1. Department of the Army
Fitzsimons General Hospital and
U. S. Army Medical Research and
Nutrition Laboratory
Denver, Colorado 80240

2. February 15, 16, and 19, 1968

3. Reinspection (4) - License No. 5-46-13
Initial - License No. 5-46-14 (5711)

4. Parts 20, 30, 35

5. License Nos. 5-46-13 and -14

6. This inspection consisted of a review of all records pertinent to the use of licensed material at the subject facility, tours of all areas in the radioisotope clinic, and in the research center and nutrition laboratory where radioactive materials are used and stored, interviews with persons who use the licensed material, and the observation of the use of the Co-60 irradiator unit.

The following items of noncompliance were observed or otherwise noted:

License No. 5-46-13

License Item 8.Y.

in that, during the period July 1966 to February 16, 1968, the licensee procured Sr-85 in the form of nitrate for use in bone scans in quantities between 1.5 and 2.0 mc, whereas, License Item 8.Y. restricts the maximum authorized possession of this isotope for use in bone scans to 1.0 mc. (See par. 12)

License Item 6.AA.
License Item 9.AA.

in that, on November 18, 1967, the licensee procured and used in the radioisotope clinic 15 uc of Cs-137, whereas, License Items 6.AA. and 9.AA. only authorize possession and use of this isotope for research studies in the U. S. Army Medical Research and Nutrition Laboratory. (See par. 13)

License No. 5-46-14 - 59/rec'd for this license hgp

10 CFR 20.401(b), "Records of surveys, radiation monitoring, and disposal."

in that, during the period February 1967 to February 16, 1968, records of radiation surveys performed during use and operation of the 23,200-curie (nominal) Co-60 irradiator for purposes of assuring compliance with 10 CFR 20.201(b), were not maintained, whereas, 10 CFR 20.401(b) states that each licensee shall maintain records showing the results of surveys required by 10 CFR 20.201(b). (See par. 37)

7. July 8, 11 and 13, 1966
(License No. 5-46-13)

8. No

A/42

Initials	H. J. Paas, Jr.	2/20/68
	Inspector	Date
[illegible]	G. D. Brown	2/27/68
Initials	Reviewer	Date

9703040160 970220
PDR FOIA
GLADE96-395 PDR

History

9. An announced reinspection (3) of the program conducted under the auspices of Byproduct Material License No. 5-46-13 was conducted on July 8, 11, and 13, 1966. As a result of this inspection, Form AEC-592 covering the following described item of noncompliance was issued to the licensee:

> " During the period of 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 millicuries 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."

10. License No. 5-46-14, which expires on September 30, 1970, was issued on September 10, 1965. This license was inactive during the period September 10, 1965 through January 1967, when it became active coincident with the procurement of the AECL Model Gamma Cell 220 irradiator. No previous inspections were conducted in regard to this license.

11. It should be noted that the item of noncompliance described in paragraph 9 was corrected by the licensee by amendment application dated August 2, 1966 and by issuance of the subject amendment on August 22, 1966. It should be noted that during the course of this inspection, the licensee was observed to be in compliance with the subject amendment.

Current Inspection

12. An unannounced inspection of the subject licenses was conducted at Fitzsimons General Hospital on February 15, 16, and 19, 1968. Personnel contacted and interviewed during the inspection portion related to the specific medical authorizations in the radioisotope clinic included Dr. Normal Hellman, Chief, Radioisotope Section, and Miss Ann Dalbow, Chief Technologist, and civilian supervisor of the Radioisotope Clinic. Contacted and interviewed in respect to the broad research aspects of the subject license which involves the medical research and nutrition laboratory were Maj. Charles G. Liddle, and Col. John E. Canham, Commanding Officer, USAMRNL. At the conclusion of the inspection, the results were discussed with members of the isotope committee and formerly reviewed with Col. Robert D. Anderson, Executive Officer and Acting Commander of FGH. Major General R. E. Blount, M. D., Commanding Officer of FGH was absent on the day the results of the inspection were reviewed.

Organization and Program

13. Licensed radioactive materials are used by two separate organizational and geographically-located departments at the Fitzsimons General Hospital. Those uses which involve specific medical authorizations (License Item 6.A. through 6.Z.) are confined to Building 511 which houses the radioisotope clinic and is under the administration of Dr. Hellman. The uses of radioactive material related to laboratory research, In Vitro studies in lower animals, and human volunteer studies are confined to Buildings S-601, 602, 603, 619, and 600 which

comprise the facilities of the medical research and nutrition laboratory under the administration of Major Charles G. Liddle, Chief. The radioisotope clinic and the medical research and nutrition laboratory operate independently in regard to assigned personnel, procurements, records, and responsibilities, however, although they are separate entities, both are under the administrative command of Major General R. E. Blount, Commanding Officer of Fitzsimons General Hospital.

14. In a civilian capacity, Miss Anne Dalbow, chief technologist (civilian supervisor), reports to Dr. Hellman and is the person responsible for radiation protection practices and records in the radioisotopes clinic. Major Liddle retains these same responsibilities for the medical research and nutrition laboratory.

Radioisotope Committee

15. This committee meets quarterly and the last meeting was conducted on January 2, 1968. The current composition of the radioisotope committee is as follows:

* Chief, Department of Medicine (Col. Edwin L. Overholt, MC) — * Chairman (Whoever is Senior)

Chief, Department of Surgery (Col. John W. White, MC)

* Chief, Radiology Service (LTC Paul E. Siebert, MC)

Chief, Pathology Service (Maj. John T. Decker, MC)

Chief, Radioisotope Section, Radiology Service (Capt. Normal Hellman, MC)

Radiation Safety Officer (WO-1 Charles L. Spinks)

Commanding Officer, USAMRNL (Col. John E. Canham, MC)

Chief, Radioisotope Sec., Physiology Div., USAMRNL (Maj. Charles G. Liddle, VC)

Chief, Purchasing & Contracting Branch, Supply & Svc Div. Non-voting member

Procurement - Radioisotope Clinic

16. Miss Dalbow stated that she initiates all actions concerning procurements that apply to the radioisotope clinic. Miss Dalbow stated that she has the responsibility for assuring that all procurements are within the authorizations of the subject license and that she originates the request which is forwarded to Dr. Hellman for approval. Approved requests are forwarded to purchasing for procurement. Miss Dalbow receives the incoming shipments and assures integrity by visual and inventory inspection. Labels are removed from incoming shipments and placed in individual bound books under the designation of the specific isotope concerned and the bound books continue to form a record of use and inventory. The procurement records were examined for the period July 1966, to date, and were tabulated for

the last six months which covers the period August 15, 1967 through February 15, 1968. The following table summarizes the results of this tabulation:

Isotope	Form	No. of Procurements in Six Months	Avg. Quantity per Procurement
I-131	Macroaggregated IHSA	27	1.4 mc
I-131	Hippuran	14	1.0 mc
I-131	Cholografin	3	1 mc
I-131	RISA	14	20 syringes @ 5 uc each
I-131	Rose Bengal	14	1 mc
I-131	Iodide	20	50 or 100 mc
I-125	RISA	3	20 syringes of 5 uc each
Hg-197	Chlormerodrin	35	1.2 or 2.2 mc
P-32	Sodium Phosphate	1	9.2 mc
Cr-51	Chromate	8	1 mc
Cs-137	Liquid	1	15 uc
Sr-85	Nitrate	13	1.5 mc
Au-198	Colloid	27	20 mc
Xe-133	Gas	3 *	2 curies
Te-99	Pertechnetate	200 mc/week	200 mc

* Procurement of Xe-133 discoatinued during late August 1967.

It was observed that during the period July 1966 to February 15, 1968, the licensee procured Sr-85 in the form of nitrate in quantities of 1.5 mc per procurement at a frequency of approximately two procurements per month. It was further observed that in an isolated case on April 18, 1967, the licensee procured 1.8 mc. Miss Dalbow was informed that procurement in these quantities was contrary to License Item 8.Y. which authorizes the maximum possession of Sr-85 in this form at any one time as 1 mc. Examination of inventory records revealed that amounts ranging from 0.1 to 0.4 mc Sr-85 were on hand coincident to the date on which the referenced procurements were placed in inventory. In specific cases the total possession of Sr-85 was 2 mc on November 17, 1967, and 1.9 mc on April 18, 1967. In discussing this item of noncompliance with Miss Dalbow, she stated that the established practice of procuring Sr-85 in quantities of 1.5 mc was in effect prior to her employment at Fitzsimons General Hospital and that since taking over the program she was not cognizant that the procurement was in excess of the amount authorized. She stated she would implement corrective action immediately by applying for an amendment which would increase the authorized possession limit from 1 mc to 3 mc. In subsequent discussions with Dr. Hellman, he concurred and stated he would apply for the amendment immediately. It should be noted that the referenced Sr-85 was used in the radioisotope

clinic for bone scan procedures at a frequency of 5 to 10 times per month, using 100 uc per procedure.

17. It was observed that on November 18, 1967, the licensee procured and used in the radioisotope clinic, 15 uc of Cs-137 in liquid form. Miss Dalbow was informed that possession of 15 uc of Cs-137 was in excess of the allowable generally licensed quantities as defined in Schedule A, 10 CFR 31.100 (Column No. 1), and that the possession of Cs-137 was not authorized in the contents of the specific authorizations for medical use in License No. 5-46-13. Further review and discussion revealed that under the provisions of the specific medical and broad research authorizations that comprise License No. 5-46-13, the possession of 15 uc of Cs-137 could be in compliance with License Items 6.AA and 8.AA which state that 500 mc may be possessed of any byproduct material with Atomic Nos. 1 - 83, inclusive. Miss Dalbow was informed that possession of the Cs-137 under the authorizations of License Items 6.AA and 8.AA would then require that the authorized use be confined to those described in License Item 9.AA which states "Laboratory research In Vitro and in lower animals." Following further discussions with Miss Dalbow it was agreeably concluded that the possession and use of 15 uc of Cs-137 in the radioisotope clinic was in noncompliance with License 6.AA and 9.AA which only authorize possession and use of this isotope for research studies in the U. S. Army Medical Research and Nutrition Laboratory. It should again be noted that as described in paragraph 13, the radioisotope clinic and the U. S. Army Medical Research and Nutrition Laboratory are separate departments that operate in widely separated geographic locations and as stated by Miss Dalbow, operate independently except for the relationship that relates to information exchange surrounding the activities of the radioisotope committee. The separate intent and interest of the two departments within the Fitzsimons General Hospital complex is further exemplified in a review of the early licenses and license applications which show that prior to February 3, 1964, when the licensee combined the specific medical and broad research programs at FGH into License No. 5-46-13, all of the separate interests referenced in the above discussions were licensed under separate licenses in the series 5-46-9, 10, 11 and 12.

Procurement - USA MRNL

18. Major Liddle stated that the need for licensed materials arrises by request from the individual investigator who forwards the request to Major Liddle's office. Major Liddle stated that he assures that the request is within compliance of the authorizations listed on license and that the procedure is in accord with the approval of the radioisotope committee and then authorizes the request to purchase. Incoming shipments are picked up by the individual investigator at the receiving desk and surveyed if visual inspection indicates damage to the shipment. Surveys are performed following the unpacking of the shipment

and prior to placement of the radioactive materials in storage.

19. Major Liddle maintains procurement records in four ways; namely, (1) a copy of each purchase request is maintained in the files, (2) a log book containing a sheet for each isotope shows the specific isotope, form, day received, amount received, and balance on hand and each investigator who works under the supervision of Major Liddle signs this log book when he withdraws material and the entries show the intended use, date, amount, investigator's signature, and balance of the specific isotope on hand. (3) An index card system is maintained for each isotope which shows all receipts and current inventory. (4) Quarterly reports are prepared for the radioisotope committee which show, for each isotope, the amount received during the quarter, amount used, transferred, disposed, the calculated decay for the remaining amount on hand, and, lastly, the net activity remaining in stock. These four sets of records were examined for the period July 1966 through February 16, 1968, and were compiled for two three-month periods during 1967. The following table summarizes the results of this compilation.

Isotope	Amount Procured April, May, June, 1967	Amount Procured Oct., Nov., Dec., 1967
C-14	4.656 mc	7.725 mc
Ca-45	5.540 mc	10.0 mc
I-125	1.0 mc	0.1 mc
P-32	6.0 mc	16.0 mc
H-3	6.05 mc	None
Xe-133	None	13.6 mc

All procurements made by the USAMRNL during the period July 1966 through February 16, 1968, and the records pertaining thereto, were observed to be in compliance with license authorizations and with the provisions of Title 10, Part 20 regulations.

Inventory - Radioisotope Clinic

20. Inventory records are maintained in the same log books which contain procurement records. These records were reviewed for the period July 1966 through February 16, 1968, in respect to the authorization of license items 6, 7, and 8, and were found to be in compliance with all authorizations except for those noted in paragraphs 16 and 17 above.

Inventory - USAMRNL

21. The inventory within this department includes the amounts of radioactive material that are used in several different buildings and several divisions within the department. These records are maintained in Major Liddle's office and include the amounts that are used by or stored in microbiology, pathology, physical, radiochemistry, and metabolic divisions. The records revealed that the summary inventory for these facilities was as follows:

Isotope	Inventory June 30, 1967	Inventory December 31, 1967
C-14	68.844 mc	73.553 mc
Ca-45	5.540 mc	14.975 mc
Cs-137	16.1 uc	16.1 uc
Co-60	3.2 uc	3.2 uc
Co-60 *	20.596 curies	20.596 curies
I-125	860.9 uc	171.0 uc
P-32	421.5 uc	1.66 mc
Sr-90	0.6 uc	0.6 uc
Sr-90 *	12.4 mc	12.4 mc
Na-22	78.0 uc	78.0 uc
S-35	559 uc	129 uc
H-3	2.7 curies	2.7 curies
Xe-133	None	1.6 mc

* Sealed sources.

The Co-60 sealed source is mounted in the AECL Model Gamma Cell 220 in accordance with authorization under License No. 5-46-14. The strontium source is stored in the Metabolic Division building, F-619, for use in the Chromolab, Model 310, gas chamber. The quantities of byproduct material possessed by the medical research and nutrition laboratory for the period July 1966 through February 16, 1968, were found to be within the authorized amounts as specified in License Item 8 of the subject license.

Use - Radioisotope Clinic

22. According to Miss Dalbow, all dosages of byproduct material are either prepared by herself or by a laboratory technician who is working directly under her supervision. Miss Dalbow stated that all administrations are performed either by Dr. Hellman or directly under his immediate supervision. Occasional administrations performed by a resident physician require approval of Dr. Hellman. All procedures used in preparation and administration have been approved by the radioisotope committee and are documented in the files at the clinic.

23. It was observed that use records are maintained in conjunction with the byproduct material procurement records. The use records show the date of administration, patient's name, name of administering physician, and amount administered. These records were reviewed for the period covered by this inspection and were compiled for the six month interval between August 15, 1967 and February 15, 1968. The following table summarizes this compilation:

Isotope	Form	Procedure	Avg. Frequency of Procedure	Average Dosage per Use
I-131	Macroaggregated IHSA	Lung scans	15-20/month	30 uc
I-131	Hippuran	Renal functions	36/month	30 uc
I-131	Cholografin	Renal functions	2/month	300 uc
I-131	RISA	Blood volumes	10/month	3-5 uc
I-131	Rose Bengal	Liver functions	6/month	150 uc
I-131	Iodide	Thyroid functions	120/month	10 uc
I-131	Iodide	Thyroid therapy	5/month	5-100 mc
I-125	RISA	Plasma volumes	2/month	5 uc
Hg-197	Chlormerodrin	Kidney scans	24/month	100 uc
P-32	Phosphate	Leukemia therapy	1/6 months	9 mc
Cr-51	Chromate	Red cell mass and survival studies, blood volume, and spleen functions	8/month	50-200 uc
Cs-137	Liquid	Plate source	1/6 months	15 uc
Sr-85	Nitrate	Bone scans	5-10/month	100 uc
Au-198	Colloidal	Liver scans	24/month	150 uc
Xe-133	Gas	Lung functions	4/6 months	75-100 mc
Tc-99	Pertechnetate	Brain scans	10-15/week	8 mc

Miss Dalbow stated that she assures that all byproduct material used in humans conforms to established pharmaceutical quality and assay in accord with the requirements of License Condition 16. She stated, and it was also observed, that all byproduct material used in the radioisotope clinic is prepared by recognized USA suppliers. Miss Dalbow also stated that she assures that I-131 labeled macroaggregated IHSA is obtained from a supplier who holds a current license in accord with DHEW requirements as stated in License Condition 19.

24. Miss Dalbow stated and it was observed that Te-99m in the form of pertechnetate is obtained from E. R. Squibb and that the dilution and preparation from the Mo-99-Te-99m generator is performed in accordance with the procedure defined in the letter submitted by the licensee on November 28, 1966.

Use - USAMRNL

25. Byproduct material in this division is used by approximately 15 investigators who work in the microbiology, pathology, physical chemistry, and metabolic divisions of the laboratory. In respect to the broad section of the license (License Item 6.AA) which authorizes any byproduct material with the Atomic Numbers 1-83 in quantities to 500 mc for laboratory research In Vitro and in lower animals, the records revealed that individual investigators use microcurie quantities in their investigations and seldom withdraw more than 100 uc from the stock inventory that is controlled by Major Liddle. The use records maintained in Major

Liddle's office are signed by the individual investigator when he withdraws byproduct material from the inventory and the entry shows the date the withdrawal was made, the amount, and the intended use. Major Liddle stated that he assures that the use intended by the investigator has been approved by the radioisotope committee. It was noted that C-14 is the prime isotope being used in animal research and that normal withdrawals made by individual investigators were in the range of 50 to 100 uc. All stated uses related to In Vitro or lower animal research studies.

26. It was observed that in respect to License Amendment 09 (License Item 9), three volunteers have participated in the metabolic and physiological tracer study program that is described in the licensee's application submitted November 18, 1966. The administrative doses in these three cases were 30, 46, and 50 uc of C-14 in the form of amino acid. The administrations were performed by a physician and all procedures and authorizations were in accord with those prescribed in the subject license.

27. It was noted that in respect to Amendment No. 11 (License Item 9.II and Item 9.JJ), ten volunteers have participated in the study to test the effects of high altitude on man. To conduct this program, Dr. Janoski (authorized user) procures C-14 in the form of ~~four~~ 4-C-14 cortisol in a 100-uc quantity and procures H-3 in the form of ~~one~~ 2-H-3- aldosterone in 1-mc quantities under the broad license authorizations of Items 6.AA and 8.AA. After performing laboratory studies related to solution preparation, standardization and calibration, Dr. Janoski administered 1 uc of C-14 and 2 uc of H-3 to the volunteers on two occasions during September 1967. The sea level studies were performed at Fort Lewis, Washington, and the high altitude studies at Pikes Peak, Colorado, in accord with the requirements of License Condition 21. No items of noncompliance were noted in respect to the program designed to study the effects of high altitude on man.

Disposal - Radioisotope Clinic

28. Miss Dalbow stated and the records reflected that a disposition is made from the inventory of radioisotopes approximately every two to three weeks. Unusable items are taken from laboratory storage and placed in a box for storage in the decay bin which is located outside and immediately adjacent to the radioisotope clinic. Coincident with this disposition to the decay bin, a form is completed which shows the isotope, lot number, concentration in uc/cc, the number of cc in the individual bottles, and the total uc in each bottle. Following completion of this form, Miss Dalbow summarizes the total activity disposed of according to individual isotope and records the values in microcuries. This material is allowed to stay in the decay bin until it has either decayed to background or has decayed to an activity level that allows disposition to the sanitary sewer as per the requirements of 10 CFR 20.303. To accomplish compliance to 10 CFR 20.303, the licensee has made calculations based on a

sanitary water discharge of 5×10^5 gallons per day. The maximum amount disposable in uc/day is calculated on the basis of the values for individual isotopes shown in 10 CFR 20.303, Item 1, Appendix B, Table 1, Column 2. Liquid dispositions made in this manner are made only on Tuesday and Friday and these dispositions were found to be in compliance in all cases. The following table summarizes the quantities of activity disposed of during each of the two most recent dispositions:

Isotope	Disposition of February 12, 1968	Disposition of January 19, 1968
I-131	0.25 mc	3.7 mc
Sr-85	0.83 mc	0.11 mc
Hg-197	0.10 mc	0.12 mc
Cr-51	0.26 mc	None
Au-198	0.27 mc	0.14 mc
P-32	None	1.2 mc

It should be noted that all records pertinent to liquid disposal are summarized by the radioisotope clinic on a quarterly basis and submitted to the radioisotope committee for review.

29. Disposal of solid material that has accumulated in the radioisotope clinic is accumulated, packaged, and placed in the decay bin until such time as it has decayed to background levels and then is disposed of in conventional trash. The licensee records the date such dispositions then enter the decay bin and records the survey records at the time the disposition is made to conventional trash.

Disposal - USAMRNL

30. Liquids designated for disposal are forwarded by the individual investigator to the waste storage room in the research laboratory where the material is allowed to remain until such time as the decay permits disposal to the sanitary sewer. Dispositions to the sanitary system are made according to the procedure described above for the radioisotope clinic except that whereas the radioisotope clinic is allowed to dispose of liquid material on Tuesday and Friday, the nutrition laboratory discards are performed on Monday, Wednesday, and Thursday. It was noted that dispositions from this facility usually are in the low order of microcurie quantities and it was observed that all such dispositions were well within the limits as defined in 10 CFR 20.303(1).

31. Solid material designated for disposal is forwarded by the individual investigator to the waste storage room where it is packaged in individual containers and placed in drums and allowed to accumulate until a full drum is attained. The metal drums are sealed and taken to waste storage which consists of a large walk-in freezer as much of the material constituting the solid waste represents disposition that originates from studies conducted in research regarding

lower animals. The contents of each drum are recorded as to isotope, activity, date, and name of investigators who submitted the material. A typed summary sheet is attached to each drum. The solid waste accumulated in the walk-in freezer is allowed to accumulate until the number of drums warrant making a disposition wherein the material is shipped to Edgewood Arsenal according to directives forwarded to the licensee by Edgewood Arsenal. Approximately two shipments are made to Edgewood Arsenal annually. The last of these occurred on June 19, 1967 and consisted of 18 drums which contained 2,709 uc of C-14, 45 uc of H-3, 152 uc of I-125, 73 uc of I-131, 38 uc of Cr-51, 124 uc of P-32, 13 uc of Ca-45, and 56 uc of S-35.

32. The records showed that on one occasion during the period since the last inspection, animal carcasses were allowed to decay to natural background and disposed of to trash. The residual activity at time of disposal in these carcasses was determined by counting techniques and the records showed that the activity was less than 0.002 uc per gram.

33. Major Liddle stated that there has been no disposition of radioactive materials to the environment. He stated and it was observed during a tour of the facilities that all hoods are equipped with filters and traps for purposes of retaining any radioactive material that may be discharged as part of chemical loss. It was noted that C-14 is the prime isotope being used in animal research and that all hoods wherein these experiments were performed were equipped with a sodium hydroxide trap for purposes of trapping CO_2.

Leak Tests

34. The licensee possesses a 13-mc Sr-90 source and a 20,596-curie Co-60 source. Leak tests were performed at regular six-month intervals on the 13-mc Sr-90 source with the last leak test being performed during the months of May and November, 1967. The Co-60 source was tested in February 1967, coincident with its procurement from the vendor and again during July 1967 and January 1968. Leak tests were performed and recorded in accord with License Condition 15 of License No. 5-46-13 and in accord with License Condition 13 of License No. 5-46-14.

Surveys - Radioisotope Clinic

35. Radiation surveys are performed weekly throughout the radioisotope clinic in locations that represent laboratory usage areas, storage areas, and counting facilities. The results of these surveys are recorded in a bound log book in units of mr/hr and the values range from 0.02 to 0.2mr/hr at all locations except an occasional reading in the range of 1 to 3 mr/hr at the storage decay bin facility. A spot survey was made by the inspector using a Frieseke Hoepfner survey meter at random locations throughout the radioisotope clinic and the maximum dose rate detected was 1 mr/hr at the closest point of access to the decay storage bin.

Surveys - USAMRNL

36. Swipe surveys are performed in [redacted] facilities which use or store byproduct material on a frequency of one survey per month. The records revealed that 109 locations are surveyed in this program. The swipes are counted on the same day they are taken and the results are recorded as d/m/swipe. A review of the results of these surveys for the period covered by this inspection showed that all counting results were within the statistical error of the counting procedure.

37. In reference to License No. 5-46-14, it was observed that the licensee had no records of radiation surveys performed in conjunction with the initial use and continued operation of the AECL Model Gamma Cell Model 220 which contains the 20,596-curie Co-60 source. Upon inquiry, Major Liddle stated that he personally made a survey of the facility when they installed the equipment in February 1967 and also made a survey at the time they initially operated the equipment. Major Liddle stated that he performed these surveys to assure compliance with 10 CFR 20.105(b) in regard to exposures outside the room which contains the source and also for purposes of assuring compliance with 10 CFR 20.201(b). Major Liddle further stated that he knew that some of the investigators who operate the equipment make radiation surveys and he confirmed this fact by placing a telephone call to Dr. Riska, who stated he had made such surveys but had not recorded them. Major Liddle was informed that the failure to maintain these records was in noncompliance with 10 CFR 20.401(b) which states that each licensee shall maintain records showing the results of surveys required by 10 CFR 20.201(b). In subsequent discussion, Major Liddle stated that he felt such surveys should be made at a frequency of at least two to four times annually and that he would institute a program to assure that these surveys are performed and are recorded in the future.

38. Due to the absence of any record of a survey being performed in the facility where the 20,596-curie Co-60 source is stored and used, the inspector conducted a survey of this facility using a Frieseke Hoepfner survey meter. The following measurements were observed:

Location	Source Position Up	Source Position Down
Contact with shield (maximum reading)	12 mr/hr	20 mr/hr
Contact with shield (average)	2 mr/hr	3 mr/hr
Distance of one meter from shield	1 mr/hr	2 mr/hr
Normal operator location	0.5 mr/hr	1 mr/hr
Corridor door	background	0.5 mr/hr
Exit door to outside	background	1 mr/hr

Dosimetry

39. All persons working with byproduct material under the purview of the subject licenses are film badged. Badges are exchanged on a monthly basis and are processed by Lexington-Blue Grass Army Depot, Lexington, Kentucky 40507. Monthly badge reports are received from

the processor and these records are transcribed to individual record form to AEC Form -5 equivalent and are placed in the individual medical record folder of the employee. The maximum annual exposure for an employee in the medical research and nutrition laboratory was 659 millirem which included a one-quarter exposure of 259 millirem. The similar maximum for an employee in the radioisotope clinic was 628 millirem annually and 220 millirem quarterly.

Posting and Labeling

40. It was observed during a tour of the facilities that all rooms and areas where licensed materials were stored or used were posted in accordance with the provisions of 10 CFR 20.203(b) and (e). It was further observed that all containers were labeled in accord with 10 CFR 20.203(f)(1

Personnel Instruction

41. Form AEC-3 was observed to be posted at the entrance to or on the bulletin board of each facility where licensed materials are used or stored. Copies of the license, along with procedures for the specific facility were posted on the bulletin board at some facilities and in the remaining facilities were available in the office of administrative personnel. Repetitive work is performed in accord with written procedures which are available in the office of supervisory personnel. Special procedures are issued to nurses for the handling of patients that have been exposed to diagnostic or therapeutic quantities of radioactive materials which require subsequent hospitalization. Procedural methods assure that patients containing I-131 or Au-198 remain hospitalized until the residual activity is 30mc or less. Miss Dalbow stated that in the case of an unusually high therapeutic administration, the nurses would receive special placement and handling instructions directly from Dr. Hellman.

Security

42. Major Liddle statedthat all facilities in which radioactive material is stored or used are locked at night, on weekends, and holidays. Building S-603 which contains Major Liddle's office maintains an on-duty officer at all times and this person has the custodial responsibility for the keys to the other facilities during off-duty hours. Special precautions include an external bolt-type padlock on the walk-in freezer wherein the solid radioactive materials are stored and the retention of custodian responsibility by Major Liddle for the key that unlocks the door to the facility where the Co-60 irradiator is kept. The entire Fitzsimons General Hospital complex has the additional security feature related to a military installation wherein admittance to any of the buildings mentioned in this report is by "authorized personnel only".

Discussion with Management

43. On February 19, the inspector, in the company of Major Liddle, met with Lt. Col. Paul E. Siebert, Chairman of the radioisotope committee, and reviewed the three items of noncompliance noted during the course of the inspection. The meeting with Lt. Col. Siebert was regarded

as an information meeting preparatory to a scheduled meeting with Col. Robert D. Anderson, Executive Officer and Acting Commanding Officer of Fitzsimons General Hospital. The meeting with Col. Anderson took place in the office of Major General R. E. Blount, Commanding Officer, who was absent on the date of the discussion. Col. Anderson invited Major Liddle, Dr. Hellman, Col. Canham, and Lt. Col. Siebert to the meeting. The three items of noncompliance discussed in paragraphs 16 , 17 , and 37 were reviewed with Col. Anderson and his staff and the previously discussed corrective actions were agreed upon during the discussion. Col. Anderson was informed that none of the items of noncompliance were regarded by the inspector as a threat to the health and safety of the public or the licensee's employees. Additionally, the inspector commented favorably to Col. Anderson on the excellent administrative program that was observed in relation to the use of radioisotopes at Fitzsimons General Hospital. Form AEC 3-91 showing the item of noncompliance closed to the inspection of license # 5-46-14 and Col. Anderson was informed the Form AEC-592 would be forthcoming from the Regional Office in regard to the inspection of license # 5-46-13.