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

JAN 28 1991

Report No.: 45-18332-01/91-01

Licensee: Stuart Circle Hospital
413 Stuart Circle
Richmond, Virginia

Docket No.: 030-14871 License No.: 45-18332-01

Facility Name: Stuart Circle Hospital

Inspection Conducted: January 11, 1991

Inspector: _____ 1/28/91
Wade T. Loo, Health Physicist Date Signed
Nuclear Materials Safety Section

Approved by: _____ 1/28/91
Charles M. Hosey, Chief Date Signed
Nuclear Materials Safety Section
Nuclear Materials Safety and
Safeguards Branch
Division of Radiation Safety and
Safeguards

SUMMARY

Scope:

This routine, unannounced inspection of activities conducted under NRC License No. 45-18332-01 included a review of the organization and administration of the licensed program, radiation safety training, personnel radiation protection, radioactive material handling procedures, radioactive waste storage and disposal and radiopharmaceutical dose administration procedures.

Results:

Several weaknesses were identified in the radiation safety program. Particular concerns included the transfer of licensed material to an unauthorized recipient, failure to establish and implement adequate procedures for the transfer of licensed material, failure to perform linearity and accuracy test on a dose calibrator after installation and prior to use and failure to check the dose calibrator for constancy each day before use.

Within the areas inspected, the following apparent violations were identified:

Failure of the licensee through the radiation safety officer (RSO) to establish and implement procedures for transferring or disposing of licensed material. (Section 3)

Failure to ensure that byproduct material was transferred to authorized persons. (Section 3)

Failure to test the dose calibrator for accuracy and linearity upon installation and prior to use. (Section 4)

Failure to check the dose calibrator for constancy each day before use. (Section 4)

Failure to conduct area radiation surveys at the end of each day when radioactive materials are used. (Section 5)

REPORT DETAILS

1. Persons Contacted

Licensee Employees

Patrick K. Burke, M.D., Radiation Safety Officer and Chairman, Radiation Safety Committee
*Ann Honeycutt, Assistant Administrator
David Horton, Staff Nuclear Medicine Technologist
Robin Phillips, Staff Nuclear Medicine Technologist
*Sherman Pillis, Director of Radiology
*Rebecca Stevens, Staff Nuclear Medicine Technologist

*Attended exit interview

2. Program Scope and Licensee Organization

The licensee is authorized to possess and use radioactive material for diagnostic and therapeutic nuclear medicine, in-vitro studies and sealed sources for diagnostic purposes.

The nuclear medicine program performs an average of five diagnostic procedures per day. This includes an average of three procedures per week utilizing xenon-133 (Xe-133). The licensee performs an average of four diagnostic bone density tests per week using a sealed one curie Gadolinium-153 (Gd-153) source, five Iodine-131 (I-131) therapeutic procedures in capsule form per year, and five diagnostic bone tissue tests per month using a Lixiscope device which contained a sealed 500 millicurie Iodine-125 (I-125) source. The licensee currently has 11 authorized users listed on the license, with two using material at the hospital on a regular basis.

The RSO is the primary user for nuclear medicine at the hospital. He is also the Medical Director of the Nuclear Medicine Department and Chairman of the Radiation Safety Committee (RSC). The licensee utilizes the services of a health physics consultant firm that performs quarterly audits and instrumentation tests. The RSO reviews the results of the tasks performed by the consultant.

Review of the RSC minutes indicated that the committee meets at the required quarterly frequency. The RSC minutes included reviews of routine radiation safety business such as radiation dosimetry reports, review and discussion of new nuclear medicine instrumentation use and application, equipment needs, and actions taken to correct deficiencies identified during the consultants quarterly program audits.

During the review of the RSC minutes, the inspector noted that the RSC minutes from December 17, 1990, discussed the theft of a Lixiscope device from the hospital. A police investigation was conducted that included interviews with the hospital staff about the theft of the device. After discussing the results of the police investigation and report, the RSC accepted the results of the police investigation and took no further action.

3. Transfer of Radioactive Material

Through discussions with licensee representatives and reviews of records, the inspector determined that on Saturday, September 29, 1990, an individual identifying himself as an employee of the nuclear pharmacy used by the licensee approached a contract x-ray technologist who was working the weekend and indicated that he was there to pick up the Lixiscope device. The individual also stated that the director of radiology knew he was coming by to pick up the Lixiscope. The technologist then retrieved the device and gave it to the individual.

On October 1, 1990, the director of radiology looked at the Lixiscope logbook and noticed that the device had not been logged back in. After further review, the director of radiology found out that an authorized user had failed to make a log entry when he returned the device on September 29, 1990. However, upon further review, the director of radiology noted that the Lixiscope device was not in its place of storage. After discussions with the contract technologist and the nuclear pharmacy, the licensee concluded that the device had been stolen. The licensee then notified the NRC Region II Office and the Richmond Police Department of the theft.

10 CFR 30.41(a) states that no licensee shall transfer byproduct material except as authorized pursuant to 10 CFR 30.41(b). The transfer to the individual was not authorized pursuant to 10 CFR 30.41(b). The transfer of the Lixiscope device to an unauthorized recipient was identified as an apparent violation of 10 CFR 30.41(a).

10 CFR 35.21(a) requires that the licensee, through the RSO, ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. 10 CFR 35.21(b)(2)(ix) requires that the RSO establish, collect in one binder or file, and implement written policy and procedures for disposing of byproduct material. The failure to ensure that procedures were established and implemented for the transfer of radioactive material was identified as an apparent violation of 10 CFR 35.21.

4. Dose Calibrator Test

Through discussions with the licensee and review of records the inspector determined that the licensee installed and put into use a new dose calibrator on May 1, 1990, to measure doses administered to patients. A geometric dependence test was performed by a consultant on the day of installation. However, the licensee did not perform a linearity and accuracy test until May 21, 1990 and June 19, 1990, respectively.

10 CFR 35.50(b)(2) and (3) require medical licensees to test each dose calibrator for accuracy and linearity upon installation. Failure of the licensee to conduct accuracy and linearity tests on the dose calibrator upon installation and prior to using the calibrator to measure doses administered to patients was identified as an apparent violation of 10 CFR 35.50(b)(2) and (3).

The inspector reviewed the records of dose calibrator constancy tests performed between November 2, 1988 and January 11, 1991, and discussed the records with the nuclear medicine staff. Those reviews and discussions indicated that on 26 occasions, dose calibrator constancy tests were not conducted when patient studies using radiopharmaceuticals were performed on weekends.

10 CFR 35.50(b)(1) requires medical licensees to check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. Failure of the licensee to test the dose calibrator for constancy before use on those 26 occasions between November 2, 1988 and January 11, 1991, was identified as an apparent violation of 10 CFR 35.50(b)(1).

5. Area Radiation Level and Contamination Surveys

The inspector reviewed the records of area radiation and removable contamination surveys performed between November 2, 1988 and January 11, 1991, and discussed the records with the nuclear medicine staff. Those reviews and discussions indicated that on 31 occasions, area radiation surveys were not being performed when radiopharmaceuticals were being administered on the weekends.

10 CFR 35.70(a) requires medical licensees to survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered. Failure of the licensee to conduct surveys of radiopharmaceutical administration areas at the end of each day of use was identified as an apparent violation of 10 CFR 35.70(a).

6. Exit Interview

The inspection scope and findings were summarized in an exit interview with the individuals indicated in Section 1. The inspector reviewed the program areas inspected and discussed in detail the inspection findings listed below. The NRC's enforcement policy was reviewed with the licensee's representatives. The licensee acknowledges the NRC concerns and provided no dissenting comments relative to the apparent violations.

DESCRIPTION AND REFERENCE

VIOLATION - Failure to ensure that byproduct material was transferred to authorized persons. (Section 3)

VIOLATION - Failure of the licensee, through the RSO, to establish and implement procedures for transferring or disposing of licensed material. (Section 3)

VIOLATION - Failure to test the dose calibrator for accuracy and linearity upon installation and prior to use. (Section 4)

VIOLATION - Failure to check the dose calibrator for constancy each day before use. (Section 4)

VIOLATION - Failure to conduct area radiation surveys at the end of each day when radioactive materials are used. (Section 5)