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

Report No.: 47-00404-02/90-01

Licensee: Cabell Huntington Hospital
1340 Hal Greer Boulevard
Huntington, West Virginia

Docket No.: 030-03370 License No.: 47-00404-02

Facility Name: Cabell Huntington Hospital

Inspection Conducted: September 13, 1990

Inspector: Sandra L. Waldron 10/4/90
Sandra L. Waldron, Radiation Specialist Date Signed
Nuclear Materials Safety Section

Approved by: Ch M. Hosey 10/4/90
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. 47-00404-02 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:

Numerous weaknesses were identified in the radiation safety program. Failure to perform the required radiation protection activities appeared to result from a lack of effective oversight of the program by management, radiation safety committee and Radiation Safety Officer (RSO). Particular concerns included failure to measure activity of doses prior to administering to patients, failure to perform daily constancy tests on the dose calibrator prior to use, failure to perform linearity, accuracy and geometry dependence tests on the dose calibrator after installation and prior to use, failure to perform required radiation surveys and failure of the RSO to implement corrective actions when deficiencies in the program were identified.

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

Failure to have all required written procedures. (Section 2)

Failure of RSO to implement corrective actions as necessary when deficiencies were noted. (Section 2)

Failure to follow procedures following a minor spill of technetium-99m. (Section 3)

Failure to adequately instruct nuclear medicine personnel in radiation safety procedures. (Section 3)

Failure to instruct ancillary personnel prior to their working in the vicinity of a restricted area. (Section 4)

Failure to test the dose calibrator for accuracy, linearity and geometry dependence upon installation and prior to use. (Section 6b)

Failure to check the dose calibrator for constancy each day before use. (Section 6b)

Failure to conduct area radiation surveys at the end of each day when radioactive materials are used. (Section 6c)

Failure to include an area drawing in the area radiation level survey records, and have the records initialed by the RSO each month. (Section 6c)

Failure to assure method of conducting removable contamination surveys is capable of detecting 2000 disintegrations per minute. (Section 6c)

Failure to measure the activity of doses prior to administering to patients. (Section 6e)

REPORT DETAILS

1. Persons Contacted

Licensee Employees

Donald Smith, President
*Robert Hickman, Vice-President, Patient Services
*Gary Tolley, M.D., Radiation Safety Officer and
Chairman Radiation Safety Committee
*John Duncan, Director of Radiology
*Fred Peatross, Chief Nuclear Medicine Technologist
David Dial, 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 and sealed sources for diagnostic purposes.

The nuclear medicine program performs an average of 10 diagnostic procedures per day. This includes an average of two procedures per week utilizing xenon-133 (Xe-133) and iodine-131 (I-131). The licensee has administered one therapeutic dose of I-131 in capsule form since September 22, 1987. The licensee also performs an average of two diagnostic bone density tests per week using a sealed 1.5 curie Gadolinium-153 (Gd-153) source. The licensee currently has 13 authorized users listed on the license, with 3 using material at the hospital on a regular basis.

The RSO is the primary authorized user for nuclear medicine at the hospital. He is also the Medical Director of the Radiology Department and Chairman of the Radiation Safety Committee (RSC). The alternate RSO listed on the license is a medical physicist employed by the radiology physicians. The RSO delegates many of his tasks to the alternate RSO such as monthly reviews of personnel dosimetry, quarterly reviews of dose calibrator tests and the annual radiation safety program review. The RSO reviews the results of the tasks performed by the alternate RSO.

The Nuclear Medicine Department Procedure Manual is written and maintained by the chief nuclear medicine technologist. The annual radiation safety program review conducted by the alternate RSO on May 16, 1990, indicated that three required procedures were not in the procedure manual.

10 CFR 35.21(b)(2)(vi),(vii), and (viii) requires, in part, that the licensee's RSO establish, collect in one binder or file, and implement written policies and procedures for: (1) taking emergency action if control of byproduct material is lost; (2) performing periodic radiation surveys; and (3) performing checks of survey instruments and other safety

equipment. The inspector reviewed the procedures prepared by the RSO to implement the radiation safety program and noted that the licensee did not have written procedures in the Nuclear Medicine Department Procedure Manual addressing these areas. Failure to establish written procedures covering the required areas was identified as an apparent violation of 10 CFR 35.21 (b)(2)(vi), (vii), and (viii).

The RSC membership includes the administrative director of radiology, chief technologist of nuclear medicine, a nursing staff representative, the senior vice-president, alternate RSO, and RSO who serves as chairman of the committee.

Review of the RSC minutes by the inspector indicated that the committee meets at the required quarterly frequency. The minutes also indicated the committee reviews personnel dosimetry reports, misadministrations, equipment needs and radiation safety audit results

During the review of the RSC minutes, the inspector noted that the alternate RSO performs a comprehensive annual review of the radiation safety program each year in conjunction with the RSO and RSC. The results of the review performed on May 16, 1990, identified several areas of noncompliance with NRC requirements, including: failure to assay radiopharmaceutical dosages prior to administering to a patient; failure to conduct dose calibrator constancy checks and area radiation level surveys when patient studies were performed on weekends; and the failure to establish, collect in one file or binder, and implement written policies and procedures for taking emergency action if control of byproduct material is lost; performing periodic radiation surveys and performing checks of survey instruments and other safety equipment. 10 CFR 35.21(b)(1), in part, requires the licensee's RSO to investigate deviations from approved radiation safety practice and implement corrective actions as necessary. In discussions with licensee representatives, the inspector determined that contrary to this, corrective actions had not been implemented for the four areas identified in the annual review.

The failure of the RSO to implement prompt corrective actions for all identified deviations from approved radiation safety practices is an apparent violation of 10 CFR 35.21(b)(1).

3. Contamination Control in the Hot Lab

The inspector performed independent contamination surveys in the nuclear medicine hot lab. During the survey, radiation levels of 15 millroentgen per hour (mR/hr) were measured in the sink in the hot lab. The nuclear medicine technologist stated he could think of no reason for the readings. Elevated radiation levels were measured in other locations in the hot lab including: 15mr/hr on the absorbent pad behind the L-block, 10 mr/hr on cotton towels placed around the sink, 12 mr/hr on tongs placed next to the L-block, and 20 mr/hr on a cardboard box storing syringe shields. The technologist then recalled that while preparing a dose that morning, the tip fell off a syringe containing Tc-99m and that he removed the syringe

from behind the L-block to the sink to allow it to drip there. License Condition 13 requires the licensee to conduct its program in accordance with the application dated January 8, 1988. Item 10.5 of the application states the licensee will implement the model spill procedures in Appendix J of Regulatory Guide 10.8., Rev. 2, August 1987.

Appendix J, Model Procedure for Minor Spills of Liquids and Solids, requires the licensee for any minor spill of liquids to: (1) notify persons in the area that a spill has occurred, (2) prevent the spread of contamination by covering the spill with absorbant paper, (3) clean up the spill using disposable gloves and absorbent paper, (4) survey the area with a low-range radiation detector survey meter and check the area around the spill, and (5) report the incident to the RSO. The procedure also requires that the RSO will follow up on the cleanup of the spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey.

In discussions with the nuclear medicine technologist and through observations, the inspector determined that the technologist did not cover the spill with absorbant paper, nor did he immediately clean up the spill. The technologist did not use absorbent paper to clean the spill but used cotton hospital towels. The technologist also did not survey the area after decontamination. The NRC inspector surveyed the area and detected additional contaminated areas around the spill. The incident was reported to the RSO, but the RSO did not complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey as required. Failure of the licensee to follow procedures for handling a minor spill was identified as an apparent violation of License Condition 13.

The training of nuclear medicine personnel consists of the individuals reading the Nuclear Medicine Department Policy and Procedure Manual and signing each section after completion. The inspector reviewed the licensee's policy and procedures manual and each technologist had signed all sections indicating that the policies and procedures had been read. The alternate RSO conducts annual refresher training for nuclear medicine personnel in the NRC regulations.

10 CFR 19.12 in part requires that all individuals working in a restricted area shall be instructed in precautions and procedures to minimize exposure and the functions of protective devices employed. Item 8 of the application dated January 8, 1988, requires the licensee to implement the model training program in Appendix A to Regulatory Guide 10.8, Rev. 2, Appendix A, which requires the licensee to instruct individuals in the appropriate radiation safety procedures. Through observations and interview of the technologist handling the contamination in the hot lab, the inspector ascertained that the individual did not possess a clear understanding of the proper procedures for handling a minor spill. Failure of the licensee to adequately instruct personnel in the proper

procedures for handling a minor spill was identified as an apparent violation of 10 CFR 19.12.

4. Radiation Safety Training for Ancillary Personnel

The chief nuclear medicine technologist distributes a memo concerning radiation safety procedures to the department managers of housekeeping, security and maintenance each year. Each department manager is instructed to have all personnel read and sign the memo. Records are kept in the nuclear medicine department and were reviewed. The licensee does not have a program in place to instruct ancillary personnel upon initial employment or prior to working in the vicinity of a restricted area. If an individual started employment at the hospital shortly after the memo was distributed, it would be a year before he received radiation safety instruction. The model training program in Appendix A of Regulatory Guide 10.8, Revision 2, requires the licensee to instruct personnel (e.g., nursing, clerical, housekeeping, security) before they assume duties with, or in the vicinity of radioactive materials. Through discussions with licensee personnel, the inspector determined that housekeeping personnel enter the nuclear medicine department in the vicinity of radioactive materials each evening to empty non-radioactive waste containers and that they do not receive instruction in radiation safety before they enter the area. Failure of the licensee to instruct ancillary personnel in radiation safety before they work in the vicinity of radioactive materials was identified as another example of a violation of 10 CFR 19.12.

5. Personnel Radiation Protection

The licensee's nuclear medicine department issues personnel dosimetry to three individuals: the chief technologist, one staff technologist and one part-time technologist as well as the authorized users who work in diagnostic X-ray imaging in addition to nuclear medicine. Whole body and extremity thermoluminescent (TLD) dosimetry is exchanged each month. The alternate RSO and RSO review the dosimetry results each month for individuals in both diagnostic X-ray imaging and nuclear medicine.

Radiation dosimetry records were reviewed by the inspector for the period beginning September 1, 1987 through July 31, 1990. The full-time technologist, who elutes the molybdenum/technetium generator each day, consistently exceeds the whole body ALARA Investigational Level I limit of 125 millrem (mrem) per quarter. This is discussed and documented in the RSC committee meeting minutes. This individual exceeded the investigational whole body ALARA Level II limit of 375 mrem per quarter in the second quarter of 1989. The individual received a 380 mrem exposure, which was investigated by the RSO. The investigation determined that the individual did not receive the exposure but it occurred when the molybdenum generator was stored next to the drawer where the film badge was stored for a short time after delivery. A report of the investigation is on file and was presented to the RSC. The highest extremity reading was 1400 mrem per quarter, with the average being 500 mrem per quarter.

The two additional technologists' average whole body and extremity exposures were 70 mrem per quarter and 120 mrem per quarter, respectively.

During a review of nuclear medicine department records, the inspector noted that one therapeutic dose of I-131 requiring patient hospitalization had been administered since September, 1987. The chief nuclear medicine technologist administered the 159-millicurie dose in capsule form. Records indicated that a thyroid burden uptake measurement was performed on the technologist who prepared and administered the dose. The result of the bioassay indicated that the uptake of I-131 was below the action limits established in Regulatory Guide 8.20, "Applications of Bioassays for I-125 and I-131."

No violations or deviations were identified.

6. Radioactive Material Handling Procedures

a. Ordering and Receipt of Radioactive Materials

In discussion with the licensee the inspector determined that all radiopharmaceuticals are ordered by the nuclear medicine department staff. Radiopharmaceuticals received during normal business hours are delivered to the nuclear medicine department. The molybdneum 99/technetium-99m generator is delivered to the radiology department each Sunday afternoon. The generator is placed in the nuclear medicine department by the staff radiologic technologist on duty and is stored under lock and key. The Chief Nuclear Medicine Technologist comes to the hospital on Sunday after delivery to monitor the package.

Review of radiopharmacutical receipt records by the inspector indicate that surveys are performed as required on all incoming packages, and the results recorded.

b. Dose Calibrator Quality Control

Through discussions with the licensee and review of records the inspector determined that the licensee installed a new dose calibrator on June 28, 1990. The licensee conducted the linearity test of the dose calibrator on August 2, 1990. A consultant performed the accuracy and geometry dependence on the dose calibrator in August 1990. The results of the test had not been received by the licensee on the day of the inspection. The licensee began using the dose calibrator to measure doses administered to patients on June 28, 1990. 10 CFR 35.50(b)(2),(3,) and (4) requires the licensee to test each dose calibrator for linearity, accuracy and geometry dependence upon installation. Failure of the licensee to conduct linearity, accuracy and geometry dependence 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),(3), and (4).

The inspector reviewed the records of dose calibrator constancy tests performed between May 16 and September 13, 1990, and discussed the records with the department staff. Those reviews and discussions indicated that dose calibrator constancy tests were not being conducted when patient studies using radiopharmaceuticals were performed on weekends.

Failure of the licensee to perform the dose calibrator constancy test and area radiation surveys when radiopharmaceuticals were administered on the weekend was identified by the alternate RSO and RSO in the annual radiation safety program review completed May 16, 1990. The technologists were instructed by the RSO to start conducting the dose calibrator constancy test on weekends when radiopharmaceuticals were administered. During the review of records, the inspector noted that patient studies were performed on Saturday, June 23, 1990 and Sunday July 22, 1990 and the dose calibrator was not tested for constancy prior to its use to measure the dose administered to the patients. Patient studies were performed on 8 additional weekend days between May 16, 1990 and September 13, 1990, and dose calibrator constancy tests were conducted.

10 CFR 35.50(b)(1) requires the licensee to check each dose calibrator for constancy at the beginning of each day of use. Failure of the licensee to test the dose calibrator for constancy before use on June 23 and July 22, 1990, was identified as an apparent violation of 10 CFR 35.50(b)(1).

c. Area Radiation Level and Contamination Surveys

The inspector reviewed the records of area radiation and removable contamination surveys and discussed the records with licensee representatives. The alternate RSO and the RSO identified in the annual radiation safety program review completed on May 16, 1990, that area radiation surveys were not being performed when radiopharmaceuticals were being administered on the weekends.

Through interviews with the licensee's staff, the inspector determined that corrective action was not implemented to assure that daily area radiation level surveys were conducted at the end of each day licensed materials were used. Between September 22, 1987 and September 13, 1990 numerous patient studies were performed on weekends and no area radiation level surveys were conducted.

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

The records of the licensee's daily area radiation level surveys included the date, area surveyed, equipment used, initials of the person making the survey, action levels and the measured dose rates in mR/hr. The records did not include a drawing of the areas surveyed nor were the records initialed by the RSO each month. 10 CFR 35.70(h) requires in part, that the licensee maintain a record of area radiation level surveys and that the record include a plan for each area surveyed. Item 10.12 of the application states that the licensee will establish and implement the procedures contained in Appendix N of Regulatory Guide 10.8, Revision 2, Model Procedure for Area Surveys. Appendix N requires that the record of daily area radiation level surveys include a drawing of the area surveyed and that the records be reviewed and initialed by the RSO each month. Failure of the licensee to include a plan of the area surveyed with the records of area radiation level surveys and to have the records initialed by the RSO each month was identified as an apparent violation of 10 CFR 35.70(h) and license condition 13.

Through discussions with licensee representatives and observations by the inspector, the inspector determined that nuclear medicine department personnel conduct removable contamination surveys of all radiopharmaceutical elution, preparation and administration areas each week. The licensee analyzes the samples with a wipe test instrument that gives a numerical readout in Kilo disintegrations per minute (kdpm), only when the action level of 2000 dpm is exceeded. The 2000 dpm level is preset by the manufacture but has not been verified by the licensee. The licensee has not determined that the readout on the unit is correct by using a source with a known activity. 10 CFR 35.70(f) requires the licensee to conduct removable contamination surveys so as to be to able detect 2000 dpm on each wipe sample. Failure of the licensee to determine that removable contamination surveys are capable of detecting 2000 dpm was identified as an apparent violation of 10 CFR 35.70(f).

A review of radiopharmaceutical therapy records by the inspector indicated that appropriate radiation surveys were performed immediately after the administration of 159 mCi of I-131 on February [illegible], 1990. Appropriate radiation surveys were also performed after the release of the therapy patient and before the room was released for unrestricted use.

The licensee possesses a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 mR/hr to 400 mR/hr and a portable radiation measurement instrument capable of detecting dose rates over the range of 0.1 mR/hr to 1.0 R/hr. The instruments are calibrated every 12 months by an NRC licensed consultant.

The licensee checks each instrument with a dedicated Cs-137 source each day of use.

d. Use of Radioactive Gases

The licensee uses Xe-133 to perform an average of 2 diagnostic pulmonary ventilation studies each week. Review of licensee records by the inspector indicated that the hospital maintenance staff performs ventilation checks every 6 months to ensure negative pressure in the nuclear medicine department and no problems with the ventilation system have been identified.

No violations or deviation were identified.

e. Administration of Radiopharmaceutical Dosages

Through a review of the licensee's patient dose administration logs and discussion with licensee representatives, the inspector determined that between September 22, 1987 and June 28, 1990, patient doses were not assayed prior to administration. Licensee representatives stated that patient doses were mathematically calculated from assayed generator elutions.

This was noted by the alternate RSO in the annual radiation safety program review on May 16, 1990. The RSO did not implement corrective action for this area of noncompliance. The problem was corrected when a new departmental computer system was installed which required the dose to be assayed before continuation of the computer program.

10 CFR 35.53(a) requires the licensee to measure the activity of each radiopharmaceutical dose containing more than 10 microcuries of photon-emitting radionuclide before medical use. Failure of the licensee to measure each radiopharmaceutical dose before medical use was identified as an apparent violation of 10 CFR 35.53(a).

7. Areas for Use and Storage of Radioactive Materials

Through discussions with the licensee, the inspector ascertained that the licensee moved the nuclear medicine department to another location within the Radiology Section of the hospital in August 1989. The new facilities were described in a amendment request dated December 27, 1988. The amendment request was granted February 3, 1989, when Amendment No. 25 to NRC License No. 47-00404-02 was issued.

The inspector observed upon arrival in the nuclear medicine department that the radiopharmaceutical storage and preparation laboratory (hot lab) door was open; however, the door was in view of a technologist who was on the telephone in an adjacent area. The hot lab is situated off the nuclear medicine department waiting room, which is separated from the imaging area and technologist office area by movable partitions approximately 5 feet in height. The door into the nuclear medicine department is located on a hospital corridor leading to the radiology department. Through observations and discussions with licensee representatives, the inspector determined that the door leading to nuclear

medicine is kept open during department business hours, and that the hot lab room door is closed but unlocked when the lab is not occupied. During normal business nuclear medicine personnel are in a position to observe the door to the hot lab. The inspector discussed security of the hot lab with licensee representatives and emphasized the need for the licensee to maintain positive control over the licensed material in the lab. The licensee agreed to begin locking the door when unattended. The inspector observe that all areas in which licensed radioactive materials were used and stored were properly posted in accordance with the requirements of 10 CFR 20.203.

During tours of the hot lab, the inspector observed that improvements could be made in Housekeeping in the hot lab. Numerous vials of radioactive materials were stored around the hot lab. The inspector also observed dirty forks in the sink. The technologist stated they had been there a long time and had been used for various patient studies. The inspector noted that clutter in the lab had made decontamination following the spill discussed above more difficult.

Spent generators are stored in a cabinet under the sink, along with other waste for decay in storage disposal. After at least 60 days, the generators are dismantled and disposed of, except for the lead shielding. The lead is stored until sold by the hospital.

No violations or deviations were identified.

8. 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 have all required written procedures. (Section 2)

VIOLATION - Failure of RSO to implement corrective actions as necessary when deficiencies were noted. (Section 2)

VIOLATION - Failure to follow procedures in decontaminating the hot lab following a minor spill of technetium-99m. (Section 3)

VIOLATION - Failure to adequately instruct nuclear medicine personnel in radiation safety procedures. (Section 3)

VIOLATION - Failure to instruct ancillary personnel prior to their working in the vicinity of a restricted area. (Section 4)

VIOLATION - Failure to test the dose calibrator for accuracy, linearity and geometry dependence upon installation and prior to use. (Section 6b)

VIOLATION - Failure to check the dose calibrator for constancy each day before use. (Section 6b)

VIOLATION - Failure to conduct area radiation surveys at the end of each day when radioactive materials are used. (Section 6c)

VIOLATION - Failure to include an area drawing in the area radiation level survey records, and have the records initialed by the RSO each month. (Section 6c)

VIOLATION - Failure to assure method of conducting removable contamination surveys is capable of detecting 2000 disintegrations per minute. (Section 6c)

VIOLATION - Failure to measure the activity of doses prior to administering to patients. (Section 6e)