U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-02639/90001(DRSS)

Docket No. 030-02639

License No. 34-00203-03 Priority I Category G1

Licensee: Veterans Administration Medical Center
Nuclear Medicine Service
10701 East Blvd.
Cleveland, OH 44106

Inspection Conducted: January 11, 1990

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

Inspector: D. R. Gibbons
Radiation Specialist
Nuclear Materials Safety
Section 1

February 26, 1990
Date

Approved By: D. J. Sreniawski, Chief
Nuclear Materials Safety
Section 1

March 6, 1990
Date

Inspection Summary

Inspection on January 11, 1990 (Report No. 030-02639/90001(DRSS))
Areas Inspected: Routine, unannounced safety inspection which included corrective action on previous violations; review of the licensee's organization structure; scope of program; audits; training; materials, facilities and instruments; receipt and transfer of radioactive material; personnel radiation protection - external; personnel radiation protection - internal; radioactive effluents and waste disposal; notifications and reports; posting; confirmatory measurements/independent measurements; posting and labeling; and transportation.
Results: Of the areas inspected, four violations of NRC requirements were identified.

DETAILS

1. Persons Contacted

*Steven W. Landgraf, M.A., Health Physicist/RSO
Suresh Kolli, M.D., Chief, Nuclear Medicine Service
*Ronald D. Lew, M.D., Acting Chief, Nuclear Medicine Service
Chris Nye, Research Service Technician
Gloria McClain, Research Service Technician
*Murray D. Altose, M.D., Chief of Staff

*Denotes those present at the exit meeting held on January 11, 1990.

2. Inspection History, Licensee Action on Previous Violations and Licensee Event Reports

The Veterans Administration Medical Center was last inspected on December 3 and 4, 1985. Three (3) violations were identified during the course of that inspection.

(Closed) Inspection No. 85-001, failure to perform daily surveys, and weekly wipe tests to measure contamination levels of all preparation and injection areas. Based on observation of licensee performance, statements by the Radiation Safety Officer and technologists, and a review of records, the inspector determined that this violation has been corrected.

(Closed) Inspection No. 85-001, failure to recalibrate survey instruments at the required intervals. Based on a review of records, the inspector determined that this violation has been corrected.

(Closed) Inspection No. 85-001, failure to wear lapel air samplers during iodination. Based on statements by the Radiation Safety Officer and a review of records, the inspector determined that this violation has been corrected.

(Closed) Misadministration report dated January 28, 1986. Diagnostic misadministration involving wrong patient. Records indicated that all technologists were retrained.

(Closed) Misadministration report dated October 17, 1986. Diagnostic misadministration involving wrong patient. Records indicated that someone outside of the Nuclear Medicine Department had signed for a Gated Blood Pool examination. The Medical Center's Chief of staff instituted administrative controls to prevent unauthorized persons.

(Closed) Misadministration report dated March 10, 1988 involving wrong radiopharmaceutical. Records showed that the individual responsible for the misadministration was counseled on the importance of carefully checking the dose label and correlating the dose assay result with the planned dose for the specific study. All technologists were retrained.

(Closed) Misadministration report dated April 15, 1986 involving wrong dosage (3.3 millicuries instead of 4 millicuries). Records showed that the technologist responsible was counseled and retrained.

(Closed) Misadministration report dated May 27, 1988 involving wrong radiopharmaceutical. The technologist responsible was counseled by the Radiation Safety Officer on the importance of checking dose labels, and to concentrate on one task at a time.

(Closed) Misadministration report dated September 28, 1989 involving wrong radiopharmaceutical. Records indicated that all personnel participated in a review training session concerning all procedures and precautions governing radiopharmaceutical dose administration.

(Closed) Misadministration report dated September 28, 1989 involving wrong patient. The technologist responsible participated in a review training session, and was supervised until staff at the Medical Center were satisfied that the individual was following proper procedures.

3. Organization

P Stajduhar, M.D., is the Director of the Hospital; Murray D. Altose, M.D., is Chief of Staff; Suresh Kolli, M.D., Chief, Nuclear Medicine Service and is the Chairman of the Radiation Safety Committee; Ronald D. Lew, M.D., Acting Chief, Nuclear Medicine Service; and will be Chairman of the Radiation Safety Committee when the license renewal is approved; Steven W. Landgraf, M.A., Health Physicist is the Radiation Safety Officer.

No violations of NRC requirements were identified.

4. Licensed Program

The licensee currently employs four full time nuclear medicine technologists who perform approximately 200 routine diagnostic procedures per month. The licensee also performs approximately 5 to 7 therapy procedures per year for hyperthyroidism and on rare occasion performs thyroid therapy for treatment of cancer. The licensee has 28 committee approved users of radioactive material either for medical use or research or both. Two persons are authorized for medical use and 26 persons are authorized for research. Of the 28 authorized users of radioactive material, 20 are currently using byproduct material in 60 different laboratories. The license authorizes any Groups I-VI, xenon-133, and any byproduct material with Atomic Nos. 3 through 83. The kinds and amount of material used is as authorized by this license. Research is currently performed using microcurie amounts of iodine-125, tritium, carbon-14 and millicurie amounts of phosphorous-32, sulphur-35 and technetium-99m. Iodinations are very infrequent at this time.

The licensee has established a Radiation Safety Committee (RSC) as required, except that a member of the nursing staff is not represented on the Committee.

The failure to have a representative of the nursing staff on the Committee constitutes a violation of 10 CFR 35.22(a)(1).

The RSC is responsible for assuring the licensed program operates in accordance with NRC regulations and the conditions of the license. The Committee has met at the required quarterly intervals, except the Committee failed to meet during the third quarter of 1986 (June 12, 1986 to December 26, 1986), during the second quarter of 1987 (February 2, 1987 to July 21, 1987) and during the fourth quarter of 1989 (September 29, 1989 to the day of the inspection, January 11, 1990).

The failure to conduct Radiation Safety Committee meetings at quarterly intervals constitutes a violation of 10 CFR 35.22(a)(2).

Two violations of NRC requirements were identified:

5. Internal Audits

Area surveys and wipe tests are performed weekly and submitted to the RSO. All orders for radioactive material are made by the RSO. The RSO suspends ordering if the authorized user has had problems in their area.

The RSO performs audits of use areas at intervals depending on the work load of those areas, and maintains records of the results. Authorized users who are found to be in violation of their use permits are put on notice and a second infraction is basis for suspension of their use of licensed material.

The RSO is continually working with authorized users, or user personnel in an effort to improve the program.

No violations of NRC requirements were identified.

6. Training, Retraining, and Instruction to Workers

The licensee's RSC reviews individuals training and experience in accordance with the requirements for a Type A Broad Scope Program. No other training is required by this license. However, the RSO performs retraining for persons who may come in contact with radioactive material or who may care for patients undergoing test and therapy procedures. Instruction is also given to persons who may enter restricted areas during the course of their work such as housekeeping, security, etc. This instruction is given at least annually and on an as needed basis.

No violations of NRC requirements were identified.

7. Materials, Facilities and Instruments

The licensee's facility appears to be as described in their application dated September 4, 1979, and the isotopes, chemical form, quantity and use appears to be as authorized. The licensee uses unit doses from a nearby radiopharmacy. A review of quality control records demonstrated that the licensee performs the proper tests for unit doses. Each unit dose is assayed in the dose calibrator before any patient is injected.

Leak tests are performed at six month intervals, and inventory of sealed sources are performed quarterly. However, the licensee did not have records of leaks tests performed during the period from January 12, 1989 to the day of the inspection, January 11, 1990.

The failure to maintain leak test records constitutes a violation of 10 CFR 35.59(d)

The licensee has a variety of radiation detection equipment. Instruments used to detect ambient radiation fields are calibrated annually by an NRC approved calibration firm. Other instruments used to quantify contamination levels and bioassay results are calibrated as needed by the licensee using known calibration standards. The dose calibrator is tested in accordance with NRC Regulatory Guide 10.8 as referenced in the licensee's application dated September 4, 1979, and 10 CFR 35.50. However, the licensee failed to perform a quarterly linearity test of the dose calibrator during the period from July 14, 1988 to February 29, 1989.

The failure to perform a quarterly linearity tests during the fourth quarter of 1988 constitutes a violation of 10 CFR 35.50(b)(3).

Two violations of NRC requirements were identified.

8. Receipt and Transfer of Radioactive Material

Packages containing radioactive material are normally received during duty hours and are delivered directly to the RSO. Upon receipt, and if a package appears undamaged, the RSO surveys the package for unusual radiation levels, and then notifies the individual ordering the package to pick up the package. That individual performs the required wipe tests of both the outer container and the inner container.

The licensee maintains records of receipt as required. Radioactive material is not normally transferred except as discussed in Section 11 of this report under waste disposal.

No violations of NRC requirements were identified.

9. Personnel Radiation Protection - External

The licensee uses an NRC approved film badge vendor as identified in their application dated September 4, 1979. Film badges are exchanged monthly and reviewed monthly by the RSO. The RSC also reviews the ALARA program at the end of each year. Extremity badges are used by individuals who are likely to receive 25% of Part 20 limits. The NRC inspector's review of personnel exposures showed that exposures to radiation workers were well below the limits set in 10 CFR Part 20. The maximum 1988 whole body exposure was 280 millirem and the maximum 1988 extremity exposure was 810 millirem. The maximum 1989 whole body exposure was 230 millirem and the maximum 1989 extremity exposure was 640 millirem. Nurses caring for patients undergoing therapy are film badged as required.

No violations of NRC requirements were identified.

10. Personnel Radiation Protection - Internal

Potential for exposure of individuals to airborne radioactive material exists on a limited scale. The licensee performs approximately 24 lung ventilation studies per week using xenon-133. Rooms used for these studies are kept under negative pressure and ventilation rates are checked periodically, and at least semiannually to assure continuance of negative pressure in use areas. In addition, the licensee uses a trap alarm to alert individuals of an accidental release of the xenon gas. The alarm is periodically checked for proper operation.

The potential for iodine-125 and iodine-131 uptake by radiation workers also exists on a limited scale. The licensee uses volatile liquid iodine-131 more often than capsules for thyroid therapy. Personnel involved in the administration of liquid iodine-131 have their thyroids checked between 6 and 72 hours after administration. The acceptance criteria is the referenced limits found in NRC Regulatory Guide 8.20. A review of bioassay results showed levels to be well below the limits specified in Guide 8.20. Researchers using iodine-125 use quantities that are well below NRC Regulatory Guide criteria requiring bioassays. None the less, the licensee performs bioassays on all researchers ordering iodine-125. Again, records showed no unusual uptakes of iodine-125. Presently, iodinations are not performed at this facility, and will not be performed until a proper hood is constructed.

11. Radioactive Effluents and Waste Disposal

The licensee disposes radioactive waste by a variety of authorized methods. Water soluble waste is disposed of via sink at levels below Part 20, Appendix B limits, short half-lived material is held for decay and long half-lived material not soluble in water is picked up by an NRC authorized waste broker at one to two month intervals. Transfer records showed that from four (4) to fifteen (15) 55 gallon drums of low level waste are normally picked up by a waste broker. Records also show that the licensee performs surveys of waste that is held for decay prior to disposal in the normal trash.

No violations of NRC requirements were identified.

12. Notifications and Reports

No overexposures, incidents, thefts or loss of material occurred during the inspection period. The licensee did have seven diagnostic misadministrations in the inspection period. All were properly reported to the Region III office A review of corrective action indicated that the licensee had initiated procedures to prevent recurrence. The frequency of misadministrations for the last two years is not unusual for the work load ($\sim$ 2 incidents per year).

No violations of NRC requirements were identified.

13. Posting of Notices

The NRC inspector's walkthrough of various use areas of the licensee's facility showed that posting of notices was adequate. The inspector noted that NRC-3 forms, license documents, Parts 19 and 20 and current exposure results were posted as required.

No violations of NRC requirements were identified.

14. Confirmatory Measurements

Radiation measurements made by the NRC inspector showed radiation levels in unrestricted areas to be well below 10 CFR Part 20 limits. Ambient radiation levels in restricted areas were no greater than 0.1 milliroentgen/hr except for measurements made at the surface of sealed sources or generators. Measurements were made at the surface of sealed sources in order to do a side-by-side comparison of survey instruments. The licensee's survey instrument compared within 0.1 milliroentgen to the NRC inspector's survey instrument.

No unusual radiation levels were identified in areas inspected.

No violations of NRC requirements were identified.

15. Posting and Labeling

The NRC inspector's 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. Packages and containers were also properly posted with required signs.

No violations of NRC requirements were identified.

16. Transportation

The licensee does not transport radioactive material outside the confines of their facility. However, some waste is transferred to a waste broker approximately every one or two months. Transfer records appeared to be appropriate, waste is classified and quantified and packaging of the waste appears to be as required.

No violations of NRC requirements were identified.

17. Exit Meeting

At the conclusion of the inspection on January 11, 1990, the inspector met with those individuals identified in Section 1 of this report. A summary of the areas inspected as well as the results were reviewed with these individuals.