UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

Report Nos: 52-01946-07/89-03 and 52-01946-08/89-02

Licensee: University of Puerto Rico
Medical Science Campus
San Juan, PR 00936

Docket Nos: 030-13584 and 030-14810 License Nos: 52-01946-07
52-01946-08

Inspection Conducted: August 29, 1989

Inspector: Sandra L. Waldron 10/12/89
S. L. Waldron, Radiation Specialist Date Signed

Approved by: C. M. Hosey 10/2/89
C. M. Hosey, Chief Date Signed
Nuclear Materials Safety Section
Nuclear Materials Safety and Safeguards Branch
Division of Radiation Safety and Safeguards

SUMMARY

Scope:

This special, unannounced inspection of activities conducted under NRC License Nos. 52-01946-07 and 52-01946-08 entailed follow-up on a worker concern relating to the safe use of radioactive materials.

Results:

Two violations were identified. Under NRC License No. 52-01946-07, the failure to conduct a survey and evaluation of an incident involving a cesium-137 brachytherapy implant was identified as a violation (paragraph 3.a). Under NRC License No. 52-01946-08, the failure to have the annual calibration of the teletherapy unit performed by the licensee's teletherapy physicist was identified as a violation (paragraph 3.g).

REPORT DETAILS

1. Persons Contacted

Licensee Employees

Maria Berrios, Health Physics Technician
*Onelio Nunez, Dean of Administration
Vilma Perez, Chief Technologist, Nuclear Medicine
Cecilia Rameriz, Teletherapy Physics Technician
Jose Robles, Health Physics Technician
*Heriberto Torres, Ph.D., Radiation Safety Officer

*Attended exit interview

2. Licensee Action on Previous Enforcement Matters

This subject was not addressed in the inspection.

3. Allegations, Discussions and Findings

Note: The pronoun "he" is used through this report without regard to the sex of the individual to protect the identify of confidential sources of information to the maximum extent possible.

a. Allegation

An incident involving a patient undergoing a brachytherapy treatment with cesium-137 sealed sources was not properly evaluated and reported.

Discussion

The inspector discussed the incident with the Radiation Safety Officer (RSO) and the Nursing Supervisor responsible for the patient in question. Through the discussions, the inspector determined that the incident occurred as follows. On May 11, 1989 at 4:20 p.m., an 85 year old woman had a tandem and ovoid (T and O) inserted for the treatment of cervical cancer. The T and O was loaded with 5 cesium-137 sealed sources. Each cesium-137 source has a source strength of 10 mg Radium equivalent (11/29/76). A treatment sheet was prepared by the Teletherapy Physics Technician. At 7:00 a.m. May 12, 1989, the nursing supervisor checked the patient's vital signs, the T and O was in place at that time. At 7:50 a.m., another nurse entered the patient's room for a routine patient check. The nurse discovered the patient in the bathroom, and that she had removed the T and O including the 5-cesium-137 sources. The nurse immediately notified the supervisor, who in turn called the Radiation Therapy Department. The RSO had not arrived at the hospital, but one of the radiation therapy physicians responded to the call, and

arrived at the patient's room at 8:00 a.m. The patient stated that the apparatus was uncomfortable, so she removed it and placed the cesium-137 sources in a night stand across the room. The physician, using forceps, took the sources out of the night stand drawer and placed them in the brachytherapy source safe. The safe is in a locked cabinet in the patient's room. The physician inventoried the sources and logged them into the brachytherapy source logbook.

The nursing supervisor prepared a Nursing Service Incident Report of the incident. License Condition 12 for License No. 52-01946-07, issued on February 7, 1986, requires the program to be conducted in accordance with the statements, representations and procedures contained in the application dated December 22, 1982, and letters dated January 31, 1987; March 21, 1983; March 1, 1983; and January 27, 1983. Item 20 of the application addresses the procedures for therapeutic use of sealed sources. Item A.2 of the procedures states that the RSO will be responsible for all aspects of radiological protection concerning the therapeutic use of sealed sources. Item 20 Section B.V. discusses the procedures for accidents arising from the handling of sealed sources. The procedures state that the nursing supervisor must notify the RSO in the event of an incident and that the RSO is responsible for actions to be taken to restore the source to a safe condition.

The NRC inspector determined through discussions with licensee representatives and review of the Nursing Service Incident Report that procedures were followed as required and that the sources were properly handled and returned to shielded safety storage by the physicians.

10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the regulations of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

10 CFR 35.21(b) requires that the RSO investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary.

The inspector determined through discussions with the RSO and a review of records that the RSO did not conduct a thorough evaluation of the incident. Brief notes concerning the patient were made in the RSO's daily log book. The RSO did not evaluate exposures received by the patient from carrying the 5 cesium-137 sources to the night

stand, other personnel who may have entered the room, nor did he attempt to interview the patient or nurses involved to determine the course of events in the incident. On the day of the inspection, the Radiation Safety Officer had not received a copy of the Nursing Service Incident Report.

Findings

The allegation was substantiated. The failure of an RSO to conduct an evaluation of an incident concerning the removal of brachytherapy sources by a patient undergoing therapy was identified as an apparent violation of 10 CFR 20.201(b).

b. Allegation

Survey instruments were not calibrated on an annual frequency.

Discussion

10 CFR 35.51 requires the licensee to calibrate survey instruments annually. The inspector reviewed the survey instrument calibration records for the eleven instruments used routinely by the licensee. Ten of the instruments had been calibrated on October 31, 1988. One instrument had last been calibrated on August 27, 1988, when it was received from the vendor. On August 29, 1989, the licensee tagged the instrument out of service until the calibration was performed. This instrument had not been used on August 28, 1989. The inspector reviewed the calibration stickers on the survey instruments in the Health Physics Office, Nuclear Medicine Department and Radiation Therapy Department. All survey instruments in active use were within the annual calibration date.

Findings

The allegation was not substantiated. The inspector could find no evidence of survey instruments in use that had not been calibrated within the last twelve months.

No violations or deviations were identified.

c. Allegation

Patients administered iodine-131 doses requiring hospitalization, were released with dose rates greater than 5 mR/hr at 1 meter.

Discussion

10 CFR 35.75(a) requires that the licensee not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either the measured dose rate at one meter from the patient is less than 5 mR/hr or the activity in the patient is less than 30 millicuries.

A review of patient records indicates that 8 patients have been administered doses of iodine-131 requiring hospitalization between January 1, 1989 and August 29, 1989. The licensee's I-131 treatment reports indicate that surveys are performed as required and the results are recorded. All records indicate that the radiation levels measured during surveys performed prior to the release of the patients were 5 mR/hr or less. On the day of the inspection, a patient was in the hospital who had been administered 151 mCi of I-131 on August 28, 1989. The inspector accompanied the HP technician to the patient's room to perform the daily radiation level surveys. The surveys were performed correctly and the results of the licensee and NRC surveys were in agreement.

Findings

The allegation was not substantiated. No evidence was identified that indicated patients were released from the hospital with dose rates greater than 5 mR/hr at one meter.

No violations or deviations were identified.

d. Allegation

Annual training for ancillary personnel not performed for 1989.

Discussion

License Condition 20 of License No. 52-01946-07, issued on June 14, 1989, requires the licensee to conduct its program in accordance with statements, representations, and procedures contained in the application dated August 29, 1988. Attachment 10.1 of the application states that all individuals working in or frequenting a restricted area must receive instruction in accordance with 10 CFR 19.12. There is no commitment to conduct annual training for employees. For nuclear medicine technologists, instruction on radiation safety is conducted annually and records maintained. Through a review of records, the inspector determined that the technical staff was last instructed on June 6, 1989.

Findings

The allegation was not substantiated. There is no regulatory requirement for the licensee to conduct annual training sessions for personnel.

e. Allegation

Research laboratories where radioactive materials are used or stored, may not be properly posted with "Caution - Radioactive Materials" signs.

Discussion

10 CFR 20.203(e) requires the licensee to conspicuously post with a sign bearing the radiation caution symbol and the words: Caution - Radioactive Materials each area or room in which licensed material is used or stored in an amount exceeding 10 times the quantity of such material specified in Appendix C of 10 CFR 20. The licensee has 22 laboratories that are required by 10 CFR 20.203(e) to be posted with Caution - Radioactive Material signs. The inspector accompanied the HP technician to all 22 laboratories. All were properly posted. The Nuclear Medicine Department and the waste storage areas were also observed to be posted as required.

Findings

The allegation was not substantiated. All laboratories, storage and rooms where radioactive materials are used are posted as required by 10 CFR 20.203(e).

f. Allegation

Radiation levels outside main waste storage area exceed regulatory limits.

Discussion

10 CFR 20.105(b)(2) requires that no licensee shall possess use or transfer licensed material in such a manner as to create in any unrestricted area from radioactive material and other source of radiation in his possession radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of two millirems in any one hour or 100 millirems in any seven consecutive days. This is equivalent to a dose rate of 0.6 mR/hr. The licensee has two main waste storage areas. Both were independently inspected by the NRC and radiation level measurements were obtained.

The waste storage area for research labs is located on the tenth floor of the Academic and Administration Building. The maximum radiation level measured by the inspector was 0.4 mR/hr at 18 inches from the door of the storage area. The waste storage area for nuclear medicine and other licensed activities is located in a freestanding building behind the Nuclear Medicine Department. The maximum radiation level recorded was 0.3 mR/hr at 18 inches from the door to the storage building.

The RSO stated that he and the HP technican had recently rearranged the waste in both areas to decrease the radiation levels in unrestricted areas. A review of the weekly radiation level survey records for the period of January 1, 1989 to August 29, 1989, by the

inspector indicated that the maximum radiation levels in unrestricted areas was 0.6 mR/hr prior to the waste being rearranged in the waste storage areas.

Findings

The allegation was not substantiated. The maximum radiation levels measured by the inspector would not result in an exposure in excess of two millirem per hour or 100 millirems in any seven consecutive days.

g. Allegation

The cobalt-60 teletherapy unit required annual full calibration and was performed by the radiation physics technician and not the named teletherapy physicist.

Discussion

10 CFR 35.632(f) requires that the full calibration measurements required by 10 CFR 35.632(a) be performed by the licensee's teletherapy physicist. NRC License No. 52-01946-08, Amendment No. 03, dated May 22, 1989, License Condition 11.B. specifies the individual who fills the position of Teletherapy Physicist. The inspector determined through discussions with licensee representatives and a review of the calibration records that the full calibration of the cobalt-60 teletherapy unit was performed by the radiation physics technician on June 9, 1989. The licensee had requested a license amendment to exempt them from the requirements for the teletherapy physicist qualification to calibrate the teletherapy unit. The NRC denied the exemption request on July 26, 1989. Licensee representatives stated that due to the long time period for a response, it was assumed, the exception was granted.

Findings

The allegation was substantiated. Failure of this licensee's teletheraphy physicist to perform the annual full calibration of the cobalt-60 teletherapy unit was identified as an apparent violation of 10 CFT 35.632(f).

4. Exit Interview

The inspection scope and findings were summarized on August 29, 1989, with those persons indicated in paragraph 1 above. The violations involving the failure to perform an adequate survey of a brachytherapy implant incident (License No. 52-01946-07) and the failure to have the annual calibration of the teletherapy unit performed by the licensee's teletherapy physicist (License No. 52-01946-08) were discussed in detail.

Licensee management acknowledged the findings. The licensee did not identify as proprietary any of the material provided to or reviewed by the inspector during the inspection.