U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-01237/89-01

Docket No. 030-01237

License No. 06-00092-05 Priority I Category G1

Licensee: Veterans Administration Medical Center
West Spring Street
West Haven, Connecticut 06516

Facility Name: Veterans Administration Medical Center

Inspection At: West Haven, Connecticut

Inspection Conducted: October 4 and 6, 1989

Inspectors: John Miller 12/11/89
John Miller, Senior Health Physicist date

John Miller 12/11/89
for Betsy Ullrich, Health Physicist date

Approved by: M. S Thanbaky 12/26/89
Mohamed M. Shanbaky, Chief date
Nuclear Materials Safety Section A

Inspection Summary: Inspection conducted on October 4 and 6, 1989 (Report No. 89-01)

Areas Inspected: Routine unannounced inspection of a medical broad scope program, including scope of operations, licensee actions on previous inspection findings, radiation safety organization, licensee internal audits, training, storage of radioactive materials, instrumentation, radioactive effluent and waste disposal, inventory control, personnel radiation protection, leak testing, and package receipt surveys.

Results: Eight apparent violations were identified: 1) use of licensed material by a physician not designated by the Radiation Safety Committee; 2) failure to perform daily constancy tests; 3) failure to perform linearity tests quarterly; 4) failure to calibrate survey instruments annually; 5) failure to deface radioactive material labels on an empty box prior to disposal; 6) failure to survey material released to the normal trash; 7) failure to survey material prior to incineration; and 8) failure to leak test a sealed source.

DETAILS

1. Persons Contacted

*Alice Wood, Associate Director
*Holley M. Dey, M[illegible] Chairperson - Radiation Safety Committee
Robert Soufer, M[illegible] Chief of Nuclear Medicine
William Simmons, Chie[illegible]lear Medicine Technologist, Acting Radiation Safety Officer
Lori Kletch, Nuclear Medicine Technologist
James Ingarra, Nuclear Medicine Technologist
*George Holman, Radiation Safety Officer (Consultant)
Pat Piscitelli, Laboratory Technologist

The inspectors also interviewed various researchers and other hospital personnel during the inspection.

*Individuals present at exit interview.

2. Scope of Operations

The Veterans Administration Hospital, West Haven, Connecticut, operates a Medical Broad Scope Program and is authorized by NRC License No. 29-17895-01 to use radiopharmaceuticals to perform any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35, to prepare and use radiopharmaceuticals to perform any diagnostic procedure listed in Group III of Schedule A, Section 35.100 of 10 CFR 35, to use radiopharmaceuticals to perform any therapeutic procedure listed in Groups IV and V of Schedule A, Section 35.100 of 10 CFR 35, and to use sealed sources to perform any therapeutic procedure listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35. In addition, the licensee is authorized to use xenon-133 gas to perform blood flow and pulmonary function studies and to use any byproduct material listed in section 31.11(a) of 10 CFR 31 for in vitro studies. The licensees Radiation Safety Committee is authorized to review and approve users and procedures involving any byproduct material with Atomic Numbers 1-83 for research and development.

The Chief of Nuclear Medicine informed the inspectors that the average patient load in the Nuclear Medicine Department is approximately 15 patients per day and the predominant isotope used is technetium-99m (Tc-99m). Half the studies performed each day are cardiac procedures. The licensee receives unit doses and does not use molybdenum-99/technetium-99m generators. The Chairperson of the Radiation Safety Committee informed the inspectors that the licensee uses iodine-131 for treating hyperthyroidism, but no iodine-131 therapy is performed which would require hospitalization and special care of the patient (e.g. thyroid carcinoma treatment). She also added that brachytherapy procedures have not been performed at the hospital for years.

The Laboratory Technologist in the Chemistry Laboratory stated that in vitro studies are routinely performed using iodine-125 in radioimmunoassay (RIA) kits. He stated that the five RIA kits in storage, containing less than 8 microcuries on the day of the inspection, are typical of the quantities normally used. Therefore, the Chemistry Laboratory would be under the requirements of a general license.

The Chief Nuclear Medicine Technologist (CNMT) informed the inspectors that there were approximately 20 to 30 researchers and approximately 10 to 15 laboratories where research is performed at the hospital. He stated that some of research involves animal use. An animal caretaker stated that the animals that are injected with isotopes, are sacrificed immediately following a procedure and, therefore, animals containing byproduct material do not require to be caged. The CNMT stated that none of the research involved radiosynthesis or iodinations, but he was aware that some of the researchers were interested in initiating iodination procedures.

3. Licensee Actions on Previous Inspection Findings

(Closed) Inspection 88-01: Failure to evaluate dose calibrator constancy tests to assure that the measured dose is within ±5 percent of the calculated activity. The licensee stated that the dose calibrator would be linked to an AT&T computer with a nuclear medicine software program that automatically calculates predicted activity and displays the percent deviation from the expected value. The inspectors verified that the software program has been introduced into the nuclear medicine program and the constancy tests were being evaluated and reviewed.

(Closed) Inspection 88-001: Failure to perform surveys of incoming packages containing radioactive material. The licensee stated that notice will be given that precise documentation of surveys of incoming packages must be maintained. Also, the RSO will increase the frequency of his spot checks. The inspectors observed a Nuclear Medicine Technologist perform a survey of an incoming package. Records of these surveys were maintained by the licensee.

(Closed) Inspection 88-01: Failure to maintain records of disposals of licensed material to the sanitary sewerage system. The licensee stated that purchases of licensed material may be suspended for researchers who fail to maintain and submit to the RSO records of sewerage disposals made in their respective laboratories. They also stated that the RSO will routinely inspect laboratories to ensure logs of disposal are kept up to date. During a tour of the licensee's facility, the inspectors verified that sink disposal logs were maintained by the researchers. In addition, a record compiling the sum total of these disposals was maintained by the RSO.

4. Radiation Safety Organization

Condition 11.A. of License No. 06-00092-05 designates Lucille Soldano, M.D., Chairperson of the Radiation Safety Committee. Dr. Soldano left the hospital at the end of June 1989. Fred Wright, M.D., was appointed interim Chairperson of the Committee at the time of Dr. Soldano's departure. At a Radiation Safety Committee meeting held on September 18, 1989, Holley Dey, M.D., was appointed Chairperson of the Radiation Safety Committee. At the time of the inspection, no request had been submitted to amend the license to reflect the current Chairperson. The licensee agreed to submit an amendment request to name Dr. Dey as the Chairperson of the Radiation Safety Committee.

Condition 11.D of the license authorizes George R. Holeman as the Radiation Protection Officer (RPO). Mr. Holeman serves the hospital in a consultant capacity. He informed the inspectors that he visits the facility once per week and spends approximately one or two hours on site. Due to Mr. Holeman's absence, the CNMT provides the day to day oversight of the radiation safety program. Mark Schaffer, CNMT had served in this capacity until his resignation which was effective September 29, 1989. Since Mr. Schaffer's resignation, William Simmons has assumed the responsibility as the Chief Technologist and "onsite" Radiation Safety Officer.

The inspectors reviewed the minutes of meetings held by the Radiation Safety Committee (RSC). The minutes of the meeting reflected that the Committee discussed and evaluated appropriate issues associated with the radiation safety program such as personnel exposures, waste disposals and permit authorizations. Meetings had been held on June 20, 1988, December 19, 1988, March 19, 1989, June 5, 1989 and September 18, 1989. The Administration's representative to the Radiation Safety Committee, Dr. Daskel, was absent from all five of these meetings. In response to Dr. Daskel's absence, the Committee Chairperson sent a memorandum dated September 22, 1989 (Attachment A) to the Director requesting him to identify a representative from management to actively serve on the Committee and attend quarterly meetings. At the time of the inspection, the Director's response was being drafted and typed.

In the RSC minutes, the inspectors could not find where the RSC had formally approved Dr. Dey to be an authorized physician in the Nuclear Medicine Department nor had they reviewed her training and experience to assure that she met the criteria established in Subpart J, 10 CFR 35. Condition 11.A of License No. 06-00092-05 requires that licensed material be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.

The use of licensed material by Dr. Dey, without the designation of the Radiation Safety Committee, is an apparent violation of Condition 11.A.

5. Training

The inspectors interviewed numerous technologists, researchers, and ancillary personnel and determined that in general individuals had received instruction commensurate with their duties and enough training to perform their jobs safely.

No violations were identified.

6. Storage of Materials

Licensed material was adequately secured in both restricted and unrestricted areas.

No violations were identified.

7. Instrumentation

a. Dose Calibrator Quality Assurance

The inspectors reviewed the licensee's records of daily constancy tests performed on the dose calibrator. The records indicated that a 174 microcurie cesium-137 standard was used daily and a 2.5 millicurie cobalt-57 standard was used weekly to test instrument constancy. The records included the percent deviation between the assayed value and the calculated value of the standards, and all the tests were within the required ±5% tolerance. The inspectors determined, through record review, that patient doses had been assayed in the dose calibrator on Saturday and Sunday, July 1 and 2, 1989. The records indicated that constancy tests were not performed on these dates, nor were the tests performed on August 21, 24, 28, 29, and 30, 1989. In addition, the Chief Nuclear Medicine Technologist stated that he performed the constancy tests on the dose calibrator on October 3 and 4, 1989, however, records of the results were not maintained. Condition 20 of License No. 06-00092-05 requires that cobalt-57 and cesium-137 reference sources be assayed daily and results recorded.

Failure to perform the constancy tests daily and record the results is an apparent violation of License Condition 20.

Records of linearity tests indicated that the tests were performed semi-annually as opposed to quarterly. The linearity of the dose calibrator was tested on June 9, 1989, January 13, 1989, and June 23, 1988, and all the tests were within the required ±5% tolerance. The most recent linearity test performed on the dose calibrator spanned the range of 421 millicuries to 12.9 millicurie.

The Chief of Nuclear Medicine Technologist informed the inspectors that doses in the range of 3 to 5 millicuries are often assayed and administered to patients. The inspectors expressed concern that the linearity tests being performed by the licensee do not cover the entire range of doses that are routinely assayed in the dose calibrator. Condition 20 of License No. 06-00092-05 requires that the dose calibrator be tested for linearity quarterly.

Failure to perform linearity tests on the dose calibrator quarterly is an apparent violation of License Condition 20.

b. Survey Instruments

The licensee's survey meters were commensurate with the isotopes and hazards associated with the licensee's program. One survey instrument, a Victoreen Model 491, used to perform required radiological surveys in a laboratory where millicurie quantities of phosphorus-32 are routinely used, had not been calibrated since July 14, 1986. The batteries tested positive and the meter did respond to radiation. Condition 20 of License No. 06-00092-05 requires that survey instruments will be calibrated annually.

Failure to calibrate a survey instrument for more than two years is an apparent violation of License Condition 20.

8. Radioactive Effluent and Waste Disposal

The inspectors reviewed the licensee's records for releases of radioactive material to the sanitary sewerage system. The total quantities and concentrations in the licensee's effluent were well within the limits specified in 10 CFR 20.303. In addition, during a tour of the research laboratories the inspectors verified that the researchers were maintaining records of disposals made to the sanitary sewerage system via the sinks in their respective laboratories.

The inspector noticed, in Dr. Gorelick's laboratory, that an empty box had been discarded to the normal waste receptacle and the box was labelled on both sides with DOT RADIOACTIVE YELLOW II labels. Neither label was defaced. Two researchers informed the inspector that the waste receptacle was intended for normal trash and was awaiting collection by the janitorial staff. 10 CFR 20.203(f)(4) requires that prior to disposal of an empty uncontaminated container to unrestricted areas, the radioactive material label must be removed or defaced.

Failure to remove or deface the radioactive material labels on a box in a normal trash receptacle is an apparent violation of 10 CFR 20.203(f)(4).

The inspector surveyed the materials in the normal waste receptacle in Dr. Gorelick's laboratory and noticed a reading of 1 millirem per hour on a Ludlum Model 14C thin end window GM survey meter (Serial No. 009662). 10 CFR 20.201(b) requires that each licensee make surveys as may be necessary to comply with all sections of Part 20.

Failure to perform a survey to assure compliance with 10 CFR 20.301, which describes authorized means of disposing of licensed material contained in waste, is an apparent violation of 10 CFR 20.201.

The CNMT informed the inspector that his predecessor had incinerated animal carcasses, but he had never been directly involved with that activity. The hospital's license does not authorize the incineration of licensed material, but the hospital can incinerate animal carcasses containing hydrogen-3 and carbon-14 in concentrations less than 0.05 microcuries per gram of animal tissue per 10 CFR 20.306. No records relative to the burning of animal carcasses, specifically, the isotopes and quantities, could be located by the CNMT or the RSO.

The inspectors examined three freezers that contained animal carcasses. Only one freezer contained an inventory record describing the isotopes and quantities contained in the frozen animals. The CNMT stated that during the summer he had noticed that all three freezers had an inventory sheet posted on them. The inspectors reviewed the inventory record and noticed that some of the animals contained cerium-141 and ruthenium-103.

The inspectors surveyed the vicinity of the incinerator with a Ludlum Model 12S micro R survey meter (sodium iodide detector). The background radiation levels were measured as 10 microrem per hour and the radiation levels in the contiguous areas around the incinerator measured 20 microrem per hour. Drums of ash were also surveyed and a small clump of ash and debris registering 0.5 millirem per hour on a thin-end window GM survey meter was identified in one of the drums. This radioactive material was undetectable with the sodium iodide detector indicating that the isotope identified was a beta emitter and did not emit a gamma or emitted a low energy gamma. Based on the response of the GM survey meter, the isotope was not carbon-14 or hydrogen-3. Licensee personnel could not identify the isotope in the ash at the time of the inspection. The inspectors discussed with the licensee their monitoring program for the incinerator area to determine if residual radioactivity and contamination is present and to determine if decontamination efforts are required. The licensee stated that the ash would be evaluated radiologically and surveys would be performed in the area of the incinerator to determine if contamination or residual radioactivity was present.

The failure to perform a survey to assure compliance with 10 CFR 20.305, which describes authorized means of disposing licensed material by incineration, is an apparent violation of 10 CFR 20.201.

The licensee's waste storage room was locked and posted with a Caution - Radioactive Material sign. Housed inside the room were approximately ten 55 gallon drums, twelve 30 gallon drums, ten 5 gallon pails, and boxes and bags strewn on the floor, all containing low level radioactive waste. Several of the containers were unlabeled and their contents were not identified. Housekeeping in this area was less than desirable. The room was full to capacity, and rust rings from the drums on the floor were noticed by the inspectors.

Records indicated that 10 drums of radioactive waste were shipped by the licensee via their waste broker on September 22, 1989, and the manifest was complete and maintained on file in accordance with 10 CFR 20.311. The CNMT stated that it had been several years prior to that shipment that licensee last made a waste disposal. The inspectors discussed the waste disposal program with the Associate Director with emphasis on the need to characterize, consolidate, and continue to dispose of their radioactive waste. The undesirable accumulation of radioactive material in the hospital and potential hazards were discussed. The inspector stated that this area will be reexamined during a future inspection.

9. Inventory Control

The inspectors reviewed the procedures for authorizing investigators for the use of radioactive material. The hospital uses a 2 year permit system to authorize such use. The information provided in the permit applications that had been approved by the RSC was adequate for them to evaluate training and radiation safety. The inspectors also reviewed the licensee's procedures for purchasing radioactive material. A representative sample of recent purchase orders were checked against the licensee's permits issued by the RSC. In all cases, material purchased by the permit holders was as authorized and the purchased orders had been checked and signed by the former CNMT.

The most recent inventory record was dated December 12, 1988 and it indicated that the licensee was below the possession limits of License No. 06-00092-05. Based on the purchase orders reviewed by the inspectors, the licensee possessed only the isotopes authorized on the license and had not exceeded its possession limits.

No violations were identified.

10. Personnel Radiation Protection

Personnel dosimetry records indicated that no individual had received an exposure in excess of the regulatory limits or in excess of the ALARA Program Investigational Levels. The dosimetry records were reviewed and signed by the former CNMT and discussed at the Radiation Safety Committee meetings.

The inspectors made independent measurements of the restricted and unrestricted areas of the Nuclear Medicine Department and laboratory area and the radiation levels were well below the permissible levels found in 10 CFR 20.105. No contamination was detected by the inspectors. The CNMT's hands were also monitored and no contamination was detected. Technologists were observed administering doses to patients. In each case, they donned gloves and lab coats, wore whole body and extremity dosimetry, assayed the dose prior to administering it to the patient, used a syringe shield, and positively verified the patient's identity prior to radiopharmaceutical administration.

A technologist informed the inspector that there had not been any significant spills in the department, no stolen or lost material, and no misadministrations.

The CNMT informed the inspectors that radiological surveys are performed frequently with a direct reading survey instrument and weekly wipes are taken and the results recorded. Records indicated that surveys were not performed from August 21 to August 31, 1989. The inspectors told the CNMT that it was good practice to survey in the nuclear medicine department on a daily basis. The CNMT stated that area surveys would be performed in the nuclear medicine department daily.

No violations were identified.

12. Leak Tests

The CNMT stated that he did not know when was the last time that the cesium-137 standard, approximately 170 microcuries, was tested for leakage. He was unable to produce a leak test record. Condition 12.C of License No. 06-00092-05 requires that each sealed source be tested for leakage at intervals not to exceed six months.

Failure to leak test the 170 microcuries cesium-137 source is an apparent violation of Condition 12.C.

13. Package Receipt Surveys

The inspectors observed the CNMT perform a package receipt survey on an incoming package of radiopharmaceuticals. He surveyed the package at 3 feet and on the surface in accordance with his procedures and recorded the results. Records indicated that package receipt surveys were performed daily.

No violations were identified.

14. Exit Interview

The inspectors discussed the results of the inspection with the individuals identified in Section 1.

The inspectors expressed their concern over the apparent lack of management oversight of the Radiation Safety Program and the lack of a full-time RSO.