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NRC Form 483
1-76
10 CFR 31

U.S. NUCLEAR REGULATORY COMMISSION

Approved by GAO
38-R0160

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

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 NRC Form 483 and received from the Commission a validated copy of NRC Form 483 with registration number.

Joseph J. Berke, M.D., Ph.D.
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3333 E. Jefferson
Detroit, MI 48207

3. I hereby apply for a registration number pursuant to §31.11, 10 CFR 31 for use of byproduct materials for *(please check one block only)*
   - [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.
4. To be completed by the Nuclear Regulatory Commission.

INSTRUCTIONS

1. Submit this form in triplicate to:
   Office of Nuclear Material Safety and Safeguards
   ATTN: Radioisotopes Licensing Branch
   U.S. Nuclear Regulatory Commission
   Washington, D.C. 20555
2. Please print or type 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. Position the first letter of the address below the left dot and do not extend the address beyond the right dot. (At NRC, a registration number will be assigned and a validated copy of NRC Form 483 will be returned.)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

8365

BRENDA L. BROWN

MARCH 2, 1988

(If this is an initial registration, leave this space blank — number to be assigned by NRC. If this is a change of information from a previously registered general licensee, include your registration number.)

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

6. 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 of Nuclear Material Safety and Safeguards within 30 days from the effective date of such change.

d. I have read and understand the provisions of Section 31.11 of NRC 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 Nuclear Regulatory Commission.

Date 2-23-88

By [signature]
Signature of person filing form

Joseph J. Berke, M.D., Ph.D., President
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 byproduct materials for certain 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.

(3) Carbon-14, 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.

(4) Hydrogen 3 (tritium), in units not exceeding 50 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.

(5) Iron 59, in units not exceeding 20 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 NRC Form 483, "Registration Certificate–In Vitro Testing with Byproduct Material Under General License," with the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and received from the Commission a validated copy of NRC Form 483 with registration number assigned or until he has been authorized pursuant to §35.14(c) of this chapter to use byproduct material under the general license in this §31.11. The registrant shall furnish on NRC Form 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, iodine 131, and/or iron 59 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 except by transfer to a person authorized to receive it by a license pursuant to this chapter or from 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 that authorizes manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), or iron-59 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:[2]

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. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

DIAGNOSTIC REAGENTS, INC. - BEETON - DICKINSON
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 of Nuclear Material Safety and Safeguards any changes in the information furnished by him in the "Registration Certificate–In Vitro Testing with Byproduct Material Under General License," NRC Form 483. The report shall be furnished within 30 days after the effective date of such change.[3]

(f) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements of Parts 19 and 20 of this chapter with respect to byproduct materials covered by that general license.

NOTES

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

[2] Material generally licensed under this section prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

[3] A new triplicate set of this Registration Certificate, NRC Form 483, may be used to report any change of information furnished by a registrant as required by §31.11(e).

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," NRC Form 313, should be filed to obtain a specific byproduct material license. Copies of application and registration forms may be obtained from the United States Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Radioisotopes Licensing Branch, Division of Fuel Cycle and Material Safety.

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 522a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on Forms NRC-482 and NRC-483. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. AUTHORITY Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. PRINCIPAL PURPOSE(S) The information is evaluated by the NRC staff pursuant to criteria set forth in 10 CFR Parts 20-36 to determine whether the application conforms to the requirements of the Atomic Energy Act of 1954, as amended, and the regulations of the NRC, for the issuance of a registration certificate authorizing the use of byproduct material for medical use or in vitro testing.

3. ROUTINE USES The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure for purposes of their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, or local agencies in the event the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.

4. WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the registration certificate, or amendment thereof, will not be processed.