APPENDIX

NUCLEAR REGULATORY COMMISSION
REGION IV

NRC Inspection Report: 30-22215/89-01 License: 35-23461-01

Docket: 30-22215

Licensee: Elk View General Hospital
429 West Elm
Hobart, Oklahoma 73651

Inspection At: Hobart, Oklahoma

Inspector: Selvan Rajendran 11/24/89
Selvan Rajendran, Radiation Specialist Date
Nuclear Materials Inspection Section

Approved By: Charles L. Cain 11/24/89
Charles L. Cain, Chief, Nuclear Materials Date
Inspection Section

Inspection Summary

Inspection Conducted August 24-25, 1989 (Report 30-22215/89-01)

Areas Inspected: Routine, unannounced safety inspection of institutional diagnostic nuclear medicine program including organization and management of program; training and qualifications of personnel; use and storage of materials; facilities and equipment; receipt and transfer of material; personnel protection - external; waste disposal; transportation; and misadministrations.

Results: Eight violations were observed:

1. Failure of the radiation safety officer (RSO) to conduct periodic audits of the radiation safety program (Section 3).

2. Failure to record the members present in the radiation safety committee (RSC) minutes (Section 3).

3. Failure to train personnel (Section 4).

4. Failure to calibrate survey instruments at proper intervals (Section 6).

5. Failure to perform linearity tests and accuracy tests on the dose calibrator (Section 6).

6. Failure to survey incoming packages within 18 hours of receipt and to record results of package surveys (Section 7).

7. Failure to record results of surveys of waste before disposal (Section 9).

8. Failure to report a misadministration to NRC (Section 11).

DETAILS

1. Persons Contacted

*Bill Finch, Administrator
*Vern Denning, Director of Radiology
*Robert Metcalf, M.D., Nuclear Medicine Physician, and Radiation Safety Officer (RSO)
Mary Jo Smith, Former Nuclear Medicine Technologist (by telephone)
Clifford W. Richter, Ph.D, Consultant (by telephone)

*Denotes attendance at exit meeting.

2. Licensee Actions on Previous Violations

(Closed) Violation (30-22215/8501-01): Failure to post the required documents as required by 10 CFR 19.11. The inspector observed that the required documents were posted.

3. Organization and Scope of Program

The licensee has operated a small nuclear medicine program staffed by one technologist. The previous nuclear medicine technologist was assigned in 1987, about 2 years after the prior inspection. She was replaced in her role by the Director of Radiology on July 17, 1989.

The nuclear medicine physician has served as the radiation safety officer (RSO). He has visited six different hospitals and has been on the licensee's site three times a week (M-W-F), for 2-4 hours a day. The inspector was told that no nuclear medicine work is done on the days the physician is not at the hospital. Approximately 15-20 scans have been performed per month. The licensee employed the services of a consultant, as of July 1, 1989, to perform audits of the radiation safety program. The RSO stated that he let the technologist oversee the program and did not get deeply involved with the radiation safety program. The inspector noted that the RSO had not conducted the quarterly and annual audits committed to in the license's application dated July 27, 1984. These commitments had been included in Appendix O of the application which described the ALARA program. This failure was identified as a violation of License Condition 16. (After the inspection, the licensee submitted an amendment request to NRC to assign RSO responsibilities to the Director of Radiology.)

The Radiation Safety Committee (RSC) has met quarterly. From looking at the RSC minutes, it was not apparent to the inspector that a quorum was achieved at all the meetings. The minutes did not identify members present and members absent. This was identified as a violation of 10 CFR 35.22(a)(4).

Two violations were identified.

4. Training and Qualification of Personnel

The inspector reviewed whether the technologists had been instructed in the proper procedure for using the dose calibrator to assay the eluate from the molybdenum-99/technetium-99m generator for molybdenum-99 contamination, how to perform checks on the dose calibrator, and the proper procedures for preparing packages containing radioactive material for shipment. No documentation was available to indicate that the previous technologist had received such training. The Director of Radiology, serving as the technologist, stated that he had not received this training. This was identified as a violation of 10 CFR 19.12.

One violation was identified.

5. Use and Storage of Materials

The inspector did not observe any nuclear medicine activities in progress. The licensee has used a 450 mCi Dupont generator, received weekly, to obtain its technetium-99m. The generator has been stored in the dark room/hot lab. Xe-133 studies have not been conducted; however, technetium aerosols have been used for lung studies. Tc-99m has been the primary material used in the nuclear medicine department.

No violations or deviations were identified.

6. Facilities and Equipment

Facilities were as described in the application based on observations during the inspection.

The Nuclear Medicine Department has been equipped with one survey instrument, a Ludlum Model 14C, equipped with a side-window Geiger-Muller probe, which meets the requirements of 10 CFR 35.220. The instrument was calibrated by Ludlum Instruments on June 28, 1984; March 16, 1987; June 18, 1988; and July 11, 1989.

The licensee's application dated July 27, 1984, references Appendix D, Section 1, of Regulatory Guide 10.8 (Revision 1) which commits the licensee to calibrate the survey meters at least annually and after servicing.

The survey instrument was not calibrated from June 28, 1984, to March 16, 1987, a period of more than 1 year. This was identified as a violation of License Condition 16.

The Nuclear Medicine Department has also been equipped with one dose calibrator, a Capentec Instruments Model CRC-7. The inspector reviewed the records of checks of instrument linearity, accuracy and geometrical variation, as well as daily constancy. The inspector noted that the linearity and accuracy checks had not been performed since 1984. However, an accuracy test was performed on July 10, 1989. The license application

dated July 27, 1984, references Appendix D, Section 2, of Regulatory Guide 10.8 (Revision 1) which commits the licensee to perform the linearity checks at installation and quarterly, and the accuracy checks at installation and annually. These tests are also required after repairs. The dose calibrator was returned from repair on August 16, 1988, and the required tests were not performed.

The failure to perform these tests was identified as a violation of License Condition 16.

Two violations were identified.

7. Receipt and Transfer of Material

All incoming radioactive material has been delivered to Security, and Security has authorized the courier to place it in the hot lab. Surveys of the incoming packages have been performed by the technologist. The generators have been delivered to the licensee on Saturday and surveyed and opened on Monday. The licensee's application dated July 27, 1984, references Appendix F of Regulatory Guide 10.8 (Revision 1) which commits the licensee to the procedures requiring packages to be surveyed within 18 hours of receipt, if the package is delivered during off-hours; and within 3 hours if it is delivered during normal hours. The generators that were delivered on Saturday and not surveyed and opened until Monday exceeded the 18 hour interval prescribed by Appendix F.

Appendix F also commits the licensee to record the results of each checked package using "Radioactive Shipment Receipt Record," or a form containing the same information. These results have not been recorded since October 1984.

The above failures were identified as a violation of License Condition 16.

One violation was identified.

8. Personnel Protection - External

Records of personnel exposure were reviewed, and no exposures (whole body or extremity) in excess of the licensee's Investigation Level I of Appendix O of the application dated July 27, 1984, were noted. Radiation levels in the Nuclear Medicine Department were measured by the inspector using a Xetex 305B, S/N 011756. In the hot lab it was 0.4 mR/hr around the generator, and the general area around the hot lab was 0.2 mR/hr. All other areas in the vicinity of Nuclear Medicine was 0.1 mR/hr.

No violations were identified.

9. Waste Disposal

All radiological waste, except spent generators, has been held for decay and surveyed before release to the ordinary trash. 10 CFR 35.92(b)

requires that records of disposal of byproduct material held for decay-in-storage be retained for 3 years and include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal. A review of the records of disposal of byproduct material held for decay-in-storage revealed that the records did not include any of the above information. The failure to record the results was identified as a violation of 10 CFR 35.92(b).

One violation was identified.

10. Transportation

The spent molybdenum-99/technetium-99m generators have been returned to the manufacturer as per manufacturer's instructions.

No violations were identified.

11. Misadministrations

One misadministration, which occurred on February 27, 1989, had been reported to the NRC by the licensee. Another misadministration, which occurred between November 13, 1985 and March 19, 1986, was not reported to NRC. This information was obtained while reviewing the RSC minutes. No further information could be obtained from the licensee. This is a violation of 10 CFR 35.33(c) which requires that in the event of a qualifying diagnostic misadministration, the licensee must notify the NRC in writing within 15 days.

One apparent violation was identified.

12. Exit Interview

The inspector reviewed the findings with the individuals indicated in Section 1. During the meeting, the inspector indicated that the number of violations and the length of time they had continued undetected by management indicated a serious lack of management oversight and control of the licensed program. The licensee stated that they hired a consultant as of July 1, 1989, and have hired a full-time person to manage their radiology department who will also serve as RSO. They also stated that they will immediately submit a request for license amendment to change the designated RSO.