduct materials for *(please check one):*

- [x] a. Myself, a duly licensed physician authorized to dispense drugs in the practice of medicine.
- [ ] b. The above-named clinical laboratory.
- [ ] c. The above-named hospital.

3. To be completed by the Atomic Energy Commission

Registration number: 0672

U. S. ATOMIC ENERGY COMMISSION

BY: Clarence A. Wehron November 6, 1970

(Leave this space blank—number to be assigned by AEC)

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

5. 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 byproduct material will be used under the general license of 10 CFR 31.11. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the byproduct materials.

c. I understand that Commission regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Director, Division of Materials Licensing, within 30 days from the effective date of such change.

d. I have read and understand the provisions of Section 31.11 of AEC regulations 10 CFR 31 (reprinted on the reverse side of this form); and I understand that the registrant is required to comply with those provisions as to all byproduct material which he receives, acquires, possesses, uses, or transfers under the general license for which this Registration Certificate is filed with the Atomic Energy Commission.

Date October 29, 1970

By Thomas J Liddy MD
Signature of person filing form

Thomas J. Liddy, M.D., Associate Director
Printed name and title or position of person filing form

WARNING.—18 U.S.C., Section 1001; Act of June 25, 1948; 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 10 CFR 31.11

§ 31.11 General license for use of iodine–125 or iodine–131 for in vitro clinical or laboratory testing.

(a) A general license is hereby issued to any physician, clinical laboratory, or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:

(1) Iodine–125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(2) Iodine–131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(b) No person shall receive, acquire, possess, use or transfer byproduct material pursuant to the general license established by paragraph (a) of this section until he has filed Form AEC–483, "Registration Certificate—In Vitro Testing with Byproduct Material Under General License", with the Director, Division of Materials Licensing, U.S. Atomic Energy Commission, Washington, D.C. 20545, and received from the Commission a validated copy of Form AEC–483 with registration number assigned. The registrant shall furnish on Form AEC–483 the following information and such other information as may be required by that form:

(1) Name and address of the registrant;

(2) The location of use; and

(3) A statement that the registrant has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with byproduct materials as authorized under the general license in paragraph (a) of this section, and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the byproduct materials.

(c) A person who receives, acquires, possesses or uses byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:

(1) The general licensee shall not possess at any one time, pursuant to the general license in paragraph (a) of this section, at any one location of storage or use a total amount of iodine–125 and/or iodine–131 in excess of 200 microcuries.

(2) The general licensee shall store the byproduct material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(3) The general licensee shall use the byproduct material only for the uses authorized by paragraph (a) of this section.

(4) The general licensee shall not transfer the byproduct material to a person who is not authorized to receive it pursuant to a license issued by the Commission or an Agreement State,[1] nor transfer the byproduct material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(d) The general licensee shall not receive, acquire, possess, or use byproduct material pursuant to paragraph (a) of this section:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of § 32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State, which authorizes manufacture and distribution of iodine–125 or iodine–131 for distribution to persons generally licensed by the Agreement State.

(2) 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, 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. Atomic Energy Commission or of a State with which the Commission has entered into an agreement for the the exercise of regulatory authority.

Name of manufacturer

(e) The registrant possessing or using byproduct materials under the general license of paragraph (a) of this section shall report in writing to the Director, Division of Materials Licensing, any changes in the information furnished by him in the "Registration Certificate—In Vitro Testing with Byproduct Material Under General License", Form AEC–483. The report shall be furnished within 30 days after effective date of such change.

(f) Any person using byproduct ma[illegible] pursuant to the general license of paragraph (a) of this section is exempt from the requirements of Part 20 of this chapter with respect to byproduct materials covered by that general license.

[1] A State to which the Commission has transferred certain regulatory authority over radioactive material by formal agreement, pursuant to section 274 of the Atomic Energy Act of 1954, as amended.

NOTE

If larger quantities or other forms of byproduct material than those specified in the general license of 10 CFR 31.11 are required, an "Application for Byproduct Material License," Form AEC–313, should be filed to obtain a specific byproduct material license. Copies of application and registration forms may be obtained from the United States Atomic Energy Commission, Washington, D.C. 20545, Attention: Isotopes Branch, Division of Materials Licensing.

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