Form AEC-592
(5-63)

UNITED STATES ATOMIC ENERGY COMMISSION
DIVISION OF COMPLIANCE

I-E, IV, B

1. LICENSEE	2. REGIONAL OFFICE
Lakewood Hospital Nuclear Medicine Department 14519 Detroit Avenue Lakewood, Ohio	REGION III, DIV. OF COMPLIANCE OAKBROOK PROFESSIONAL BLDG. OAK BROOK, ILLINOIS
3. LICENSE NUMBER: 34-1197-1	4. DATE(S) OF INSPECTION: January 22, 1965

5. The following activities under your license (identified in Item No. 3 above) appear to be in noncompliance with AEC regulations or license requirements, as indicated.

A. Your byproduct material inventory of December 1964 included 10 microcuries of Cobalt 60, contrary to License Condition No. 8(E) which authorizes the maximum amount of 5 microcuries of Cobalt 60 to be possessed at any one time.

B. Records of waste disposals were not maintained contrary to 10 CFR 20.401(b).

C. Records of survey results of the isotope laboratory were not properly maintained as required by 10 CFR 20.401(b).

D. The isotope storage areas in isotope laboratory and urinalysis laboratory were not posted in accordance with 10 CFR 20.203(e)(1).

It is noted that Item D. was corrected at the time of the inspection by the posting of signs in the respective areas showing the radiation caution symbol in the colors of magenta on yellow and the words "Caution - Radioactive Material."

Supplementary page None attached.

Edgar C. Ashley Edgar C. Ashley 2-5-65
AEC Compliance Inspector Date

ORIGINAL: LICENSEE. COPIES: ☑ CO REGION ☐ CO HEADQUARTERS ☐ L&R HEADQUARTERS.

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REPORT COMPILED SHEET

Indentifying Information

Type report 591 (592) (circle)

1. Licensee Lakewood Hospital
2. Address Nuclear Medicine Department
   14519 Detroit Avenue
   Lakewood, Ohio
3. License No(s) 34-1197-1
4. Date of Inspection January 22, 1965
5. Inspector Edgar C. Ashley
6. Status of Compliance Noncompliance

Items of Noncompliance

7. Section of Regulation or License Condition		Details Paragraph	
A	License Condition 8.E	A	15
B	10 CFR 20.203(e)(1)	B	30 & 31
C	10 CFR 20.401(b)	C	39 & 40
D		D	
E		E	
F		F	
G		G	

Classified Information

8. This report contains classified or business confidential information. Yes (No)

EC Ashley 2-1-65
Inspector Date

[signature] 2-4-65
Reviewer Date

HEALTH PHYSICS ANALYSIS

The licensee's facilities, equipment and staff organization appear to be adequate for the conduct of his current byproduct material program.

No significant health and safety problems appear to exist from the use of radioisotopes under this license.

592 DETAILS

GENERAL INFORMATION

9. This was an announced inspection conducted on January 22, 1965. Dr. T. W. Knickerbocker, Director of Radiology at Lakewood Hospital, was telephonically notified of this forthcoming inspection on January 15, 1965.

10. Mr. James Wynd of the State of Ohio Department of Health was notified of this forthcoming inspection by telephone on January 13, 1965. No member of that organization accompanied the inspector on this inspection.

11. The following persons were interviewed during the course of this inspection. They are: Mr. Arthur Lepino, Hospital Administrator; Dr. William Fayen, Internist and "User" under this license; Dr. T. W. Knickerbocker, Director of Radiology and RSO; Mrs. Frick, Isotope Laboratory Technician. All information is given in substance unless otherwise indicated.

INSPECTION HISTORY

12. The last previous inspection of this license was conducted on October 10, 1957, and was the initial inspection of this license. No items of noncompliance were noted as a result of that inspection. The first reinspection of this license was conducted on January 22, 1965, and is the subject of this report.

PROGRAM

13. The licensee utilizes radioisotopes for diagnostic and therapeutic purposes as authorized under this license.

14. The licensee stated that the current rate of use and procurement of the various radioisotopes possessed under this license are as follows:

A. Iodine 131 as iodide - between 20 and 30 capsules per month. ~~Each~~ capsule ~~is~~ 15 ~~or~~ 50 microcuries maximum when received. These capsules are procured on an as needed basis.

B. Iodine 131 as Iodinated Human Serum Albumin. Not used now, and has not been used for approximately six months.

C. Iodine 131 as labeled fats and/or fatty acids - about [redacted] 50 microcuries every three months in capsule form and ordered as needed.

PROGRAM, Cont'd.

14. continued.

D. Phosphorus 32 as soluble phosphates. This isotope is not used now and has not been used for approximately three years.

E. Cobalt 60 as labeled Vitamin B-12 - approximately 3 to 4 microcuries are used per month and are ordered 10 microcuries at a time.

F. Mercury 203 as neohydrin. This isotope is procured approximately once per month which is equal to about 1 millicurie maximum per use.

G. Chromium 51 as sodium chromate. This isotope is used about three times per year at about 50 microcuries each time. The isotope is sometimes ordered at the rate of two doses at a time.

H. Gold 198 as colloidal. Gold is used approximately at the rate of 4 to 15 microcuries per month. Five millicuries are purchased at one time by the licensee.

I. Iodine 125 as iodinated human serum albumin is used at the rate of four 5 to 10 microcurie doses per month. The licensee stated that between five and ten syringes each containing 10 microcuries are purchased at a time. It can be noted here that this item Iodine 125 has replaced Item B, Iodine 131 as the iodinated human serum albumin.

J. Mercury 197 as neohydrin. The licensee uses about three 1 millicurie doses per month and they purchase approximately 1 to 2 millicuries at a time.

15. The licensee stated that all of the above byproduct materials are procured from Nuclear Consultants Corporation with the exception of the Iodine 125 which is received from Volk Radiochemical Company. It is noted that license Item 8.E. for Cobalt 60 shows the maximum amount of ~~microcuries~~ plus isotope which may be possessed at any one time to be 5 microcuries. Dr. Fayen was advised

PROGRAM, Cont'd.

15. continued.

that the procurement and possession of 10 microcuries of Cobalt 60 at one time constituted noncompliance with License Condition 8(E).

ORGANIZATION AND ADMINISTRATIVE CONTROL

16. The licensee stated that radioisotopes are used only within the Nuclear Medicine Department of the hospital with Dr. Fayen at the head of that department. The Nuclear Medical Department is within the Division of Medicine. The Head of this division is Dr. Homer T. Yoder.

17. In the event that any problems would arise from the use of radioactive isotopes, Dr. Fayen stated that he would report to the Chief of Medicine or to Dr. Yoder or to Mr. Lepino or to the Isotope Committee for consultation and advise.

18. The licensee also stated that the minutes of the Radioisotope Committee meeting are read in the hospital's executive committee meeting.

RADIOISOTOPE COMMITTEE

19. During 1964 Dr. Fayen was the chairman of this committee. New committee membership and chairmanship of this committee is appointed at the beginning of each calendar year. This committee known as the Therapeutics Committee of the hospital includes the following membership for 1965:

Dr. Robert Wallace, Hospital Anesthesiologist as Chairman.

Dr. Oliver Eitzen, Chief Pathologist

Dr. William Fayen, Internal Medicine

Dr. L. James Regan, General Practice

Dr. William Wilder, Internal Medicine

Mr. Robert Todia, Pharmacist

In the past this committee has met on an as needed basis. However, in that the isotope program has increased over the years, the committee plans to meet on a quarterly basis to discuss procedures, proposals, pharmaceutical problems, etc.

RADIOLOGICAL SAFETY OFFICER

20. Dr. Knickerbocker has been appointed the RSO by the Executive Committee of the medical staff of this licensee. Dr. Knickerbocker's duties as RSO are a continuous function in all radiology and isotope operations.

RADIOLOGICAL SAFETY PROCEDURES

21. Hospital personnel have received both written and oral instructions concerning the use of radioisotopes. Dr. Fayen has written a brochure concerning the general aspects of isotope handling. Mrs. Frick, the laboratory technician, receives oral instruction as needed from Dr. Fayen. Floor nurses at the hospital have instructions printed on the cards in the procedural books on each floor. Isotope information is shown on the patient's chart, including the fact that the patient has been to the isotope lab.

22. Dr. Fayen stated that he approves all byproduct material usage for each patient. He either sees the patient, which is 90 to 95 percent of the time, or he reviews the diagnostic report of the attending physician. Diagnostic capsules are ordinarily given by Mrs. Frick. Dr. Fayen stated that all therapeutic intravenous dosages are given by him personally. Diagnostic intravenous doses are either given by Mrs. Frick or one of the resident physicians. Mrs. Frick ordinarily performs all scanning and counting operations. Following these operations Dr. Fayen interprets all data.

23. Although no specific area in the hospital is set aside for isotope patients, all dosages are administered in the isotope laboratory according to the licensee.

FACILITIES

24. The licensee's radioisotope laboratory is located on the second floor in the Clinical Laboratory Section of the hospital.

25. The isotope laboratory was noted to be in an out of the way location. The laboratory is on a slightly higher level than the second floor. Access to the laboratory is by an inclined ramp. The licensee exercises complete control over these facilities. There are no living quarters located in the vicinity of these facilities.

FACILITIES, Cont'd.

26. A lead brick enclosure has been constructed on a windowsill in the rear corner of the radioisotope laboratory. This window faces a courtyard. This courtyard is approximately 20 to 25 feet wide which is a natural restriction for anyone working in the vicinity of the storage area. A refrigerator located in the uranalysis laboratory on the second floor of the hospital is used for the storage of Iodine 125 albumin.

EQUIPMENT

27. Located in the radioisotope laboratory are a patient examination table, a Tracerlab "1000" scaler, associated well counter, and a Nuclear Chicago photo scanner. The laboratory also includes standard handling devices and miscellaneous laboratory equipment comparable to that of a standard radioisotope hospital laboratory. The licensee possesses one Jordan portable instrument Model No. AGB-10-SR. This instrument has three log scales ranging from 0.01 mr/hr to 10,000 mr/hr. This instrument is calibrated by the licensee's consultant during his annual survey.

PERSONNEL MONITORING AND EXPOSURE DETERMINATION

28. The licensee does not prescribe to a film badge service. The licensee does, however, possess fifteen pocket dosimeters. Each person who works in the radiology or isotope program is assigned his own personal dosimeter and is worn at all times when on duty. Dr. Fayen and Mrs. Frick are the only two persons involved with byproduct material at this hospital. The pocket dosimeters are Victoreen Models 541/A direct reading type with 0 to 200 mr/hr range. The licensee stated that the dosimeters are read once per month and recorded in a notebook.

RADIATION SURVEYS AND/OR EVALUATIONS

29. An annual survey is made by the licensee's consultant, Mr. Leopold Rovner, Certified Radiation Physicist. During this annual survey Mr. Rovner surveys the isotope laboratory and evaluates equipment and visually checks all aspects of the facility and program. The licensee stated that in addition to this annual survey, a monthly routine survey is performed in the laboratory plus any other time that it is believed that something may have been spilled.

POSTING AND LABELING

30. The lead storage area in the radioisotope laboratory was posted with a sign showing magenta on yellow colors with a standard radiation caution symbol and the words "Radiation Hazard." The licensee was advised that this type of sign was improper and constituted noncompliance with 10 CFR 20.203(e)(1) in that the sign did not show the words "Caution - Radioactive Materials."

31. The refrigerator area in the uranalysis lab used for the storage of Iodine 125 albumin was not posted with any signs. The licensee was therefore advised that this constituted noncompliance with 10 CFR 20.203(e)(1). It was noted that all containers holding radioactive materials were labeled in accordance with 10 CFR 20.203(f)(1) and (f)(4).

32. The two storage areas mentioned above in paragraphs 30 and 31, respectively, were properly posted by the licensee in the presence of the AEC representative in accordance with section 20.203(e)(1) during the time of the inspection to correct the posting deficiencies noted.

WASTE DISPOSAL

33. Unused byproduct material dosages, and decayed residues are flushed down the sanitary sewerage system by way of a large commode located in the radioisotope laboratory. Used vials and syringes are rinsed and labels are removed and then they are disposed of through the regular hospital trash after it is determined by survey that no radioactivity is present.

REPORTS OF THEFT AND LOSS

34. The licensee stated that no material has been lost or stolen.

INCIDENTS OR UNUSUAL OCCURRENCES

35. The licensee stated that no incidents or unusual occurrences have occurred.

REPORTS OF OVEREXPOSURES AND EXCESSIVE LEVELS OR CONCENTRATIONS

36. The licensee stated that no overexposures have occurred nor have excessive levels and concentrations been noted.

RECORDS

37. The licensee maintains receipt records for all byproduct material. These records show the form, the amount, the isotope, the dates ordered, the dates received. All receipts noted appeared to be within authorized possession limits excep

RECORDS, Cont'd.

37. continued.

for the above noted Cobalt 60 (please see paragraph 15). This record showed that 10 microcuries of Cobalt 60 was ordered and received in December, 1964 from Nuclear Consultants Corporation. This receipt record showed that twenty vials of 0.5 microcuries per vial were received.

38. The licensee has made no transfer of byproduct material other than the waste disposal mentioned previously in paragraph 33 above.

39. The licensee stated that no record has been kept of the waste disposals of the ~~liquids~~ insoluble and dissolved byproduct material into the sanitary sewerage system. The licensee was therefore advised that failure to maintain records of waste disposal constituted noncompliance with 10 CFR 20.401(b).

40. The licensee maintains an isotope laboratory survey log which shows monthly entries beginning in January, 1964. One entry is made for each month of the year and the results of this survey are shown as "O.K." and initialed by Dr. Fayen. Dr. Fayen stated that the O.K. means nothing above instrument background. The licensee was advised that failure to maintain the results of the surveys in [redacted] the same units as shown in 10 CFR 20 constituted noncompliance with 10 CFR 20.401(b).

41. The licensee maintains reports submitted by Mr. Rovner, the Health Physics Consultant, concerning the results of his annual surveys. These survey records show that at the time of his inspection no excessive levels of radiation nor contamination existed. The licensee's dosimeter result records beginning in March, 1964, show monthly entries for both Dr. Fayen and Mrs. Frick. Dr. Fayen's monthly results were all less than 20 mr/one month except for one 85 mr maximum reading and Mrs. Frick's dosimeter readings were all less than 26 mr per month.

42.

INDEPENDENT MEASUREMENTS

43. Independent measurements were made by the AEC representative during this inspection with an Eberline Model E-500B survey meter. Containers in the lead enclosure located on the windowsill of the radioisotope laboratory showed a maximum of 40 mr/hr at the surface of the containers; over the top of the

INDEPENDENT MEASUREMENTS

43. continued.

lead brick enclosure showed a reading of 1 mr/hr maximum at a distance of approximately six inches from the nearest container; through the side of the lead brick enclosure showed a reading of 0.03 mr/hr at the surface of the lead bricks. The lead containers housing the Iodine 125 in the refrigerator storage in the uranalysis lab showed a reading of 0.03 mr/hr at the surface of the container.

LICENSE CONDITIONS

44. License conditions of this license were reviewed with the licensee at the conclusion of this inspection.

MANAGEMENT DISCUSSION

45. The results of this inspection were discussed with Mr. Arthur Lepino, Hospital Administrator, and Dr. T. W. Knickerbocker, RSO. The licensee representatives stated the following actions would be taken concerning the items of noncompliance noted throughout this report: Records will be kept of all byproduct material waste disposals; Isotopes will be procured and possessed in quantities not to exceed the possession limits of this license; Laboratory survey results will be kept in mr/hr units; and storage areas will be kept posted in accordance with 10 CFR 20.

In addition, Mr. Lepino stated that a refrigerator would be procured for the Isotope Laboratory in order to keep all isotopes in that one location.

10/18/65

AEC-374
(11-57)

ATOMIC ENERGY COMMISSION
BYPRODUCT MATERIAL LICENSE

License No. 34-1197-1
Amendment No. 7 (Jan)

Pursuant to the Atomic Energy Act of 1954 and Title 10, Code of Federal Regulations, Chapter 1, Part 30, Licensing of Byproduct Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer and import byproduct material listed below, and to use such byproduct material for the purpose(s) and at the place(s) designated below. This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, and is subject to all applicable rules, regulations, and orders of the Atomic Energy Commission now or hereafter in effect and to any conditions specified below.

6 IV R-1/69

Licensee	In accordance with application dated October 4, 1965 dtd
1. Name: Lakewood Hospital, Nuclear Medicine Department	3. License number: 34-1197-1 is amended in i entirety to read as follows:
2. Address: 14519 Detroit Avenue, Lakewood, Ohio	4. Expiration date: October 30, 1967
	5. Reference No.

6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time
A. Iodine 131	A. Iodide	A. 100 millicuries
B. Iodine 131 and/or Iodine 125	B. Iodinated Human Serum Albumin	B. 2 millicuries

(See page 2)

9. Authorized use

A. Diagnosis of thyroid function and thyroid scans. Treatment of hyperthyroidism and cardiac dysfunction.

B. Determination of blood volumes.

(See page 2)

CONDITIONS

10. Unless otherwise specified, the authorized place of use is the licensee's address stated in Item 2 above:

11. The licensee shall comply with the provisions of Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards for Protection Against Radiation."

12. Byproduct material shall be used by, or under the supervision of, William J. Fayen, M.

13. Byproduct material shall not be used in humans until its pharmaceutical quality and assay have been established.

14. Iodine 131 labeled Macroaggregated Iodinated Human Serum Albumin shall be procured from a supplier who holds an unsuspended or unrevoked license issued by the Secretary, Department of Health, Education, and Welfare, to propagate or manufacture and prepare, label, or distribute this material pursuant to Title 42, Code of Federal Regulations, Part 73, "Biological Products."

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