UNITED STATES
ATOMIC ENERGY COMMISSION
DIVISION OF COMPLIANCE, REGION IV
10395 WEST COLFAX, ROOM 200
DENVER, COLORADO 80215

April 20, 1971

File please

Gen W. Roy, Chief
Materials and Fuel Facilities Branch
Division of Compliance, HQ

COMPLIANCE INQUIRY MEMORANDUM —
DEPARTMENT OF THE ARMY, FITZSIMONS GENERAL HOSPITAL,
DENVER, COLORADO — LICENSE NO. 05-00046-13

This memo responds to the request for inquiry referencing the subject licensee, dated January 6, 1971. The following described inquiry was conducted by Herman J. Paas, Jr., at Fitzsimons General Hospital on April 8, 1971, in conjunction with an inspection of License No. 05-00046-13.

Lt. Col. John Campbell, M.D., Chairman of the Isotope Committee, and Chief, Department of Radiology; and, Major Gerald A. King, Alternate Radiation Protection Officer, were interviewed, and all available records related to the ^{90}Sr medical applicator were reviewed.

The earliest documents possessed by the licensee consisted of the Instruction Manual that accompanied the source at the time of purchase, and the vendor's certification of leak test and dose rate calibration. Each of the documents bore the date of December 27, 1951, indicating that the licensee received the ^{90}Sr applicator shortly after that date. Records established that the applicator was obtained from Tracerlab, Inc., 130 High Street, Boston 10, Massachusetts, and the documents established that the serial number of the applicator was No. 170. Observations made by the inspector on April 8, 1971, verify that the only applicator in the licensee's possession is identified by Serial No. 170. It was noted that neither the Instruction Manual, nor the vendor's certification report, identified the nominal activity contained in the ^{90}Sr source at the time of licensee procurement. The dose rate calibration on December 27, 1951, was shown by Tracerlab to be 38.7 roentgen equivalent betas per second; Exhibit A is a copy of this record.

Subsequent records maintained by the licensee showed that the licensee returned the ^{90}Sr medical applicator to Tracerlab at approximate 12-month intervals for purposes of obtaining a recalibration of the surface dose rate. The calibration records documented on Tracerlab letterhead, over the signature of a Tracerlab employee, show that the dose rate decreased over the 20-year period of

5/5/71 Called Col. Anderson (Surgeon Gen. Office) re results. 1/8d

4/1/66

possession, in accord with the 28-year half-life of ^{90}Sr. Exhibit B, attached, is typical of these reports and, as noted on the third line, Tracerlab identifies the content of the ^{90}Sr sealed source as 25 mCi. The report shown in Exhibit B represents the first piece of correspondence in the licensee's records that define the amount of activity in the ^{90}Sr sealed source. Major King stated that it was apparent that the information, as described on Exhibit B, accounted for the 25-mCi possession limit, as stated on the license prior to amendment.

The sequence dose rate calibration records continue to identify the activity in the source as 25 mCi until April 4, 1968, when the recalibration report received from Tracerlab (Exhibit C) shows that the source contained 50 mCi of ^{90}Sr. The Tracerlab calibration report, after this date and through February 23, 1970, continued to show that the activity contained in the source was 50 mCi.

The discussion with Lt. Col. Campbell and Major King established that the discrepancy between the authorization for a 25-mCi source and the actual possession of a 50-mCi source was first observed by the licensee during the conduct of the annual military general inspection for fiscal year 1971. The apparent overpossession is clearly documented in the formal minutes of the Isotope Committee meeting, dated July 7, 1971, and subsequent records include a notification to the Surgeon General regarding a request to amend the license for an authorized possession of 50 mCi under the date of October 29, 1970, and ultimate receipt of the amendment as Amendment 21 to the license, dated December 18, 1970.

Discussion with Major King, who stated he is the direct user of the medical applicator, established that all radiation doses administered to patients were determined on the basis of the roentgen-equivalent beta per second output of the source on the date that the patient was treated. These calibrations were performed by Tracerlab in accord with standard procedures as shown in Exhibits A through C. He stated that the source size was never considered in any medical application. Lt. Col. Campbell verified this statement in a separate discussion with the inspector. Each of the interviewees stated that the fundamental reason for obtaining a recalibration on an annual basis was to update and verify the dose rate emanating from the source so that proper exposures to personnel could be determined. It was apparent from the discussion and from the procedure that the licensee's use of the medical applicator did not involve any radiation dose to the patient above that which was intended and calculated by the user.

In summary, based on the information obtained from the records maintained by the licensee, and from the interviews and discussions conducted with the Chairman of the Isotope Committee, and those using the medical applicator, it was concluded by the inspector that:

1. The failure of the vendor and recalibrator to identify the ^{90}Sr medical applicator, Serial No. 170, possessed by Fitzsimons General Hospital

during the period December 27, 1951, to April 4, 1968, to contain 50 mCi of ^{90}Sr instead of 25 mCi of ^{90}Sr, did not result in the administration of any radiation dose to a patient in excess of the dose intended at time of administration (see Exhibits A and B). All administrations during this period were based on the surface dose rate emanating from the source, which the licensee determined from periodic recalibrations performed without regard to the amount of activity contained in the source.

2. Information contained in the complete set of records maintained over a 20-year period was clearly substantive in content and provided the prime information which precluded any possibility of overexposure to a patient.

3. The discrepancy as to source size apparently originated with the vendor at the time of sale, and continued to exist through April 4, 1968. The cause, or reason, for the discrepancy, as documented by the vendor, was not apparent from the review of the licensee's records.

Glen D. Brown

Glen D. Brown
Senior Radiation Specialist

CO:IV:HJP

Attachments:
1. Exhibit A
2. Exhibit B
3. Exhibit C

cc: Paul Nelson, CO:I, w/attachments

Note: Per page 127 of old Tracerlab Catalog "E", the Model RA-1 used a 50 mc Sr^{90} source, and the surface dose rates described are compatible with this one. Apparently this source originally was 50 mc (nominal) and the "25 mc" was in error by Tracerlab

Tracerlab INC.
130 HIGH STREET • BOSTON 10, MASSACHUSETTS
HAncock 6-4150

CERTIFICATE

PERTAINING TO

RA-1 MEDICAL APPLICATOR

Serial No. 170

Leakage Test.-

This Medical Applicator exhibited no detectable leak of activity previous to shipment.

The method used to demonstrate the absence of leakage is described in Section IV-B of the Instruction Manual Pertaining to the Usage of the RA-1 Medical Applicator.

Dosage Rate.-

The surface dosage rate of RA-1 MEDICAL APPLICATOR,

SERIAL NO. 170 ON 12/27/51

WAS 36.7 ROENTGEN-EQUIVALENT-BETAS PER SECOND,

as measured by the method described in Section III-B of the Instruction Manual. With respect to absolute calibration, this dosage rate is to be construed as tentative; it may be adjusted at a future date as a result of more absolute measurements which will develop upon forthcoming basic improvements in the calibration technique.

EXHIBIT A

Tracerlab inc. 130 HIGH STREET • BOSTON 10, MASSACHUSETTS
HUbbard 2-7900

CERTIFICATE

FOR

RA 1R MEDICAL APPLICATOR

Serial No. 170

Sold to: Fitzsimmons Army Hospital

AEC Authorization No. 6762

Content: 95 mc Sr^{90}

Leakage Test

This Medical Applicator exhibited no detectable leak of activity previous to shipment.

The method used to demonstrate the absence of leakage is described in Section VI-A of the Instruction Manual Pertaining to the Usage of the RA 1R Medical Applicator.

Dosage Rate

The surface dosage rate of RA 1R MEDICAL APPLICATOR, SERIAL NO. 170 ON 4-25-56 WAS 27 ROENTGEN-EQUIVALENT-BETAS PER SECOND, as measured by the method described in Section III-B of the Instruction Manual. With respect to absolute calibration, this dosage rate is to be constructed as tentative; it may be adjusted at a future date as a result of more absolute measurements which will develop upon forthcoming basic improvements in the calibration technique.

Signed Charles B. Killian
Tracerlab, Inc.

EXHIBIT B

TRACERLAB
A DIVISION OF LABORATORY FOR ELECTRONICS, INC.
1601 TRAPELO ROAD • WALTHAM, MASSACHUSETTS 02154

AREA CODE 617
894-6000
CABLE ADDRESS
LFE WALTHAM, MASS

CERTIFICATE

FOR

RA 1A MEDICAL APPLICATOR

Serial No. 170

Sold to: Finance and Accounting Office
Fitzsimmons General Hospital
Denver, Colorado 80240

AEC License:

Content: 50 mc Strontium-90

Leakage Test

This Medical Applicator exhibited no detectable leak of activity previous to shipment.

The method used to demonstrate the absence of leakage is described in Section VI-A of the Instruction Manual Pertaining to the Usage of the RA 1A Medical Applicator.

Dosage Rate

The surface dosage rate of RA 1A MEDICAL APPLICATOR, SERIAL NO. 170 ON 4/4/68 WAS 19.6 ROENTGEN-EQUIVALENT-BETAS PER SECOND, as measured by the method described in Section III-B of the Instruction Manual. With respect to absolute calibration, this dosage rate is to be construed as tentative; it may be adjusted at a future date as a result of more absolute measurements which will develop upon forthcoming basic improvements in the calibration technique.

Signed John Kempt
Tracerlab, A Division of
Laboratory for Electronics, Inc.

EXHIBIT C

File

Issued 4-26-71

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Form HQ 272
(10-64)

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. 21272 (KSD) 3. Department
4. Name and title of trained individual Raymond F. Burk, Jr., M.D.	5. Type program: ☐ Private practice. ☐ Private practice in hospital. ☒ Institutional.
6. Review: ☒ First. ☐ Second.	7. Previous application control No.(s) 16753 21431

8. Remark on checked items:

☐ A. All radioisotopes and uses stated in application.

☒ B. Use of carbon 14 as glucose for metabolic studies

☐ C. Training and experience of user.

REVIEW: all members

☐ 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:

4/20/71

George V. LeRoy

Signature

(Member of subcommittee)

Form HQ 272
(10-64)

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City: Denver State: Colorado

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3. Department

4. Name and title of trained individual

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5. Type program:

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

☐ G. Other

9. Action of Subcommittee on Human Applications:

xx☒ Approve. ☐ Disapprove.

Remarks:

Harold H. Rossi

4/20/71
(Date of appraisal)

Signature H.H. Rossi
(Member of subcommittee)

☆ U. S. GOVERNMENT PRINTING OFFICE: 1964 — 747-515

Form HQ 272
(10-64)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Department of the Army
Fitzsimons General Hospital
Address:
City: Denver State: Colorado

2. Control No. 21431 (JEB)

3. Department

4. Name and title of trained individual

Raymond F. Burk, M.D., CPT, MC

5. Type program:

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☐ Private practice in hospital.

☒ Institutional.

6. Review:

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7. Previous application control No.(s)

8. Remark on checked items:

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☒ B. Use of Selenium 75, Selenite for determine site and nature of selenium protein bond in human plasma to evaluate nutritional liver disease.

☐ C. Training and experience of user.

REVIEW: all members

☐ 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: **Although I doubt some of the assumptions in their dose calculation (especially for liver and kidneys). It is understood that this is approval for no more than 10 cancer patients.**

I still think that self-signed preceptor statements should be automatically rejected.

HR

Harold H. Rossi

4/20/71
(Date of appraisal)

Signature H.H. Rossi
(Member of subcommittee)

☆ U. S. GOVERNMENT PRINTING OFFICE: 1964 — 747-315

Form HQ 272
(10-64)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

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Fitzsimons General Hospital
Address:
City: Denver State: Colorado

2. Control No. 21431 (JEB)

3. Department

4. Name and title of trained individual

Raymond F. Burk, M.D., CPT, MC

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Harold H. Rossi

4/20/71
(Date of appraisal)

Signature

H.H. Rossi
(Member of subcommittee)

☆ U. S. GOVERNMENT PRINTING OFFICE: 1964 — 747-315

Form HQ 272
(10-64)

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☐ G. Other

9. Action of Subcommittee on Human Applications:

☒ Approve. ☐ Disapprove.

Remarks:

4-19-71
(Date of appraisal)

Signature Joseph B. Workman

Joseph B. Workman, M.D.
(Member of subcommittee)

☆ U. S. GOVERNMENT PRINTING OFFICE: 1964 — 747-315

Form HQ 272
(10-64)

U.S. ATOMIC ENERGY COMMISSION
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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. 21272 (KSD)

3. Department

4. Name and title of trained individual

Raymond F. Burk, Jr., M.D.

5. Type program:

☐ Private practice.

☐ Private practice in hospital.

☒ Institutional.

6. Review:

☒ First. ☐ Second.

7. Previous application control No (s)

16753 21431

8. Remark on checked items:

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☐ C. Training and experience of user.

REVIEW: all members

☐ D. Dosage(s) indicated.

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

☐ G. Other

9. Action of Subcommittee on Human Applications:

☒ Approve. ☐ Disapprove.

Remarks:

4-19-71
(Date of appraisal)

Signature Joseph B. Workman, M.D.
(Member of subcommittee)

☆ U. S. GOVERNMENT PRINTING OFFICE: 1964 — 747-515

Form AEC 272
(1964)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

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Fitzsimons General Hospital and
Address: U.S. Army Medical Research and
Nutrition Laboratory
City: Denver State: Colorado

Control No. 21272 (KSD)

3. Department

4. Name and title of trained individual

Raymond F. Burk, Jr., M.D.

5. Type program:

- ☐ Private practice.
- ☐ Private practice in hospital.
- ☒ Institutional.

6. Review:

- ☒ First.
- ☐ Second.

7. Previous application control No.(s)

21423 21431

8. Remark on checked items:

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- ☒ B. Use of carbon 14 as glucose for metabolic studies
- ☐ 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

REVIEW: all members

9. Action of Subcommittee on Human Applications:

- ☐ Approve.
- ☐ Disapprove.

Remarks:

(Date of appraisal)

Signature

(Member of subcommittee)

☆ U. S. GOVERNMENT PRINTING OFFICE: 1964 — 747-315

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(10-64)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

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Fitzsimons Gen. Hosp. and U.S. Army
Address: Medical Research & Nutrition Lab.
City: Denver State: Colorado

2. Control No. 21272 (KSD)

3. Department

4. Name and title of trained individual

Raymond F. Bunk, Jr. M.D.

5. Type program:

☐ Private practice.

☐ Private practice in hospital.

☑ Institutional.

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☑ First. ☐ Second.

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16753

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(Date of appraisal) Signature (Member of subcommittee)

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