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

DASG-HCH-E

23 November 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 License No. 05-00046-13 for Fitzsimons Army Medical Center, Denver, COL.

Sincerely,

Edward W Blackburn

EDWARD W. BLACKBURN
Lieutenant Colonel, MSC
Radiological Hygiene Consultant
Health and Environment Division

1 Incl
as

CF:
CDR,USAEHA

COPIES SENT TO COMPLIANCE

42903

A/93

AEC-317
(1944)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Department of the Army Address: City: Denver State: Colorado	2. Control No. 39841 3. Department
4. Name and title of trained individual Dr. John E. Canham	5. Type Program: ☐ Private practice ☐ Private practice in hospital ☐ Institutional
6. Review ☐ First ☐ Second	7. Previous application control No.(s)

8. Remark on checked items:

☐ A. All radioisotopes and uses stated in application

☐ B. Use of _____ for _____

☐ C. Training and experience of user

FOR YOUR INFORMATION

☐ D. Dosage(s) indicated

☐ E. Clinical techniques and procedures outlined

☐ F. Type patient used (i.e., terminal, infants, normal)

☐ G. Other

9. Action of Subcommittee on Human Applications:

☐ Approve ☐ Disapprove

Remarks:

Thank you.

20 Oct 73
(Date of appraisal)

Signature David E. Kl, M.D.
(Member of subcommittee)

HQ-272
(1944)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

File

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☐ G. Other

FOR YOUR INFORMATION

9. Action of Subcommittee on Human Applications

☐ Approve ☐ Disapprove

Remarks: Thank you

10-1-73
(Date of appraisal)

Signature: E W Webster
(Member of subcommittee)

Form AEC-313a (11-63) 10 CFR 30 PAGE 1

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

Form approved Budget Bureau No. 38-R0080

If byproduct material is for "human use" (internal administration of byproduct material, or the radiation therefrom to human beings), complete this supplement and attach to the application for byproduct material license.

1. (a) USING PHYSICIAN'S NAME

(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a). Include ZIP Code.)
Department of the Army, Fitzsimons Army Medical Center, and U.S. Army Medical Research and Nutrition Laboratory, Denver, Colorado 80240.

2. THE USING PHYSICIAN INDICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO.
See application dated 12 March 1973 (Control No. 35871)
CIRCLE ANSWER — YES — NO

3. A STATEMENT OF USING PHYSICIAN'S CLINICAL RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT OF THIS APPLICATION. IF ANSWER IS NO, USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS.
See application dated 12 March 1973 (Control No. 35871)
CIRCLE ANSWER — YES — NO

PROPOSED DIAGNOSIS OR TREATMENT

4. (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary):

Renal Imaging

(b) CHEMICAL FORM ADMINISTERED:

Tc-99m-Fe-Ascorbate DTPA (inclosure 1)

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL:

See other side of this sheet.

(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE
(1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE)
See inclosure 1
CIRCLE ANSWER — (YES) — NO
(2) ON FILE WITH THE ISOTOPES BRANCH
REFER TO APPLICATION NO _____
CIRCLE ANSWER — YES — NO

5. PROPOSED DOSAGE SCHEDULE
(a) In millicuries for internally administered byproduct material other than discrete fixed sources; and in roentgens or rads, as appropriate, for internal or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each condition or disease (use page 2 if necessary):

dose = 3 to 5 mCi as prescribed in Inclsoure 1
as Tc-99m Iron - Ascorbate DTPA

(b) INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment should include outline of conditions to be evaluated, including data from animal studies and/or abstract of literature reference if any, number and type of patients (i. e. age group, moribund, etc.))
CIRCLE ANSWER — YES — NO

N/A

6. IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED AND STERILIZED FORM FOR PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES:
Tc-99m obtained as eluate from E.R. Squibb and Son, Ind. Technetope II sterile generator (08871) Mo contact 300 mCi. Eluate assayed in Nuc. Chicago Dose Calibrator Model 6362.

7. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE.
CIRCLE ANSWER — YES — NO

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE.
CIRCLE ANSWER — YES — NO

(b) A COPY OF INSTRUCTIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS TO BE TAKEN AND AVAILABLE RADIATION INSTRUMENTATION IS ATTACHED.
CIRCLE ANSWER — YES — NO

This page may be used for providing additional information. Please cross reference to specific items.

Paragraph 4c.

All personnel involved are equipped with film badges processed at 30 day intervals. All personnel receive periodic review instructions in the use of the Tc-99m generator. All personnel will receive instruction from the Chief, Nuclear Medicine Service and the Radiation Protection Officer in use of the Squibb RENOTEC kit. Routine nuclear medicine procedures (wearing of gloves, use of syringe covers, etc.) are used at all times. Periodic studies of exposure levels using TLD techniques are conducted (Eberline TLD Systems TLR-5).