U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-13378/90001(DRSS)

Docket No. 030-13378

License No. 24-15235-03 Category G(1) Priority 1

Licensee: V. A. Harry S. Truman
Memorial Veterans Hospital
800 Hospital Drive
Columbia, MO 65201

Inspection Conducted: July 11, 1990

Purpose of Inspection: Routine, unannounced safety inspection to determine compliance with Commission rules, regulations and license conditions.

Inspector: S. J. Mulay 8/9/90
S. J. Mulay Date
Radiation Specialist

Approved By: R. J. Caniano 8/10/90
R. J. Caniano, Chief Date
Nuclear Materials Safety
Section 2

Inspection Summary

Inspection on July 11, 1990 (Report No. 030-13378/90001(DRSS))
Areas Inspected: This routine, unannounced safety inspection included a review of the licensee's organizational structure; scope of program; audits; training; materials; facilities; instrumentation; receipt and transfer; personnel radiation protection - external; personnel radiation protection - internal; waste disposal; notifications and reports; posting; transportation; and confirmatory measurements.
Results: Of the areas inspected, one apparent violation of NRC requirements was identified: failure to perform annual training of supervisory nursing personnel, License Condition 23.A. (Section 6).

DETAILS

1. Persons Contacted

+Richard Holmes, M.D., Chief of Nuclear Medicine Service
*William Logan, Ph.D., Radiation Safety Officer (RSO)
*Richard Poelling, Health Physicist

+Exit meeting by telephone July 11, 1990.
*Present at exit meeting on July 11, 1990.

2. Inspection History

The licensee was last inspected on February 13 and 14, 1989. Two violations were identified: (1) failure to perform day of use constancy checks for dose calibrator; (2) failure to perform day of use surveys of elution, preparation, and injection areas. A review of these areas during the inspection indicated that the licensee has taken corrective action and these issues are considered closed.

3. Organization

Mr. J. L. Kurzejeski is the Hospital Director, Richard A. Holmes, M.D. is the Chief of Nuclear Medicine Service and Chairman of the Radiation Safety Committee (RSC), K. William Logan, Ph.D., is the Radiation Safety Officer (RSO). The RSC meets at regular quarterly intervals and are held jointly with RSC meetings with the University of Missouri. Membership of the committee appears to be in accordance with license condition.

In addition to required quarterly meetings of the RSC, the radiation safety staff conduct monthly meetings to discuss pertinent top s such as exposure data and QA/QC

No violations of NRC requirements were identified.

4. Licensed Program

This broad scope medical and research program currently employs approximately 20 committee approved users of licensed material for both medical use and medical research. Currently, licensed activity is performed in approximately 20 laboratories including the Nuclear Medicine Department. The license authorizes any byproduct material in 10 CFR 35.100 through 35.500, and any byproduct material with Atomic Numbers between 3-83 inclusive with a total possession limit of 25 curies. The lic nse also authorizes the possession of certain isotopes to be used fo medical research and research and development as defined in 10 CFR Part 30 including animal studies. One cesium-137 sealed source (135 millicuries) is used for onsite instrument calibration and is stored within a locked shielded container in the Radiation Safety Office.

The nuclear medicine program employs three full-time technologists and two full-time technicians for in-vitro laboratory procedures. Approximately, 150 diagnostic procedures are performed monthly including 12 technetium-99m aerosol studies per month for lung ventilation evaluations.

Iodine-131 therapies are performed using both liquid and capsule form. Approximately six therapies for hyperthyroidism (average dose of 10 millicuries) are performed per year and 1-2 treatments for thyroid cancer (average dose of 100 millicuries) are performed per year.

The licensee is authorized to possess sealed sources for brachytherapy. However, no sources are stored at this facility at the present time and no brachytherapy procedures have been performed since the last inspection. Sources, when needed, are obtained from the University of Missouri, Radiation Oncology Department, as per License Condition No. 23.

Research applications involve in vitro and small animal studies. The limited animal research program utilizes technetium-99m and samarium-153. No iodination procedures have been performed since approximately 1988. Other isotopes used in research include tritium, carbon-14, iodine-125, phosphorus-32 and sulfur-35.

All authorized users in the medical research program have their permits reviewed and renewed at two year intervals.

No violations of NRC requirements were identified.

5. Surveys/Internal Audits

Radiation surveys and inventories are the primary responsibility of the authorized users in research laboratories. Frequencies of such surveys vary depending on the type, amount and frequency of material used. During routine audits by the RSO, survey and inventory reports are reviewed. Laboratories with millicurie amounts of byproduct material are surveyed daily by the users and weekly by the RSO. Laboratories with microcurie amounts of material are surveyed monthly by users and quarterly by the RSO.

Areas in the Nuclear Medicine Department where radionuclides are used are surveyed for contamination on day of use and surveyed for removable contamination weekly. Records of these surveys showed that the surveys have been conducted as required. A review of records for laboratory audits revealed that Radiation Safety Personnel are completing these audits in a timely manner. Additionally, the RSO conducts an annual review of the entire radiation safety program.

No violations of NRC requirements were identified.

6. Training, Retraining and Instruction to Workers

The RSC reviews, with assistance from the RSO, any applicant's users training and experience in accordance with the requirements for a broad scope program.

Initial instruction is given to workers in accordance with 10 CFR 19.12 and annual training is given to ancillary personnel as well as nuclear medicine staff members.

Training is given to research workers by the individual authorized users with additional annual lectures from the Radiation Safety Staff. Sign-in sheets are used to document attendance at training and retraining sessions. Nursing Personnel who are responsible for care of therapy patients are trained on an individual basis before treatment begins.

License Condition No. 23.A. which references application dated February 10, 1989, states in Item 8 that training for supervisory nursing personnel will be given at least once each year. Contrary to this requirement, training for supervisory nursing personnel has not been given since September 1988. Licensee representatives stated that this was primarily due to scheduling difficulties with supervisory nursing staff. Failure to provide in-service training for supervisory nursing personnel since 1988 constitutes an apparent violation of License Condition No. 23.A.

One apparent violation of NRC requirements was identified.

7. Materials, Facilities and Instruments

The licensee's facility appears to be as described in application dated February 10, 1989, and the isotopes, chemical form, quantity and use appears to be as authorized. The nuclear medicine department receives a 2.0 curie molybdenum-99m generator on a weekly basis. Breakthrough tests are performed on each elution as well as chromatography and alumina breakthrough for kit preparation. A review of breakthrough test records revealed molybdenum concentrations below 10 CFR 35.204 limits. In addition to primary hot lab area, the licensee has a separate area designated as a radiopharmacy in which kits are prepared and patient injections are performed.

Leak tests and inventories of sealed sources are performed at the required frequencies. A record review of leak tests and inventories revealed no leaking or unaccounted for sources. Areas of storage and use of byproduct material appear adequate to prevent unauthorized removal.

The licensee uses a variety of radiation detection instrumentation. Survey instruments used in nuclear medicine are calibrated annually by the RSO with the cesium-137 instrument calibration source authorized by this license. Survey instruments used in research laboratories are calibrated annually and as needed. Area monitors in use areas are

checked for response monthly. Survey instruments and monitors available in use areas were tested during the inspection with a dedicated check source as well as side-by-side comparison with a Xetex 305B survey instrument. This test revealed appropriate operation.

The licensee possesses three dose calibrators. One (No. 5236) is used for patient dose and kit assay prior to administration and is calibrated in accordance with 10 CFR 35.50. Records are maintained with RSO signature as required. The second instrument is used as a back-up unit and is checked for constancy on a day of use basis. Accuracy and linearity verification have been performed at annual and quarterly frequencies respectively. The third unit is used in the research area as a quantifying instrument and is not involved in human use and is therefore not calibrated. A review of records indicated that patient doses are assayed as required by 10 CFR Part 35.53.

No violations of NRC requirements were identified.

8. Receipt and Transfer of Radioactive Material

With the exception of licensed material delivered directly to the Nuclear Medicine Department, packages containing radioactive material are delivered to the health physics laboratory where they are inspected for damage, surveyed for external contamination and logged in. Authorization for intended recipients to possess the material is also verified. The RSO stated that procedures for the delivery of radioactive material for use in the Nuclear Medicine Department during off hours will soon be revised to allow the courier to bring the materials directly to the hot lab used for elution. Presently, material is being delivered to a separate, secured room and then brought to the elution hot lab by nuclear medicine staff members. A review of records of material received revealed no problems.

Radioactive material is not normally transferred except as discussed in Section 11 (Waste Disposal).

No violations of NRC requirements were identified.

9. Personnel Radiation Protection - External

The licensee provides radiation workers with personnel dosimetry supplied by a NVLAP approved vendor. Whole body film badges and TLD ring badges are exchanged monthly. A review of records from March 1988 to June 1990 revealed a maximum whole body annual exposure of 50 millirem and a maximum extremity annual exposure of 1230 millirem. Nurses caring for patients undergoing therapy are also monitored as required. The licensee uses syringe shields routinely as required by 10 CFR Part 35.60.

No violations of NRC requirements were identified.

10. Personnel Radiation Exposure - Internal

Since approximately 1988, the licensee has been using technetium-99m DTPA aerosol for lung ventilation studies. The potential for iodine-131 uptake by radiation workers exists, however, on a limited scale. The licensee uses volatile liquid iodine-131 for the majority of hyperthyroid and thyroid cancer treatments. Although this material is normally handled and/or administered in or by a fume hood, personnel involved with the administration of liquid iodine-131 have their thyroids checked for uptake after administration in accordance with Regulatory Guide 8.20.

A review of bioassay records by the inspector (including the most recent iodine-131 treatment of approximately 200 millicuries) did not identify any significant uptakes.

No violation of NRC requirements were identified.

11. Waste Disposal

The licensee disposes of radioactive waste in a variety of authorized methods. Molybdenum-99/technetium-99m generators are held for 30 days after the calibration date, surveyed and returned to the manufacturer in the same container in which it was received. Longer-lived isotopes such as hydrogen-3 and carbon-14 are disposed of to the sanitary system or by incineration as authorized. The limits set forth in 10 CFR Part 20 are adhered to for both sanitary sewer and incineration disposals.

The licensee also decays radioactive waste in storage. When it is surveyed so that it cannot be distinguished from background levels it is disposed of as ordinary trash as authorized.

The hospital also has a contract with a waste broker for pick-up of low level radioactive material. However, this service has not been utilized since approximately 1981 and no future use of this broker is anticipated.

The door to the outside storage area is properly posted and locked when not attended.

No violations of NRC requirements were identified.

12. Notifications and Reports

No overexposures, incidents or theft of material occurred during the inspection period.

No misadministrations have occurred since the last inspection. Corrective actions taken following two diagnostic misadministrations in 1988 appear adequate to prevent recurrence.

No violations of NRC requirements were identified.

13. Posting and Labeling

A walkthrough of various areas in the licensee's facility showed that restricted areas are posted with Caution Radioactive Materials signs and/or Caution Radiation Area signs. Other drums and containers were also properly posted with required signs.

NRC-3 forms were posted in general use areas and contained information that Parts 19 and 20 and license documents are available for review.

No violations of NRC requirements were identified.

14. Confirmatory Measurements

Radiation level measurements made by the inspector in the nuclear medicine area were performed with a Xetex 305B survey instrument, Serial No. 9003, calibrated February 14, 1990. A Ludlum 14C, Serial No. 13162 with a pancake probe calibrated February 14, 1990 was used in various research laboratories.

Of the use areas reviewed and visited during the inspection, no areas of contamination were detected and radiation levels were found to be comparable to licensee measurements during side-by-side evaluations and were within 10 CFR Part 20 limits.

No violations of NRC requirements were identified.

15. Exit Meeting

At the conclusion of the inspection on July 11, 1990, the inspector met with the individuals identified in Section 1 of this report. A summary of the areas inspected, the apparent violation and the forthcoming letter and Notice of Violation were discussed. The licensee did not indicate that any information reviewed during the inspection was proprietary in nature.