U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report No. 030-01295/96-001 Program Code 02110

Docket No. 030-01295

License No. 06-13022-02 Priority 1 Category G1

Licensee: University of Connecticut Health Center
Route 4
Farmington, Connecticut 06030

Facility Name: University of Connecticut Health Center

Inspection At: Route 4
Farmington, Connecticut

Inspection Conducted: October 21 to October 25, 1996

Inspectors: _____ 11/15/96
Ihor Czerwinskyj date
Health Physicist

Approved By: _____ 11/15/96
Mohamed M. Shanbaky, Ph. D., Chief date
Branch 1
Division of Nuclear Materials Safety

Inspection Summary: Routine, unannounced safety inspection conducted on October 21 to October 25, 1996. (Inspection Report No. 030-01295/96-001)

Areas Inspected: Licensee's action on previous inspection findings; organization and scope of licensed activities; radiation protection committee; nuclear medicine program; radiation therapy program; quality management program; research; security of radioactive materials; personnel radiation protection; and waste disposal.

Results: One apparent violation was identified: 10 CFR 20.1801- Failure to secure stored radioactive materials; Two examples. (Section 9.0).

DETAILS

1. Persons Contacted

*Paul F. Davern, Associate V.P., U. Conn. Health Systems
*Leonard Paplauskas, Assistant V.P. for Research
*Daniel J. Penney, Director, Facilities Operation
*Richard Spencer, M.D., Director, Nuclear Medicine
*Julius Kocsondy, Director of Imaging and Rehabilitation Services
*Ronald Weiner, Ph.D., Radiopharmacist
*William Pickett, Director, Research Safety
*Raymond Ryan, Ph.D., Director Laboratory Medicine, Chairman RSC
*Kenneth Price, Radiation Safety Officer
*Andres Sinisterra, Health Physicist
*Dominic Romano, Operations Manager, Imaging Services
Jim Fomenko, Health Physicist
Sandra Weller, Ph.D., Researcher
Jim Maikowski, H.P. Technologist
Richard Martinez, Research Technologist
Miriam Scerone, Nuclear Medicine Technologist
Ester King, Radioimmunoassay Laboratory Supervisor
Denise Emerson, Chief Nuclear Medicine Technologist
Sandra Weller, Nuclear Medicine Technologist, Oncas on Thames Hospital
various researchers, doctoral and post doctoral students and research technologists

2. Licensee's Actions on Previous Inspection Findings

No violations were identified during the last inspection on October 3 to October 6, 1995.

3.0 Organization and Scope of Licensed Activities

University of Connecticut Health Center currently holds a type-A medical broad scope license authorizing the possession and use of radioactive materials for medical diagnosis and therapy, and research and development.

The Radiation Safety Officer (RSO) is responsible for the day to day operation of the licensed program at the University of Connecticut Health Center. For radiation safety matters, the RSO reports to the licensee's Radiation Safety Committee (RSC). Administratively, the RSO reports to Assistant Vice President for Research. The Office of Radiation Safety (ORS) is staffed by the RSO, two assistant RSOs, and four Health Physics technologists.

The RSO and staff respond to incidents, provide training, develop policies and procedures, perform periodic audits of users, collect and dispose of waste, evaluate personnel radiation exposures, assist in the review of requests to use radioactive materials, perform radiation surveys, monitor orders for radioactive materials, and maintain radioactive materials inventories.

No safety concerns were identified.

4.0 Radiation Safety Committee

The inspector reviewed the minutes of the RSC since the last NRC inspection. The meetings were held quarterly, as required. The inspector noted that the RSC reviewed the ALARA reports prepared by the RSO, reviewed and approved new researchers for the use of radioactive materials, reviewed the Quality Management Audits,and discussed incidents.

No safety concerns were identified.

5.0 Nuclear Medicine Program

Approximately 400 nuclear medicine diagnostic studies are performed monthly at the University of Connecticut Health Center (UCHC) in Farmington and an additional 5 studies are done at the geriatric center at Uncas on Thames Hospital (UTH). The studies mainly consist of bone and heart wall studies, followed by lung and liver studies. Technetium 99m DTPA is used for lung ventilation-perfusion studies. A 2.5 Ci Mo-Tc generator is received weekly. The generator is kept for two weeks(second week as an emergency supply of technetium only), at which time it is picked up by the vendor. In addition the nuclear medicine department uses various unit doses, if it is more economical than making up their own radiopharmaceuticals. Uncas on Thames Hospital receives unit doses from a commercial radiopharmacy. At Farmington the nuclear medicine department is staffed by three nuclear medicine technologists and a supervisor. There is one part time nuclear medicine technologist at the Uncas on Thames Hospital, who also performs the duties of a full time X-ray tech. There are two full time attending physicians. A health physicist from the Office of Radiation Safety visits the department at least weekly. He performs the required surveys and other tests.

The inspector reviewed records of area and removable contamination surveys, dose calibrator tests, sealed source leak tests and inventories for both hospitals (UCHC and UTH). The inspector found that surveys and tests were performed at the required frequencies and that the records included the required information. The inspector toured the nuclear medicine facilities, and the Hot Laboratory, interviewed staff, and reviewed selective records. The inspector observed that the nuclear medicine technologists wore protective clothing, appropriate whole body and extremity

dosimeters, and used syringe shields during preparation and administration of radiopharmaceuticals. The inspector noted that the Hot Laboratory was properly posted and that the radiopharmaceutical containers were appropriately labeled.

The Nuclear Medicine Department radiopharmaceutical therapy consists of iodine-131, and strontium-89 administration. Iodine-131 is administered exclusively at UCHC, and strontium-89 at UTH. Thirty nine iodine-131 therapies (including whole body scans) were performed since the last inspection. Included in the above number are six ablations with the amount of iodine-131 administered ranging between 104 and 151 millicuries. Twelve strontium-89 doses were administered at UTH. The inspector reviewed all of the required records and determined that the required surveys were performed by the ORS personnel. For procedures requiring patient hospitalization, the room was decontaminated to less than 200 disintegrations per minute per 100 square centimeters. Thyroid uptakes were performed for all personnel assisting in the administration of iodine-131. For thyroid uptakes above minimum detectable level, the personnel uptakes were transmitted to film badge vendor for inclusion in the person's personnel monitoring record.

5.1 Radioimmunoassay Laboratory

The use of radioactive kits for radioimmunoassay testing at UCMC is decreasing. Currently only six different test protocols are performed. The total annual inventory of iodine-125 was 0.8146 millicurie. There was no sink disposal. All liquid waste was collected and transferred to ORS for decay. The lab generated about 1 drum (30 gallons) of solid waste per month. The drums were subsequently stored at the licensee's radioactive waste facility for decay-in-storage.

No safety concerns were identified.

6.0 Brachytherapy

Even though UCMC possesses 47 cesium-137 sources (needles, tubes, Heyman sources), no procedures using those sources have been performed in several years. Only two brachytherapy procedures were performed since the last inspection. Both procedures were implants of iridium-192 seeds in ribbons for head and neck tumors. The licensee has a dedicated room for the therapy patients requiring hospitalization. The room has built in lead shielding in all inside walls. This room is used for hospitalization of both brachytherapy and iodine-131 ablation patients. The inspector checked all of the required survey, inventory and use records, and found them to be satisfactory. There are two strontium-90 eye applicators, one at each hospital (UCMC and UTH). A few eye therapy procedures are performed at each location per year.

No safety concerns were identified.

7.0 Quality Management Program

The inspector verified that the licensee submitted its Quality Management Program (QMP) to the NRC on January 22, 1992. Several modifications to the QMP were subsequently submitted by the licensee, the latest dated July 18, 1995. Based on interviews with nuclear medicine technologists and a review of records, the inspector determined that the QMP regulations and the licensee's QMP procedures were followed.

No safety concerns were identified.

8.0 Research

The Office of Radiation Safety oversees the use of radioactive materials for research in 135 laboratories. Currently there are 39 principal investigators, with 410 users. The ORS personnel visit each lab at least quarterly. They check the required records, conduct area surveys, and surveys for removable contamination. A written report of the inspection is provided to the principal investigator by the ORS. In addition each lab is required to perform a full radiation survey at least monthly. The inspector noted that most researchers used small quantities of phosphorus-32 (P-32), iodine-125 (I-125), tritium (H-3), carbon-14 (C-14), and/or sulfur-35 (S-35). There is one dedicated lab for performing protein iodination. There were 26 iodinations, using no more than 2 millicuries of iodine-125 per iodination, performed in 1996. The inspector, accompanied by ORS personnel, visited several research laboratories. All of the labs visited were either attended by the research personnel, or locked. The inspector checked pertinent records of inventories, surveys, radioactive materials disposal, and found the records to be in order. The inspector observed that personnel working with radioactive materials wore protective clothing, and noted that personnel interviewed received the required radiation safety training, and were familiar with pertinent regulations.

No safety concerns were identified.

9.0 Security of Radioactive Materials

On Monday October 21, 1996, at the start of an unannounced safety inspection, the inspector walked into the Nuclear Medicine department at the University Hospital. The inspector was not challenged by the receptionist at the entrance to the department. The inspector proceeded to conduct a preliminary walk-through of the department and noticed that the door to the combined injection room, Hot Lab suite was wide open. The inspector observed that the outside door to the injection room was equipped with a push button combination lock, but the lock was not engaged and the door was wide open. Both rooms were unattended. The inspector walked into the Hot Lab and observed that there were two 2.5 Ci molybdenum-technetium generators on the bench

top. One generator was calibrated for that morning (October 21), the other was calibrated for the previous Monday (October 14). In addition, there were various other calibration sources and unit dose syringes of radiopharmaceuticals. The Hot Lab remained unsecured and unattended for about 15 minutes. At this time the inspector, using the telephone in the Hot Lab, notified the University RSO of the fact that the Hot Lab was unsecured and unattended. In about five minutes the assistant RSO arrived in the Hot Lab, he was followed by the chief nuclear medicine technologist. The inspector informed them of the apparent security violation found in the Hot Lab. Before departing, the inspector verified that the Hot Lab-injection room suite was locked as required. During the week the inspector passed the Hot Lab-injection room suite on several occasions and observed that the suite was locked, and that a sign was placed on the outside door reminding the technologists to lock the door, whenever they were not present in the room. In addition, the inspector observed that a mechanical door closer was installed on the outside door sometime during that week, to insure that this door would be locked at all times.

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Failure to secure from unauthorized removal or access licensed materials in storage is an apparent violation of 10 CFR 20.1801.

While reviewing the minutes of the Radiation Committee meeting of March 20, 1996, the inspector noted that sometime between February 10 and February 16, 1996 a loss of up to 160 microcuries of phosphorus-32 (P-32) was identified by the licensee. The inspector examined the licensee's incident file of this incident and the following is the chronology of the incident:

> February 8, 1996--250 microcuries of P-32 as alpha ATP in 25 microliters of solution was received by a Microbiology research laboratory.
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> February 10, 1996--45.4 microcuries of P-32 in 5 microliters was removed for an experiment.
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> February 16, 1996--a researcher from another lab attempted to borrow some alpha ATP solution. She found the vial empty. The borrower did not notify anybody of the missing material. At this time the vial should have contained approximately 122 microcuries of P-32, had the material not been removed. Later the RSO determined that the vial still held approximately 2 microliters of solution.
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> February 26, 1996--The authorized user attempted to remove 10 microliters of reagent from the P-32 vial. She found the vial empty, except for

approximately 2 microliters, which she removed. It appears that the authorized user did not notice that a large portion of the material was missing at that time.

February 29, 1996--The research lab personnel discovered, during a routine survey, extensive contamination in the laboratory hood, and reported it to the RSO. The RSO's technician surveyed the contamination, determined it to be caused by P-32, and decontaminated the hood. The maximum removable contamination was found to be 384,000 disintegrations per minute per 100 square centimeter. The research personnel informed the RSO's technician that on February 26, 1996, the authorized user attempted to draw 10 microliters of the reagent from the vial and found only 2 microliters there.

February 29, 1996 and after--RSO's staff conduct extensive surveys of the research lab and its personnel. Urinalysis was performed on all lab personnel. The results were negative. Laboratory record books of all personnel, in all laboratories that used alpha ATP were reviewed by RSO's staff. No record of any unauthorized use of alpha ATP was discovered. As a result of the contamination incident, the licensee performed a material balance and accounting and determined that approximately 107 microcuries of material was missing (as of February 29, 1996).

The inspector interviewed the principal investigator and other personnel from the research lab and determined that the freezer where the alpha ATP was stored was unlocked; that it was a common practice for researchers from different labs to borrow radioactive reagents from each other; that the lab was open 24 hours of the day, and at times it was left unattended.

As a result of this incident a hasp and a padlock has been installed on the freezer where radioactive reagents are stored. Only one person in the lab has the key to the freezer, and he must be contacted in order to obtain any material stored in the freezer. The RSO has initiated an extensive program of Security Awareness using letters to the principal investigators, and security inspections conducted by RSO's staff during 24 hours of the day. During an extensive walk-through of research labs conducted by the inspector, no labs were found to be unlocked and unattended.

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled and unrestricted area and that is not in storage.

Failure to secure from unauthorized removal or access of licensed materials in storage is an apparent violation of 10 CFR 20.1801.

10.0 Training

During the tour of the licensee's medical and research facilities, the inspector interviewed numerous individuals; authorized users, medical technologists, and laboratory workers about their use of radioactive materials. The inspector determined that the individuals contacted had sufficient training in radiation safety, regulations, and the requirements of the license, to perform their job safely. The ORS offers twenty-one separate courses to different groups that require training. A computer file is maintained on all radiation workers to insure that they receive the required training or retraining.

No safety concerns were identified.

11.0 Personnel Radiation Protection

The licensee provides employees with monthly film badges to monitor radiation exposures to the whole body, and thermoluminescent dosimeters (TLDs) to monitor radiation exposures to extremities. The inspector reviewed dosimetry reports from October 1, 1995 to August 31, 1996 and noted that the whole body and extremity exposures for users of byproduct materials were well within the NRC's regulatory limits.

No safety concerns were identified.

12.0 Waste Disposal

The inspector reviewed the licensee's waste disposal methods and records. The licensee uses decay-in-storage (DIS) for all medical radioactive waste. Waste from Radioimmunoassay (RIB) lab and from research is separated by half-life and deposited in the licensee's waste storage facility. Short, and medium, half-life material is decayed and disposed as non-radioactive waste, and the long half-life waste is stored, and periodically picked-up by the licensee's waste broker. The licensee's radioactive waste broker (U.S. Ecology) has resumed shipping long-life waste to Barnwell, SC. Licensee generates only minimum amounts of liquid waste. All liquid waste is collected and picked-up by the ORS for decay and/or disposal. Only glassware washings are disposed into the sewer.

No safety concerns were identified

13.0 Exit Interview

The inspector met with the licensee's representatives identified in Section 1 of this report at the conclusion of the inspection. The inspector summarized the scope and findings of the inspection.