U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-12833/89001(DRSS)

Docket No. 030-12833

License No. 24-17486-01 Category G Priority III

Licensee: Pemiscot County Medical Center
East Reed Street and Highway 61
Hayti, MO 63851

Inspection Conducted: November 21, 1989

Inspector: Roy J. Caniano for
Bryan A. Parker
Radiation Specialist
Date December 23, 1989

Reviewed By: Roy J. Caniano
Roy J. Caniano, Chief
Nuclear Materials Safety Section 2
Date December 23, 1989

Approved By: Roy J. Caniano for
Bruce S. Mallett, Ph.D., Chief
Nuclear Materials Safety Branch
Date December 23, 1989

Inspection Summary

Inspection from November 21, 1989 (Report No. 030-12833/89001(DRSS))
Areas Inspected: This was a routine unannounced safety inspection of the licensee's nuclear medicine program. The inspection included a review of the licensee's organization; materials, facilities, and equipment; instrument calibrations; receipt and transfer of materials; training; personnel radiation protection; misadministrations; waste disposal; postings; and independent measurements.
Results: Six apparent violations were identified. The specific violations were:

1. Failure to properly train a nuclear medicine technologist in areas specified in 10 CFR 19.12.

2. Failure to hold Radiation Safety Committee meetings during the third quarter of 1988 and the third quarter of 1989 (10 CFR 35.22(a)(2)).

3. Failure to conduct daily constancy check and quarterly linearity check on dose calibrator. Also, failure to carry linearities down to 10 microcuries (10 CFR 35.50(b)).

4. Failure to conduct daily surveys and weekly wipes in preparation and administration areas (10 CFR 35.70).

5. Failure to wear personnel finger exposure monitors during preparation, assay and injection of radiopharmaceuticals (License Condition No. 14).

6. Failure to maintain decay-in-storage disposal records (10 CFR 35.92).

In addition to the apparent violations, the inspector identified the following areas of concern:

1. The Radiation Safety Officer (RSO) does not appear actively involved with the safety aspects of the nuclear medicine program.

2. There does not appear to be sufficient management oversight of the nuclear medicine program due to their limited knowledge about the NRC license and regulations.

3. There is no one knowledgeable about the NRC license and regulations who oversees the day-to-day operation of the nuclear medicine program.

The details of these areas of concern are described in Section 4 of this report.

DETAILS

1. Persons Contacted

△*Glenn Haynes, Administrator
△*Jo Stanwood, Assistant Administrator
△ James Hazel, M.D., Radiation Safety Officer
△*David Burton, Nuclear Medicine/X-ray Technologist
△ Bob Rimel, Certified Nuclear Medicine Technologist

*Attended exit meeting held on November 21, 1989.
△Participated in management teleconference held on December 8, 1989.

2. Purpose of Inspection

This was a routine unannounced safety inspection of the licensee's nuclear medicine program authorized by NRC License No. 24-17486-01.

3. Inspection History

The last inspection conducted at the facility was on May 16, 1986, at which time three violations were identified. The violations pertained to an inadequate method for analyzing wipe tests, failure to measure air flow rates in the imaging area semiannually, and failure to maintain air flow rates to specified limits. An inspection conducted in 1982 revealed two violations pertaining to a failure to maintain dosimetry records and a failure to possess an adequate, calibrated survey meter. An inspection conducted in 1979 revealed seven violations pertaining to unauthorized use, disposal records, dose calibrator checks, inoperable survey instrument, Radiation Safety Committee meetings, area surveys and an unlabeled waste container.

4. Organization and Summary of Program

Pemiscot County Medical Center is a small rural hospital serving Hayti, Missouri and the surrounding communities. The nuclear medicine program at Pemiscot consists of one cross-trained X-ray technologist performing approximately 8-12 diagnostic procedures per month. The majority of the studies are technetium-99m (Tc-99m) related with an occasional xenon-133 (Xe-133) lung study. All licensed materials are received from a major radiopharmaceutical supplier in the form of prepackaged kits of Xe-133 and multidose vials of Tc-99m.

The Radiation Safety Officer (RSO) is Dr. James Hazel, who is also the only authorized user at Pemiscot at the present time.

The aforementioned technologist that performs all of the procedures replaced a certified nuclear medicine technologist who retired in July 1989 after approximately 30 years with Pemiscot. The new technologist began cross-training in nuclear medicine in June 1988 under the supervision of the retiring technologist, but the training received

does not meet NRC requirements. This training violation is discussed in detail in Section 5 of this report. In short, the new technologist, although adequately trained in the "mechanics" of nuclear medicine, lacks knowledge in the regulatory aspects of the program.

The licensee is required to have a Radiation Safety Committee (RSC), which is responsible for carrying out certain duties specified in 10 CFR 35.22. One of the duties specified in 10 CFR 35.22(a)(2) is for the Committee to meet at least quarterly. Contrary to this requirement, the RSC failed to meet during the third quarter of 1988 and the third quarter of 1989 which constitutes a violation of 10 CFR 35.22(a)(2).

As discussed during the inspection and at the management meeting held on December 8, 1989, the RSO does not appear to be actively involved in the licensed program. The NRC views this as an area of concern, due to the fact that many of the apparent violations could have been avoided had the RSO maintained sufficient interest in the program, especially after the longtime technologist left the program in July 1989.

Also, the management of Pemiscot does not appear to have sufficient oversight of the nuclear medicine program as a whole. Discussions with management representatives at Pemiscot reveal that there is limited knowledge about the NRC license and regulations. The NRC views this as an area of concern as the hospital is ultimately responsible for the licensed activities.

Finally, there does not appear to be anyone knowledgeable about the NRC license or regulations who is intimately involved in the day-to-day operation of the licensed program. The licensee appears to rely too heavily upon their consultant for oversight of the program. The NRC views this as an area of concern since further lack of daily oversight could result in more significant health and safety issues if left uncorrected.

One apparent violation was identified.

Three areas of concern were identified.

5. Training and Retraining

The training needed to work in the licensee's nuclear medicine program is described in 10 CFR 19.12. Some of the areas that must be covered include the terms and conditions of the NRC license, the regulations pertinent to the program, the potential hazards associated with radioactive material, and basic radiation safety procedures and practices.

From discussions with the new technologist, it appears that, although he is adequately trained in nuclear medicine administrations, he lacks knowledge in the aforementioned areas of 10 CFR 19.12. The licensee failed to initially provide instruction in these areas when the technologist began cross-training in June 1988 as well as failing to provide the required training once the technologist took over the program in July 1989. The licensee's failure to provide appropriate instruction to the technologist constitutes a violation of 10 CFR 19.12.

One apparent violation was identified.

6. Radiation Protection Procedures

Basic radiation protection procedures for the nuclear medicine license appear adequate except where noted elsewhere in this report. The use of gloves, syringe shields and vial shields was observed during the course of the inspection and no evidence of eating, drinking, smoking, or food storage was found in the restricted area.

No violations were identified.

7. Materials, Facilities and Instruments

The licensee is authorized for any diagnostic radiopharmaceutical listed in 10 CFR 35.100 and 35.200 on an "as needed" basis. The licensee only handles technetium-99m in a standing order multidose vial and xenon-133 as needed in unit doses.

The licensee's nuclear medicine hot lab is as described in their application received August 18, 1988, as referenced in License Condition No. 14.

The licensee's instrumentation consists of a thin-end window G-M survey meter and a dose calibrator. Both instruments were operable and calibrations were up-to-date.

The licensee is required by 10 CFR 35.50(b) to perform certain checks on the dose calibrator. These checks are: (1) constancy, on each day of use; (2) linearity, at installation and quarterly; (3) accuracy, at installation and annually; and (4) geometric variation, at installation. In addition, linearity checks are to be performed over the range of use between the highest dosage administered and 10 microcuries.

On November 8, 1988, the licensee performed a study and, thus, used licensed material. However, the licensee failed to check the dose calibrator for constancy on that day. Also, a linearity check was not conducted between April 6, 1989, and the date of the inspection, thus missing the third quarter of 1989. Finally, of the linearity checks conducted after October 13, 1988, the required lower limit of 10 microcuries was not reached. The inspector requested that a linearity check be conducted as soon as possible by the licensee to insure the proper operation of the dose calibrator. This was accomplished during the week of November 26, 1989, and the results were verbally relayed to the inspector on December 1, 1989. No deviations regarding the operability of the dose calibrator were noted. The licensee's failure to properly calibrate the dose calibrator constitutes a violation of 10 CFR 35.50(b).

One apparent violation was identified.

8. Receipt and Transfer of Radioactive Material

Incoming packages containing radioactive material are checked in by the supplier's delivery person, who performs and records the required surveys and leaves the package in the hot lab. The technologist then, upon arrival, checks the delivery record and opens the package for preparation if studies are scheduled. Unused portions are repackaged by the technologist and the delivery person performs the required surveys before removing the package from the hot lab for return and/or disposal.

No violations were identified.

9. Personnel Monitoring

For personnel monitoring, the licensee utilizes both whole body film badges and TLD extremity badges supplied by a NVLAP-approved vendor. Dosimetry reports are reviewed as they are received by the technologist and the reports include all required information (birthdates, Social Security number, etc.). Film badge results for the period of January 1988 through September 1989 were reviewed and the maximum annual whole body dose was 160 millirem for 1988 and 120 millirem for 1989. The extremity dose on all dosimetry reports read zero. Through discussions with the licensee, it was determined that although extremity monitors were issued, they were never worn while conducting licensed activities.

The licensee is required by Item 10.4 of the application received August 18, 1988, as referenced in License Condition No. 14 to establish and implement the model safety rules outlined in Appendix I of Regulatory Guide 10.8, Revision 2.

Within Appendix I is a requirement that finger exposure monitors are to be worn during the preparation, assay and injection of radiopharmaceuticals. According to the technologist, the monitors have not been worn since he began performing studies in June 1988. The licensee's failure to wear finger exposure monitors constitutes a violation of License Condition No. 14.

One apparent violation was identified.

10. Personnel Radiation Exposure - Internal

The licensee is authorized by 35.200 to possess and use xenon-133 for diagnostic studies and performs approximately 2-3 lung ventilation studies per month. Exhaust system checks are performed every six months by the licensee's consultant and emergency procedures for xenon spills are posted.

No violations were identified.

11. Surveys

Certain surveys are required by 10 CFR 35.70 to be performed in preparation and administration areas. These surveys include ambient exposure rate surveys at the end of each day of use and wipe surveys for removable contamination once each week. Also, records of these surveys must be maintained.

From a review of records and discussions with the licensee, the inspector determined that on approximately six days of use between July 12, 1989, and August 8, 1989, the licensee failed to perform ambient exposure rate surveys. Also, the licensee failed to perform wipe surveys for removable contamination once each week for approximately nine weeks between August 28, 1989 and November 13, 1989. The licensee's failure to perform proper surveys constitutes a violation of 10 CFR 35.70.

One apparent violation was identified.

12. Waste Disposal

The licensee is required by 10 CFR 35.92 to conduct their waste disposal program by following certain guidelines. These guidelines include holding radioactive waste for decay and discarding it as normal trash if, after surveying, the waste is determined to be at background. Also, records of the disposals are required to be maintained and must include certain information such as the dates the waste was discarded and disposed, the survey results, the radionuclides, and the initials of the person conducting the surveys.

According to the licensee, radioactive waste (residual Tc-99m on syringes, gloves, etc.) accumulated from nuclear medicine procedures is held for decay for approximately two months, at which time it is surveyed and disposed of as normal trash, if readings are at background. However, records of an unknown number of disposals made between August 18, 1989, and the date of the inspection have not been maintained. The licensee's failure to properly maintain disposal records constitutes a violation of 10 CFR 35.92(b).

One apparent violation was identified.

13. Leak Tests and Inventories

The only sealed source in possession of the licensee is a nominal 104 microcurie (May 1979) cesium-137 dose calibrator check source. Since May 1979, the source has decayed to approximately 82 microcuries, thus exempting it from the six month leak test requirement as allowed by 10 CFR 35.59(f)(3).

10 CFR 35.59(g) requires that all sealed sources be inventoried on a quarterly basis and records of said inventories be maintained. The licensee has been conducting and maintaining records of sealed source inventories.

No violations were identified.

14. Posting and Labeling

All areas under the nuclear medicine license which require postings were posted with the appropriate sign and labeling of items in the hot lab was found to be in accordance with regulatory requirements. Also, all required notices (NRC-3 form, emergency procedures, etc.) were posted in the appropriate area.

No violations were identified.

15. Notification and Reports

According to the licensee, no misadministrations, overexposures, incidents, thefts, or losses have occurred under this license.

No violations were identified.

16. Confirmatory Measurements

A survey of the hot lab was conducted by the inspector using a Xetex instrument (NRC Serial No. 008996, last calibrated September 28, 1989). Maximum readings in all areas were at or below 0.2 milliroentgen per hour.

No violations were identified.

17. Exit Interview

An exit interview was held with the Hospital Administrator and others on November 21, 1989, at the licensee's facilities. The apparent violations, areas of concern, corrective actions and possible alternatives were discussed as well as the NRC policy regarding enforcement.

18. Management Teleconference

A management conference was held with the licensee via telephone on December 8, 1989. The purpose for the meeting was to review the apparent violations, discuss the corrective actions to be taken and inform the licensee of the NRC enforcement policy. The licensee agreed with all six of the apparent violations and responded that the recordkeeping violations have been corrected since the day of the inspection. In response to the other violations and the areas of concern, the licensee stated that (1) nuclear medicine operations were voluntarily shutdown shortly after the inspection and will remain shutdown until administration is satisfied with their own corrective actions; (2) a linearity check was accomplished on the dose calibrator shortly after the inspection and another will be performed before resuming operations; (3) a full-time certified nuclear medicine technologist was hired to oversee the day-to-day operations; (4) the RSO will become intimately involved in the program; (5) an upper management representative will personally supervise the continued compliance with all NRC requirements; and (6) internal audits will be conducted to identify future violations.