Form AEC-482
(7-65)
10 CFR 35

U.S. ATOMIC ENERGY COMMISSION

FORM APPROVED
BUDGET BUREAU NO.
38 R-0027

REGISTRATION CERTIFICATE—MEDICAL USE OF BYPRODUCT MATERIAL UNDER GENERAL LICENSE

Section 35.31 of 10 CFR 35 establishes a general license authorizing physicians to possess certain small quantities of I 125, I 131, Co 58, Co 60, and Cr 51 for specified diagnostic uses. Possession of byproduct material under 10 CFR 35.31 is not authorized until the physician has filed Form AEC-482 and received from the Commission a validated copy of Form AEC-482 with registration number assigned.

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-482 will be returned. Please print or type your name and address* (including ZIP code), *within the shaded area.*

LEONARD H. GABA, D.O.
52895 MOUND ROAD
UTICA, MICHIGAN 48087

Registration number: 6060

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

Shirley A. Crutchfield August 12, 1981

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

I am a duly licensed physician authorized to dispense drugs in the practice of medicine. My license(s) is (are) valid under the laws of:

STATE(S) OF LICENSURE	LICENSE NUMBER(S)
MICHIGAN	R-5669

CERTIFICATE

I hereby certify that:

1. All information in this registration certificate is true and complete.
2. I have appropriate radiation measuring instruments to carry out the diagnostic procedures for which I will use byproduct material under the general license of 10 CFR 35.31 and I am competent in the use of such instruments.
3. 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 date of such change.
4. I have read and understand the provisions of Section 35.31 of AEC regulations (10 CFR 35) reprinted on the reverse side of this form; and I understand that I am required to comply with those provisions as to all byproduct material which I receive, possess, use, or transfer under the general license for which this Registration Certificate is filed with the Atomic Energy Commission:

Date JULY 31, 1981

By Leonard H. Gaba DO
(Signature of Registrant)

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 35.31

§ 35.31 General License for Medical Use of Certain Quantities of Byproduct Material.

(a) A general license is hereby issued to any physician to receive, possess, transfer, or use for any of the following stated diagnostic uses, in accordance with the provisions of paragraphs (b), (c), and (d) of this section, the following byproduct materials in capsules, disposable syringes or other forms of prepackaged individual doses;

(1) Iodine 131 as sodium iodide (NaI^{131}) for measurement of thyroid uptake;

(2) Iodine 131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(3) Iodine 125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(4) Cobalt 58 for the measurement of intestinal absorption of cyanocobalamin;

(5) Cobalt 60 for the measurement of intestinal absorption of cyanocobalamin;

(6) Chromium 51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time.

NOTE: Section 32.70 of this chapter requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to include the following statement in the label affixed to the container or in the leaflet or brochure which accompanies the radiopharmaceutical;

This radioactive drug may be received, possessed, and used only by physicians licensed to dispense drugs in the practice of medicine. Its receipt, possession, use, and transfer are subject to the regulations and a general license of the United States Atomic Energy Commision or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of manufacturer)

(b) No physician shall receive, possess, use, or transfer byproduct material pursuant to the general license established by paragraph (a) of this section until he has filed Form AEC-482, "Registration Certificate—Medical Use of 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 the Form AEC-482 with registration number assigned. The registrant shall furnish on Form AEC-482 the following information and such other information as may be required by that form:

(1) Name and address of the registrant;

(2) A statement that the registrant is a duly licensed physician authorized to dispense drugs in the practice of medicine, and specifying the license number and the State in which such license is valid; and

(3) A statement that the registrant has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use byproduct material under the general license of § 35.31 of this chapter and that he is competent in the use of such instruments.

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

(1) He shall not possess at any one time, pursuant to the general license in paragraph (a) of this section, more than:

(i) 200 microcuries of iodine 131,

(ii) 200 microcuries of iodine 125,

(iii) 5 microcuries of cobalt 58,

(iv) 5 microcuries of cobalt 60, and

(v) 200 microcuries of chromium 51.

(2) He shall store the pharmaceutical until administered in the original shipping container or a container providing equivalent radiation protection;

(3) He shall use the pharmaceutical only for the uses authorized by paragraph (a) of this section;

(4) He shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age;

(5) He 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, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(d) The registrant possessing or using byproduct material under the general license of paragraph (a) shall report in duplicate to the Director, Division of Materials Licensing, any changes in the information furnished by him in the "Registration Certificate—Medical Use of Byproduct Material Under General License," Form AEC-482. The report shall be submitted within 30 days after the effective date of such change.

(e) Any person using byproduct material 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 the byproduct materials covered by the general license.

NOTE

If larger quantities or other forms of byproduct material than those specified in the general license of 10 CFR 35.31 are required, the physician should file an "Application for Byproduct Material License," Form AEC-313 and 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.

* U.S. GOVERNMENT PRINTING OFFICE : 1968 O—293-790