

1. Department of the Army
Fitzsimons General Hospital and
U. S. Army Medical Research and
Nutrition Laboratory
Denver, Colorado 80240
2. July 8, 11, 13, 1966
3. Reinspection
4. 10 CFR 20, 30
5. License No. 5-46-13, issued February 3, 1964, expiration July 31, 1966
6. The following item of noncompliance was noted:

License Condition No. 7
License Condition No. 9

in that, during the period November 18, 1965, through
July 15, 1966, I-131, in the form of macroaggregated
iodinated human serum albumin, was procured in
quantities up to 1.63 mc on twenty-one occasions,
contrary to License Condition No. 7. In addition,
this material was used to perform lung scans on sixty-four
occasions, contrary to License Condition No. 9.
(See pars. 15, 17, 20 and 21)

7. April 26, 27, 28, 1965
8. No

	Original signed by Roger T. Woolsey	JUL 21 1966
Initials	Inspector	Date
	ORIGINAL SIGNED BY G. D. BROWN	JUL 22 1966
Initials	Reviewer	Date

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HISTORY

License Status

9. Byproduct Material License No. 5-46-13 was issued on February 3, 1964. This license superseded Byproduct Material License Nos. 5-46-9, -10, -11, and -12. License No. 5-46-8 was incorporated into License No. 5-46-11 prior to the incorporation of the aforementioned licenses into 5-46-13. License No. 5-46-13 was due to expire on January 31, 1966. However, application for renewal was considered timely, and the expiration date was extended to July 31, 1966.

Previous Inspections

10. Reinspections of the programs conducted under the auspices of Byproduct Material License Nos. 5-46-8, -9, -10, -11, and -12, were conducted on February 14 and 15, 1963. Clear Form AEC-591's were processed to cover the inspection of four of these licenses. A Form AEC-591 was issued against Byproduct Material License No. 5-46-9, which stated that records of disposals were not properly maintained, contrary to the provisions of 10 CFR 20.401(b). The most recent inspection of the broad license was made on April 26 through 28, 1965. As a result of this inspection, a Form AEC-592 was processed covering three instances of over possession of byproduct material and one instance wherein byproduct material was used at a location not authorized on the license. All items of noncompliance found during the previous inspection were noted to have been corrected at the time of the current inspection.

CURRENT INSPECTION

11. An announced, reinspection of the subject licensed facility was conducted on July 8, 11, and 13, 1966. The following persons were contacted during the course of the subject inspection:

Maj. Gen. R. E. Blount, M. D., M. C., Commanding Officer,
Fitzsimons General Hospital (FGH)
Lt. Col. Paul Siebert, M. C., Chief of Radiology
Maj. D. F. Preston, Radiological Safety Officer and Chief,
Radioisotope Clinic
Capt. Charles E. Liddle, D. V. M., V. C., Chief,
Radioisotope Laboratory, USAMRNL
Capt. Leonard Griff, Chief of Radiation Therapy
M. Sgt. M. E. Gilbert, Senior Technician, Radioisotope
Laboratory, FGH
M. Sgt. Joseph E. Abernathy, X-Ray Specialist, USAMRNL

Radioisotope Committee

12. The Radioisotope Committee has been established pursuant to Army Regulation 40-37.

The current Radioisotope Committee, according to Maj. Preston, is as follows:

Col. Edwin Overholt, President of the Committee, Chief,
Department of Medicine
Col. John White, Chief of Surgery
Lt. Col. Siebert, Chief of Radiology
Lt. Col. John E. Carnahan, Director of USAMRNL
Maj. D. F. Preston, Radiological Safety Officer and Chief,
Radioisotope Clinic, FGH

The Radioisotope Committee meets on a quarterly basis. The most recent meeting was on July 5, 1966. Formal minutes are maintained for each meeting. There has been no change in the Committee's functions since the previous inspection. Attached as Exhibit A is a form used by the Committee to grant approval to use radioisotopes for research.

Facility Organization

13. According to Maj. Preston, and Capt. Liddle, licensed radioactive materials are used exclusively by three departments at the Fitzsimons General Hospital complex. These departments are the Radioisotope Laboratory, FGH, of which Maj. Preston is the Chief; the Radiation Therapy Service, FGH, of which Lt. Col. Stebert is the Chief; the Radioisotope Laboratory, USAMRNL, of which Capt. Liddle is the Chief. The only licensed material used by the Radiation Therapy Service is a Sr-90 eye applicator. All other clinical use of licensed material was at the Radioisotope Laboratory, FGH, and all research use of licensed material is conducted at the Radioisotope Laboratory, USAMRNL. Maj. Preston and Capt. Liddle are directly responsible for the uses of radioisotopes in their respective sections and they maintain complete records of isotope procurement, use, transfer, disposal, personnel monitoring, and all surveys which are conducted. Additionally, these records are compiled quarterly and copies of these records are maintained both in a central file and in their respective facilities. Although the Fitzsimons General Hospital and the USAMRNL are separate entities, both are under the administrative command of Maj. Gen. Blount.

FACILITIES - RESTRICTED AREAS

14. It was observed that the facilities of the Radioisotope Laboratory, FGH, the Radioisotope Laboratory, USAMRNL, and the Radiation Therapy Section, FGH, are as described in the report of February 14 and 15, 1963, inspection, and in the licensee's application for license. All areas where licensed materials are used or stored are considered restricted areas according to Maj. Preston. Access to the base is controlled by military police on a 24-hour basis. Access to the restricted areas is controlled by the licensed users during

PROCUREMENT

Summary

15. During the period November 18, 1965, through July 15, 1966, the licensee, on twenty-one occasions, procured macroaggregated iodinated human serum albumin, a form of I-131 not authorized by the license.

General

16. Maj. Preston and Capt. Liddle stated that all procurements of licensed material for use in specific departments must be approved by the Isotope Committee; that they (Preston and Liddle) must approve each specific order for isotopes.

Radioisotope Laboratory, FGH

17. A review of the isotope procurement records for the Radioisotope Laboratory revealed the following procurements of macroaggregated iodinated human serum albumin:

	<u>Date</u>	<u>MC Procured</u>
1.	November 18, 1965	1.371
2.	December 1, 1965	1.02
3.	December 22, 1965	1.13
4.	January 3, 1966	1.41
5.	January 14, 1966	1.33
6.	January 28, 1966	1.06
7.	February 11, 1966	1.24
8.	February 18, 1966	1.38
9.	March 4, 1966	1.32
10.	March 11, 1966	1.15
11.	March 18, 1966	1.32
12.	April 1, 1966	1.63
13.	April 8, 1966	1.15
14.	April 29, 1966	1.11
15.	May 13, 1966	1.18
16.	May 20, 1966	1.23
17.	June 10, 1966	1.05
18.	June 24, 1966	1.20
19.	July 1, 1966	1.10
20.	July 8, 1966	1.13
21.	July 15, 1966	1.14

With the exception of the aforementioned receipts, the review of the procurement records for the Radioisotopes Laboratory, FGH, revealed that there were no procurements of licensed material in excess of the limits specified in the subject license. Maj. Preston stated that the aforementioned isotopes were procured solely for clinical use in human patients. It should be noted that License Item 7.B. limits I-131 in the form of iodinated human serum albumin only. These procurements were covered with Maj. Preston during the inspection and Maj. Gen. Blount on July 13, 1966, and are covered in the section of the report entitled Discussion With Management. A compilation of the licensed material procured by the Radioisotope Laboratory, FGH, for the period January 1, 1966, through March 31, 1966, is being retained in the Region IV files. A tabulation of the licensed material inventory, as of March 31, 1966, is being retained in the Region IV files.

Radioisotope Laboratory, USAMRNL

18. A review of the procurement records of the Radioisotope Laboratory, USAMRNL, revealed that there were no procurements of radioisotopes in quantities in excess of the limits specified in the subject license. A compilation of the quantities of the materials procured for use in this laboratory during the quarter ending 27 June 1966 is being retained in the Region IV files. A compilation of the quantities of radioisotopes on hand as of 30 June 1966 at the USAMRNL is being retained in the Region IV files.

Radiation Therapy, FGH

19. Lt. Col. Siebert stated that the Radiation Therapy Section has not procured licensed materials since October 21, 1961, when a 17.75-mc Sr-90 sealed source, contained in a Tracerlab, Model RA-1, medical applicator, was obtained. This is the only licensed material which is possessed by the Radiation Therapy Section.

USE

Summary

20. During the period November 18, 1965, through July 15, 1966, macroaggregated iodinated human serum albumin was used in doses of 300 uc on sixty-four occasions for lung scans, contrary to License Condition No. 9.B., which does not cover use of this material for lung scans.

Radioisotope Laboratory, FGH

21. A review of the licensee's records indicated that there were sixty-four usages of macroaggregated iodinated human serum albumin during the period November 18, 1965, through July 15, 1966. Doses of 300 uc were used on each occasion. These doses were administered i. v. following a preliminary dose of a saturated solution of potassium iodide which was used to block the thyroid. This usage constituted the only unauthorized use performed by the Radioisotope Laboratory, FGH, during the inspectable period. License Condition No. 9.B. does not authorize use of I-131, in any form, for lung scans. In order to show a typical cross-section of radioisotope usage at the Radioisotope Laboratory, FGH, the following tabulation, for the period April 13, 1966, to June 21, 1966, is shown:

<u>Radioisotope</u>	<u>Physical Form</u>	<u>Diagnostic or Therapeutic Procedure</u>	<u>Avg. No. of Procedures per 10-week Period</u>	<u>Avg. Doses Per Procedure</u>
I-131	Iodide	Uptakes	92	10 uc
I-131	Iodide	Scans	40	100 uc
I-131	Iodide	Hyperthyroid therapy	9	5 mc to 7.5mc
I-131	Iodide	Carcinoma therapy	1	60 to 150 mc
Au-198		Liver scans	41	50 to 100 uc
Cr-51	Sodium chromate	Spleen scans	11	200 uc
Hg-197	Chlormerodrin	Kidney scans	39	100 uc
Hg-197	Chlormerodrin	Brain scans	48	950 uc max.
I-131	Macroaggregated iodinated human serum albumin	Lung scans	19	300 uc
Sr-85	Strontium nitrate	Bone scans	26	100 uc
I-131	IHSA	Blood volume	22	< 5 uc
Cr-51	Sodium chromate	Blood volume	2	50 uc
I-131	RISA or Cholografin	Heart scans	2	300 uc
I-131	Hippuran	Renal gram	72	25 to 40 uc
I-131	Rose bengal	Liver scans	2	150 uc
I-131	RISA	Placentogram	2	5 uc

Radiation Therapy, FGH

22. Lt. Col. Siebert stated that the medical applicator is used only about three or four times per year.

Radioisotope Laboratory, USAMRNL

23. The licensee is authorized on the broad section of the license to use any isotope with Atomic Nos. 33 in quantities up to 5 mc for laboratory research in lower animals. Hydrogen-3 is accepted and the licensee is permitted to use up to 5 curies of this radioisotope for research in lower animals. This material all must be used at the U. S. Army Medical Research and Nutrition Laboratory in Denver, Colorado. At the present time, according to the licensee's records, C-14 is the prime radioisotope being used for animal research. The radioisotope is being used in microcurie quantities. The following research activity is being conducted at Pikes Peak at the present time on a rather intermittent basis. The primary objective of this research is to determine the effect of diet on metabolism of glucose and acetate at high altitudes. In this study, five rats are used in each treatment group. Each rat is injected with either 5 uc of glucose C-14 or acetate C-14. The rats are then sacrificed after each injection. According to Capt. Liddle, less than 100 uc total of C-14 has been used at any one time. This research is being conducted under the authorization of Amendment No. 4, dated June 15, 1964, which allows 1 mc of C-14 in any form to be used on the summit of Pikes Peak, Colorado, for metabolic studies in lower animals.

DISPOSAL

Summary

24. The licensee disposes of licensed material by either release to the sanitary sewage system or by shipment to an authorized disposal agency. A review of the disposal records revealed that all quantities of licensed material released to the sanitary sewage system were below the maximum quantities listed in 10 CFR 20.203.

Sanitary Sewage System

25. Maj. Preston stated that the Fitzsimons General Hospital complex maintains its own sewage treatment plant. According to Maj. Preston, the minimum recorded flow through this treatment plant is 480,000 gallons per 24 hours. Maj. Preston performed some calculations in the inspector's presence which shows the following quantities of respective radioisotopes which may be released in a 24-hour period without exceeding 10 CFR 20.303:

<u>Radioisotope</u>	<u>MC Allowed</u>
Hg-203	950
P-32	950
Sr-85	5200
Au-198	3800
Cr-51	90,000
I-131	3840
C-14	38,400
H-3	19,200

In comparison, the maximum quantities of radioisotopes released by the Radioisotope Laboratory, FGH, during the entire period January 1, 1966, through March 31, 1966, is as follows:

<u>Radioisotope</u>	<u>MC Released</u>
Hg-203	0.996
P-32	0.165
Au-198	0.254
Cr-51	0.725
I-131	4.679

The maximum quantities of respective radioisotopes released in any one day by the Radioisotope Laboratory during the period January 1, 1966, through March 31, 1966, at USAMRNL is as follows:

<u>Radioisotope</u>	<u>MC Released</u>
P-32	61
Cr-51	10
I-131	10.0
I-131	10
C-14	250
H-3	1250

A complete summary showing the total quantities of radioisotopes released by the Radioisotope Laboratory, FGH, during the period January 1, 1966, through March 31, 1966, is retained in the Region IV files. Also, a complete summary showing the total quantities of radioisotopes released during the period April 1, 1966, through June 30, 1966, by the Radioisotope Laboratory, USAMRNL, is retained in the Region IV files.

Solid Disposal

26. It was observed that each laboratory where licensed materials are used or stored is equipped with a stainless steel, plastic-lined waste can. Capt. Liddle said that all materials which come in contact with licensed materials are placed in these cans. This includes syringes, bench top coverings, papers, mops, rubber gloves, paper containing animal excrements, etc. It was noted that all cages used for animal experiments had a roll of brown paper at each end of the cage such that a sheet of paper could be unreeled underneath the cage to catch all animal droppings. When sufficient droppings have been collected, the paper is rolled up to include the waste material and placed in the waste can. Capt. Liddle said that all solid radioactive waste generated is transferred to him in sealed plastic bags and that these wastes are stored in a locked, walk-in freezer which is located behind the USAMRNL; Capt. Liddle said that he possesses the only key to the freezer. M. Sgt. Abernathy stated that he was responsible for collecting all waste generated at Pikes Peak. Capt. Liddle said that all animal carcasses, excreta, etc., are placed in plastic bags and placed in the freezer; he said that once each quarter he contacts Edgewood Arsenal and informs them of the exact quantity of radioactive material he possesses and wishes to dispose of. Capt. Liddle said that the Edgewood Arsenal ships him the 55-gallon drums for packaging the material and gives him detailed

instructions as to the method of disposal. Capt. Liddle said that Edgewood Arsenal instructs him to ship the barrels in refrigerated common carriers to the Edgewood Arsenal for further shipment to an authorized land disposal agency. The inspector reviewed records of solid licensed material disposed of and it was noted that each list contained the quantity of isotope disposed of, date of shipment, and number of barrels per shipment. The records reviewed by the inspector showed that shipments of solid waste are in accordance with ICC regulations as to packaging, labeling, and radiation levels. Records of some of these disposals will be retained in the office files.

LEAK TESTS

27. The licensee has a 13-mc Sr-90 sealed source installed in a gas chromatograph in Building S-619 and a 17.7-mc Sr-90 eye applicator which is stored in the Radiology Section of the main building. Records of leak tests were reviewed by the inspector and it was noted that both sources have been leak tested at the prescribed six month frequency during the inspectable period.

SURVEYS

Summary

28. Radiation and contamination surveys are conducted in all rooms and areas where licensed materials are used or stored on a weekly basis. M. Sgt. Abernathy is responsible for performing all of the USAMRNL radiation surveys at both the Denver facilities and at Pike's Peak.

External Radiation

29. Maj. Preston and Capt. Liddle stated that all rooms or areas where licensed materials are used or stored are surveyed for external radiation weekly or whenever new quantities of materials are received. It was observed that records of these surveys are maintained; a review of these records revealed that all external radiation levels in the areas surveyed were less than 0.04 mr/hr. It was noted that a SPINCO, beta-gamma meter, range 0 to 20 mr/hr, Army issue survey meter was used for these surveys. It was noted that the licensee possessed numerous portable radiation survey instruments including Eberline alpha instruments and an Eberline soft beta poppy. Maj. Preston said that he uses radium sources to check operation of his instruments. All licensee instruments are calibrated by the Pueblo Signal Depot on a quarterly basis.

Contamination

30. All rooms or areas where licensed materials are used or stored are surveyed for removable contamination weekly and immediately following use of licensed materials. In rooms or areas where C-14 or tritium-labeled compounds are used or stored the smears are evaluated on a Packard Tri-Carb liquid scintillation counter. Capt. Liddle

said they do not have a maximum level of acceptable contamination but that any area where removable contamination in excess of background is noted is decontaminated.

PERSONNEL MONITORING

Film Badges

31. It was noted that all personnel handling licensed material in the Radiation Therapy Section and the Radioisotope Laboratory wear film badges. It was noted that apparently sixty-four of the one hundred eighty people in the USAMRNL who handle byproduct material are film badged. The inspector reviewed the results of these film badges which are processed by the U. S. Army Signal Corps at Lexington, Kentucky, for the period since the previous inspection. No instances were noted wherein any personnel handling licensed material received in excess of 25% of the dose permitted by 10 CFR 20.101(a). It was noted that Form AEC-5's have been processed for all personnel handling licensed material. It was noted that Sgt. Abernathy, who performs all x-rays and calibrates ^{some} ~~all~~ survey instruments for the USAMRNL accumulated a total of 500 mr during the period January 1956, to March 1966, his total period of employment at FGH.

POSTING AND LABELING

32. It was observed that all rooms and areas where licensed materials were used or stored were posted in accordance with the provisions of 10 CFR 20.203(e)(1). All containers which were observed by the inspector were noted to be labeled in accordance with 10 CFR 20.203(f)(1) and (f)(4). A review of the radiation survey records revealed no rooms or areas which required the posting specified in 10 CFR 20.203(b) or (c).

PERSONNEL INSTRUCTION

33. It was observed that Form AEC-3 and the standard operating procedures for use of radioactive materials were posted at the entrance to each room or area where licensed materials are used or stored. Capt. Liddle showed the inspector records which indicated that personnel who use licensed material had signed statements that they had received instructions in radiation safety and 10 CFR 20 and of the procedures for working with licensed material.
34. All patients bearing > 30 mc of any radioisotope are hospitalized until such time as the radioisotope has decayed to < 30 mc. Maj. Preston informed the inspector that all ward nurses are alerted when radioisotope-bearing patients are placed in their ward; the rooms are surveyed and the nurses are informed of acceptable occupancy time; the rooms are posted as a reminder to the nurses and floor personnel. Only nurses may enter the patients' rooms and then only in the event of an emergency; they must wear a dosimeter.

INDEPENDENT MEASUREMENTS

35. The inspector toured all areas and rooms where isotopes are used and stored with both Maj. Preston and Capt. Liddle. With the exception of the walnut box used to store the Sr-90 medical applicator, the maximum dose rate noted in any room to store radioisotopes was about 0.03 mr/hr. The maximum dose rate noted on the front of the box used to store the medical applicator was 50 mr/hr at the surface (this is the side of the box facing the Sr-90 source). The dose rate at one foot from this surface of the box was 2 mr/hr. The maximum dose rate noted on any other surface of the box was < 2 mr/hr. The applicator was removed from the box and the dose rate at the handle of 2 mr/hr was measured. This dose rate was obtained behind the lucite shield.

DISCUSSION WITH MANAGEMENT

36. During the morning of July 13, the inspector, accompanied by Maj. D. F. Preston, visited the office of Maj. Gen. R. E. Blount. The inspector covered the single items of noncompliance with Maj. Gen. Blount wherein macroaggregated iodinated human serum albumin was procured and administered on sixty-four occasions to patients at the Radioisotope Laboratory, FGH. Maj. Gen. Blount was informed that the present license did not authorize possession of this material nor use of this material for lung scans. Previously, the inspector complimented Maj. Gen. Blount for the excellent radiation safety program and the excellent manner in which records were being maintained relative to usage of radioisotopes. Maj. Gen. Blount informed the inspector that an amendment would be obtained to permit use of this material.