

JUN 17 1964

Dr. Edith H. Quimby
Department of Radiology
630 West 168th Street
New York 32, New York

Dear Dr. Quimby:

This refers to your review of an application from the Fitzsimons General Hospital and U. S. Army Medical Research Laboratory, Denver, Colorado, Control Number 58638 (NB).

The Army has developed a program for its hospitals whereby all isotopes and uses are specified in the license. The criteria for setting up such a program are described in the enclosed Army regulation AR 40-37, "Medical Service-Radioisotope License Program (Human Use)." The applicant has set up an Isotopes Committee which supervises the radioisotope program in accordance with the regulations. Also enclosed for your information is a copy of the makeup of the committee and a copy of the license issued to the hospital. We understand that the Office of the Surgeon General does not wish all its hospitals to have a broad license which permits use of isotopes for research without the specific approval of the Office of the Surgeon General and the Atomic Energy Commission.

In light of the above information, we would appreciate a second review of the application.

Sincerely yours,

Original Signed by
Nathan Bassin

Nathan Bassin
Isotopes Branch
Division of Materials
Licensing

Enclosures:
As stated above

cc: Dr. Reynold S. Brown
Dr. Wallace D. Armstrong
Dr. Donald S. Childs, Jr.

Dr. John A. Cooper
Dr. George B. Leroy
Dr. Rulon W. Rawson

bcc: Compliance Region I

OFFICE	ML:LB					
SURNAME	NBassin/mb					
DATE	6/17/64					

JUN 7 1964

Dr. Edith H. Quinby
Department of Radiology
630 West 158th Street
New York 32, New York

Dear Dr. Quinby:

This refers to your review of an application from the Fitzsimons General Hospital and U. S. Army Medical Research Laboratory, Denver, Colorado, Contract Number D6628 (MB).

The Army has developed a program for its hospitals whereby all isotopes and uses are specified in the license. The criteria for getting up such a program are described in the enclosed Army regulation AR 45-27, "Medical Service-Radiolabeling License Program (House War)." The applicant has set up an Isotopes Committee which supervises the radiolabeling program in accordance with the regulations. Also enclosed for your information is a copy of the makeup of the committee and a copy of the license issued to the hospital. We understand that the Office of the Surgeon General does not wish all its hospitals to have a broad license which permits use of isotopes for research without the specific approval of the Office of the Surgeon General and the Atomic Energy Commission.

In light of the above information, we would appreciate a second review of the application.

Sincerely yours,

Original Signed by
Nathan Bassin

Nathan Bassin
Isotopes Branch
Division of Materials
Licensing

Enclosures:
As stated above

cc: Dr. Reynolds S. Brown
Dr. Wallace B. Armstrong
Dr. Donald S. Childs, Jr.

Dr. John A. Cooper
Dr. George R. Loney
Dr. Nelson W. Roman

cc: Compliance Region I

DL:EB

MB:EB

6/17/64

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Department of the Army Fitzsimons General Hospital and Address: U.S. Army Medical Research and Nutrition Laboratory City: Denver State: Colorado	2. Control No. 58638 (NE)
4. Name and title of trained individual Individuals authorized by Radioisotopes Committee	3. Department Radiology Service
6. Review: <input checked="" type="checkbox"/> First. <input type="checkbox"/> Second.	5. Type program: <input type="checkbox"/> Private practice. <input type="checkbox"/> Private practice in hospital. <input checked="" type="checkbox"/> Institutional.
8. Remark on checked items: <input checked="" type="checkbox"/> A. All radioisotopes and uses stated in application. <input checked="" type="checkbox"/> B. Use of for <input type="checkbox"/> C. Training and experience of user. <input type="checkbox"/> D. Dosage(s) indicated. <input type="checkbox"/> E. Clinical techniques and procedures outlined. <input type="checkbox"/> F. Type patient used (i.e., terminal, infants, normal). <input type="checkbox"/> G. Other	7. Previous application control No.(s)

9. Action of Subcommittee on Human Applications:

☐ Approve. ☐ Disapprove.

Remarks:

Recommend broad general license.

APR 30 1964

(Date of appraisal)

Signature



John A. D. Cooper, M.D.
303 East Chicago Avenue
Chicago 11, Illinois

(Member of subcommittee)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Department of the Army Fitzsimons General Hospital and Address: U.S. Army Medical Research and Nutrition Laboratory City: Denver State: Colorado	2. Control No. 58638 (NB)
4. Name and title of trained individual Individuals authorized by Radioisotopes Committee	3. Department Radiology Service
6. Review: <input checked="" type="checkbox"/> First. <input type="checkbox"/> Second.	5. Type program: <input type="checkbox"/> Private practice. <input type="checkbox"/> Private practice in hospital. <input checked="" type="checkbox"/> Institutional.
	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.

☐ 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:

Can they qualify for a broad license?
If not do we have any middle ground.

4-21-64

(Date of appraisal)

Signature

Reynold F. Brown, M.D.

(Member of Subcommittee)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Department of the Army Fitzsimons General Hospital and Address: U.S. Army Medical Research and Nutrition Laboratory City: Denver State: Colorado	2. Control No. 58638 (NB)
4. Name and title of trained individual Individuals authorized by Radioisotopes Committee	3. Department Radiology Service 5. Type program: <input type="checkbox"/> Private practice. <input type="checkbox"/> Private practice in hospital. <input checked="" type="checkbox"/> Institutional.
6. Review: <input checked="" type="checkbox"/> First. <input type="checkbox"/> Second.	7. Previous application control No.(s)

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☒ B. Use of for

☐ C. Training and experience of user.

☐ 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: Good application except who is the individual to be licensed and his qualification. Should they wish the Radioisotopes Committee to approve then we must know the qualification of this Committee and they must be experienced and of high quality.

D. S. Childs, Jr., M.D.

Signature

(Member of subcommittee)

4-23-64
(Date of appraisal)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Department of the Army Fitzsimons General Hospital and Address: U.S. Army Medical Research and Nutrition Laboratory City: Denver State: Colorado	2. Control No. 58638 (NB)
4. Name and title of named individual Individuals authorized by Radioisotopes Committee	3. Department Radiology Service
6. Review: <input checked="" type="checkbox"/> First. <input type="checkbox"/> Second.	5. Type program: <input type="checkbox"/> Private practice. <input type="checkbox"/> Private practice in hospital. <input checked="" type="checkbox"/> Institutional.
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9. Action of Subcommittee on Human Applications:

☐ Approve. ☐ Disapprove.

Remarks:

This, in effect, appears to be an application for a kind of broad general
licence. Can we approve such requests? Is there not a mechanism for
approval of such licences? The documentation is excellent and I can see no
specific objections from the radiologic dose standpoint. If others have no
objections in principle I will approve.

4-14-64
(Date of appraisal)

Signature

W. de. Armstrong

W. de. Armstrong, M.D.

(Member of subcommittee)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Department of the Army
Fitzsimons General Hospital and
Address: U.S. Army Medical Research and
Nutrition Laboratory
City: Denver State: Colorado

2. Control No. 58638 (NB)

3. Department
Radiology Service

4. Name and title of trained individual

Individuals authorized by Radioisotopes
Committee

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.

☐ 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: This is a sort of bob-tailed general authorization- limited as to
nuclides to be used, but transferring authority for evaluating training and
experience from the AEC sub-committee to an institutional isotope committee.
I do not believe this is a good precedent to establish. They can have many
individuals work if they are properly supervised by authorized personnel.
Why don't they do it that way?

4/10/64
(Date of appraisal)

Signature

Edith H. Quimby
Edith H. Quimby
(Member of subcommittee)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Department of the Army Fitzsimons General Hospital and Address: U.S. Army Medical Research and Nutrition Laboratory City: Denver State: Colorado	2. Control No. 58638 (NB) 3. Department Radiology Service
4. Name and title of trained individual Individuals authorized by Radioisotopes Committee	5. Type program: <input type="checkbox"/> Private practice. <input type="checkbox"/> Private practice in hospital. <input checked="" type="checkbox"/> Institutional.
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☐ 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:

I agree with Drs. Quimby and Childs.

4/28/64

(Date of appraisal)

Signature

R. W. Rawson, M.D.

(Member of subcommittee)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Department of the Army Fitzsimons General Hospital and Address: U.S. Army Medical Research and Nutrition Laboratory City: Denver State: Colorado	2. Control No. 58638 (NB) 3. Department Radiology Service
4. Name and title of trained individual Individuals authorized by Radioisotopes Committee	5. Type program: <input type="checkbox"/> Private practice. <input type="checkbox"/> Private practice in hospital. <input checked="" type="checkbox"/> Institutional.
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☐ C. Training and experience of user.

☐ 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:

Evidently our requirements for documentation are not so stringent that qualified users find them embarrassing!

4/11/64

(Date of appraisal)

Signature

George V. LeRoy, M.D.

(Member of subcommittee)