APPENDIX A

U. S. NUCLEAR REGULATORY COMMISSION

REGION IV

NRC Inspection Report: 30-11841/85-01 License: 25-16906-01

Docket: 30-11841

Licensee: Frances Mahon Deaconess Hospital
621 Third Street South
Glasgow, Montana 59230

Facility: Frances Mahon Deaconess Hospital

Inspection At: Glasgow, Montana

Inspection Conducted: April 17, 1985

Inspector: C. A. Hooker 5/28/85
C. A. Hooker, Radiation Specialist Date

Approved: R. J. Everett 6/24/85
R. J. Everett, Acting Chief, Nuclear Materials Safety and Safeguards Branch Date

Inspection Summary

Inspection Conducted April 17, 1985 (Report: 30-11841/85-01)

Areas Inspected: A routine, unannounced inspection of the licensed nuclear medicine activities and associated radiation safety program including organization, management, and training; facilities, equipment, and materials; radiation exposure control; and independent measurements and waste disposal. The inspection involved 8 inspector-hours onsite by one NRC inspector.

Results: Within the four areas inspected, three violations were identified in two areas as follows:

1. Failure to have an authorized user present to supervise the use of licensed materials (paragraph 3).

2. Failure to use licensed materials in accordance with statements in the application as follows (paragraphs 3 and 4):

a. failure to conduct Radiation Safety Committee meetings quarterly; (This is a repeated violation from the previous inspection.)

b. failure to calibrate survey meters and maintain calibration records; and

c. failure to perform necessary calibrations and tests on the dose calibrator.

3. Failure to conduct leakage or contamination tests on a sealed source (paragraph 4).

(This is a repeated violation from the previous inspection.)

DETAILS

1. Persons Contacted

*Kyle Hopstad, Administrator
*Rocco Di Gioacchino, M.D., Radiologist
*David Van Auken, RT, Chief of Radiology
R. Britzman, Nuclear Medicine Technician

*Denotes those present at the exit briefing.

2. Licensee Action on Previous Inspection Findings

(Open) Violation (30-11841/81-01): Failure to conduct radiation safety committee meetings quarterly. The NRC inspector determined from records review that such meetings had been conducted quarterly during the period April 21, 1982 to April 25, 1984, in accordance with the licensee's commitment. However, the NRC inspector noted that the licensee had only conducted two meetings during the period April 25, 1984 to April 17, 1985. This item has recurred.

(Open) Violation (30-11841/81-01): Failure to perform leakage or contamination tests on a dose calibrator sealed source. The NRC inspector could not determine from records review and by statements from the licensee's representatives that tests, determined to be sealed source leak tests, had been conducted in accordance with the licensee's commitment during the period of May 21, 1982 to April 17, 1985. This item has recurred.

3. Organization, Management and Training

The NRC inspector reviewed the organizational structure and determined that the individual (radiologist) who was supervising the use of licensed material was not listed on the license as an authorized user. The NRC inspector was informed that the individual who had been the active authorized user had moved to the state of North Carolina, about June 1, 1984. The NRC inspector was also informed that the individual who was the authorized user had returned and supervised the use of licensed material during the period November 15-27, 1984, while the current radiologist was on vacation. However, during the period November 27, 1984, to the day of inspection, April 17, 1985, licensed material was being used and under the supervision of the radiologist who was not the approved authorized user of licensed material. The use of licensed material without an authorized user was identified as a violation of License Condition 12.

During the inspection, the NRC inspector noted from records review that the Radiation Safety Committee had conducted quarterly meetings as required during the period April 21, 1982 to April 25, 1984 (date of last meeting). However, it was also noted that the next and last meeting was conducted on November 23, 1984. The failure to conduct such meetings quarterly was identified as a violation of License Condition 16. This was

also noted to be a repeated violation from the previous inspection on October 14, 1981.

The NRC inspector interviewed two individuals who were performing the duties of nuclear medicine technicians in regard to their training and qualifications. These individuals had started working in the nuclear medicine department during the month of August 1983. The NRC inspector noted from records review that training for these individuals had been provided as required for the use of licensed material in the performance of conducting nuclear medicine scans. However, both of these individuals were not familiar with the frequency of the required tests and calibration of the dose calibrator nor had experience in performing all of the required tests (accuracy and linearity). Since there are no NRC requirements for these individuals to be qualified to perform such tests, this was not identified as a violation. However, concerns were expressed to the licensee on this matter.

4. Facilities, Equipment and Materials

The NRC inspector toured the facility and observed that the nuclear medicine laboratory (isotope preparation area) was as described in the license application. The NRC inspector also observed that the lab was properly posted as required by 10 CFR Part 20.203. The NRC inspector also observed that licensed material was properly stored and secured from unauthorized removal.

The NRC inspector noted from records review that the licensee received a 0.25 curie Mo-99/Tc-99m generator weekly and other authorized materials as needed. The NRC inspector also noted that the licensee only performs about ten routine nuclear medicine scans per month and maintained records of such scans. The NRC inspector also noted from records review and was informed that Mo-99 breakthrough tests are performed each time the Mo-99/Tc-99m generators are eluted and written procedures maintained for such tests.

The NRC inspector noted from records review and was informed by the licensee that the dose calibrator was only being tested at 6-month intervals instead of daily, or when used, for instrument constancy. In addition, the licensee had not performed any annual accuracy or quarterly linearity tests since being issued a new license dated February 25, 1982. The licensee committed to performing these tests in accordance to the recommendations of Regulatory Guide 10.8 in the license application received October 22, 1981. Failure to perform the proper calibrations and tests of the dose calibrator was also identified as a violation of License Condition 16.

The NRC inspector noted from records review that tests considered by the licensee to be sealed source leak tests, for dose calibrator sources, were actually dose calibrator constancy tests that were done at 6-month intervals. When explained by the NRC inspector to what constituted sealed source tests, the licensee representatives stated that such tests had not

been performed. The NRC inspector also noted from records review that only one source containing a nominal 200 millicuries of barium-133 was required to be leak tested. Failure to conduct such tests was identified as a violation of 10 CFR Part 35.14(e)(1)(i). This was noted to be a repeated violation from the previous inspection.

The NRC inspector noted from records review that incoming packages of radioactive materials were surveyed and the results of the survey were properly recorded. The NRC inspector also noted from records review and was informed that the licensee had not fully implemented the radiation and contamination survey program as outlined in the license application until January 1985. Since the licensee identified this problem and made the necessary corrections, this item was not cited.

The NRC inspector noted that the licensee maintained two survey meters of which one meter had been returned for repair and calibration, after having found to be inoperable when returned from purportedly being calibrated in February 1985. The NRC inspector also noted that the licensee did not maintain any records of meter calibrations and was informed by the nuclear medicine technicians that since their employment of August 1983, no calibrations had been performed with the exception of the one meter in February 1985. Failure to calibrate survey meters annually and maintain records of calibration was also identified as a violation of License Condition 16.

5. Radiation Exposure Control

The NRC inspector reviewed the vendor monthly film badge reports from September 1981 through February 1985. The NRC inspector noted that film badge and TLD finger ring results indicated minimal exposure with a maximum of 250 millirem whole body exposures for the calendar year of 1983.

6. Independent Measurements and Waste Disposal

The NRC inspector obtained radiation measurements of the walls and areas adjacent to where licensed material was being used and found all readings to be $\leq$ 0.1 mR/h. The NRC inspector also observed that the general working area within the nuclear medicine laboratory averaged 0.2 mR/h.

The NRC inspector was informed and noted from records review that spent Mo-99/Tc-99m generators were held for 60 days decay then returned to the manufacturer for ultimate disposal. The NRC inspector also noted from records review that the licensee met the transportation requirements for returning the spent generators. The NRC inspector also noted from records review that general laboratory radioactive waste was held for decay and properly surveyed prior to disposed to normal trash.

7. Exit Meeting

On April 17, 1985, the NRC inspector met with the licensee representatives referenced in paragraph 1. The NRC inspector discussed the possibility of escalated enforcement action and reviewed the Commission's enforcement options. In particular, the use of licensed material without having an authorized user at the facility. The licensee committed to discontinue the use of licensed material based on a conference call between the licensee and the Region IV office during the inspection. This commitment was obtained in writing from the licensee at this meeting and a copy was obtained by the NRC inspector.