DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
WASHINGTON, DC 20314

DASG-HCH

25 April 1973

Mr. John Bowyer
Isotopes Branch
Division of Materials Licensing
US Atomic Energy Commission
Washington, DC 20545

Dear Mr. Bowyer:

Recommend approval of the inclosed application for amendment to AEC Byproduct Material License No. 05-00046-13 for Fitzsimons Army Medical Center, Denver, CO.

Sincerely,

Kirby B. Adcock LTC
For JAMES E. ANDERSON
Colonel, MSC
Radiological Hygiene Consultant
Health and Environment Division

1 Incl
as

CF:
CDR, USAEHA

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DEPARTMENT OF THE ARMY
FITZSIMONS GENERAL HOSPITAL
DENVER, COLORADO 80240

MEDEO-X

12 April 1973

SUBJECT: Application for Amendment to AEC License 05-00046-13

HQ DA (DASG-HEQ)
WASH, DC 20314

1. Reference letter DAAG-PAP-A (M) (26 Jan 73) DASG-HEQ, Subject: Use of Radioactive Byproduct Material for IN-VITRO Testing.

2. In response to the referenced letter, the attached amendment application is forwarded for your review and submission to the USAEC.

JAMES A. WIEH, M.D.
Major General, MC
Commanding

36968

DEPARTMENT OF THE ARMY
OFFICE OF THE ADJUTANT GENERAL
WASHINGTON, D.C. 20310

IN REPLY REFER TO

DAAG-PAP-A (M) (26 Jan 73) DASG-HEQ

6 February 1973

SUBJECT: Use of Radioactive Byproduct Material for IN-VITRO Testing

SEE DISTRIBUTION

1. Commanders possessing an AEC License which authorizes IN-VITRO testing will, for the present time, use this material only in the areas described in the license application to the Atomic Energy Commission. If it is the desire of the Commander to perform IN-VITRO testing in additional areas an amendment to the current AEC License will be required. This application is the reference document applicable to the conditions of the AEC License.

2. Commanders who do not have AEC license authorizing IN-VITRO testing must submit an application to the AEC in accordance with AR 40-37.

3. Commanders desiring only to use limited quantities of I-125 or I-131 for IN-VITRO testing may submit AEC form 483. See inclosure 1 for information relating to this type license.

4. Commanders must have the proper AEC license to use radioactive byproduct materials. This radioactive material will not be used in medical facilities without the proper authority, nor in areas not stipulated in AEC license.

BY ORDER OF THE SECRETARY OF THE ARMY:

Verne L. Bowers

VERNE L. BOWERS
Major General, USA
The Adjutant General

1 Incl
as

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SUBJECT: Use of Radioactive Byproduct Material for IN-VITRO Testing

DISTRIBUTION:

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Fifth US Army, Fort Sam Houston, TX 78234
Sixth US Army, Presidio of San Francisco, CA 94129
Brooke General Hospital, Fort Sam Houston, TX 78234
Fitzsimons General Hospital, Denver, CO 80240
Letterman General Hospital, San Francisco, CA 94129
Walter Reed Army Medical Center, Washington, DC 20012
Madigan General Hospital, Tacoma, WA 98431
Valley Forge General Hospital, Phoenixville, PA 19460
William Beaumont General Hospital, El Paso, TX 79920

Copies Furnished:
The Surgeon General

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.
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>
> 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 the effective date of such change.

(f) 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 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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