APPENDIX B

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

NRC Inspection Report: 30-20277/90-01 License: 49-23121-01

Docket: 30-20277

Licensee: Community Hospital
2000 Campbell Drive
Torrington, Wyoming 82240

Inspection At: Community Hospital
Torrington, Wyoming

Inspection Conducted: October 10-24, 1990

Inspectors: Anthony D. Gaines 11/13/90
Anthony D. Gaines, Radiation Specialist Date
Nuclear Materials and Safeguards Inspection
Section

Gilbert Guerra 11/13/90
Gilbert Guerra, Radiation Specialist Trainee Date
Nuclear Materials and Safeguards Inspection
Section

Approved: Charles L. Cain 11/14/90
Charles L. Cain, Chief, Nuclear Materials and Date
Safeguards Inspection Section

Inspection Summary

Inspection Conducted October 11-24, 1990 (Report 30-20277/90-01)

Areas Inspected: This was a routine, unannounced radiation safety inspection of a byproduct material program authorizing the medical use of radiopharmaceuticals for clinical diagnostic procedures. The inspection included the review of organization and management, dose calibrator use, survey instrument use, and radiation surveys.

Results: This inspection identified various violations of NRC requirements. Collectively, the violations identified are indicative of a lack of management oversight of the radiation safety program.

Within this inspection, the following violations were identified:

Organization and Management

- Failure of the radiation safety committee to meet at least quarterly. (Section 4)

Dose Calibrator Use

- Failure to check frequently used isotope settings during dose calibrator constancy checks. (Section 5)
- Failure to test the linearity of the dose calibrator quarterly. (Section 5)
- Failure to properly measure the molybdenum-99 concentration in generator eluates. (Section 5)

Survey Instrument Use

- Failure to calibrate the lowest scale on the survey meter. (Section 6)
- Failure to possess a survey instrument that measures dose rates from 1 millirem per hour to 1000 millirem per hour. (Section 6)

Radiation Surveys

- Failure to ascertain that wipe samples surveys were able to detect contamination levels as low as 2000 disintegrations per minute. (Section 7)

DETAILS

1. Individuals Contacted

*Douglas McMillan, Administrator
*William T. Ward, M.D., Radiation Safety Officer and Authorized User
*John Goddard, Consultant
Kathy Schwartzkopf, X-Ray Technologist

*Indicates those present during exit interview.

2. Followup on Previous Inspection Findings (June 15, 1987)

(Open) Violation of 10 CFR 35.22(a)(2) (30-20277/87-01): Failure of the radiation safety committee (RSC) to meet quarterly. The inspectors determined during the current inspection that the RSC did not meet quarterly. This item is considered open.

(Closed) Violation of 10 CFR 35.22(a)(4) (30-20277/87-01): Failure of the licensee to include in RSC meeting minutes an ALARA review. The inspectors determined by reviewing the RSC meeting minutes that ALARA reviews were included in the minutes. This item is considered closed.

3. Program Overview

The licensee is authorized to use medical products for diagnostic clinical procedures. The only radioisotope used by the licensee for diagnostic procedures has been technetium-99m. The technetium has been obtained from a molybdenum-99/technetium-99m generator. The licensee has received a generator approximately every 2 weeks.

The licensee has experienced some organizational changes since the last inspection on June 15, 1987. The nuclear medicine technologist (NMT) that was employed during the last inspection left February 22, 1988. The licensee could not find a replacement for the technologist until August 24, 1989. Because of this, the licensee had closed the nuclear medicine department from February 22, 1988, to August 24, 1989. Since reopening the nuclear medicine department, the licensee performed on the average only 5 - 6 diagnostic procedures a month. The license was renewed in June 1990.

4. Organization and Management

The organizational structure was found to be as required, and key personnel have been identified in Section 1 of this report. The radiation safety officer (RSO) and the consultant had been employed by the hospital in their current capacities during previous inspections. The administrator and the NMT were employed after the June 15, 1987, inspection.

The RSO has been the authorized user for the program and also had performed radiology services for other hospitals in the area. Many of the RSO's duties have been, therefore, performed by a consultant.

Quarterly and annual reviews required by 10 CFR 35.22 were performed. The findings of the reviews have been discussed briefly in the RSC meetings, as indicated by RSC minutes.

The RSC, according to 10 CFR 35.22(a)(2), is required to meet at least quarterly. The inspectors, by reviewing records and through discussions during the telephonic exit meeting conducted October 17, 1990, observed that the RSC did not meet during the fourth quarter of 1989. At the exit meeting the consultant stated that the meeting was not held during the fourth quarter of 1989 due to the fact that they believed the meeting held in August 1989, just after reopening the nuclear medicine department, would suffice. The failure of the RSC to meet at least quarterly was identified as a repeat violation of 10 CFR 35.22(a)(2).

One violation was identified.

5. Dose Calibrator Use

The licensee has maintained a Picker dose calibrator, Serial Number 217056-R. The dose calibrator has been used to assay generator elutions, which have ranged from 60 to 540 millicuries, and patient doses that generally have ranged from 5 to 20 millicuries.

It was noted by the inspectors that when the dose calibrator constancy checks had been performed, the technetium-99m setting was not checked. The constancy checks were only performed on the cesium-137 and the cobalt-57 settings. The failure to check the dose calibrator for constancy on a frequently used setting was identified as a violation of 10 CFR 35.50(b)(1).

The inspectors could not be provided a dose calibrator linearity record for the fourth quarter of 1989. The consultant stated during the telephonic exit meeting that the dose calibrator had not been tested for linearity during the fourth quarter of 1989. He again stated that this was due to the fact that they performed a linearity test in August 1989 after resuming licensed activities and thought that that would suffice. Also, it was noted by the inspectors that the record of the linearity test performed in September 1990 was not signed by the RSO. The failure to test the dose calibrator quarterly for linearity and to have the RSO sign a linearity test were identified as violations of 10 CFR 35.50(b)(3) and 10 CFR 35.50(e)(3), respectively.

10 CFR 35.204(b) requires that a licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical measure the molybdenum-99 concentration in each eluate or extract. The licensee used the above type of generator and prepared technetium-99m radiopharmaceuticals. A review of molybdenum-99

breakthrough records for August 1989 to October 1990, by the inspectors, indicated that the molybdenum-99 concentrations in the eluates were routinely greater than .15 microcuries of molybdenum-99 per millicurie of technetium-99m. This level is greater than what is allowed to be administered to humans. After discussing this with the consultant at the exit meeting, it was apparent that the NMT used an improper procedure to measure the molybdenum-99 activity, therefore giving inaccurate results for the molybdenum-99 concentrations. The failure to properly measure the molybdenum-99 activity, which in turn gave inaccurate results for the molybdenum-99 concentrations in the eluates was identified as a violation of 10 CFR 35.204(b).

Three violations were identified.

6. Survey Instrument Use

The inspectors observed that the licensee only had one survey instrument, a Victoreen Model CDV-700. This survey instrument was last calibrated in September 1990. From the record of this calibration it was noted that on the lowest scale the calibration factors at two different points were 1.57 and 1.38. This indicated that the lowest scale was not calibrated within plus or minus 20 percent. At the exit meeting the consultant stated that the lowest scale could not be calibrated to within plus or minus 20 percent. The failure to calibrate the lowest scale by no more than 20 percent was identified as a violation of 10 CFR 35.51(b).

The Victoreen Model CDV-700 survey instrument that the licensee possessed had a range of 0 to 50 millirem per hour. Therefore, this survey meter was not capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour. This was identified as a violation of 10 CFR 35.220.

Two violations were identified.

7. Radiation Surveys

The licensee routinely performed area wipe surveys and obtained results of these surveys by reading the wipes in the dose calibrator. The dose calibrator was not evaluated by the licensee to show that it was able to detect contamination on the wipe sample of 2000 disintegrations per minute. This device would not reasonably be expected to detect this level of contamination. Therefore, this was identified as a violation of 10 CFR 35.70(f).

One violation was identified.

8. Exit Interview

The inspectors and the Chief, Nuclear Materials and Safeguards Inspection Section, held a telephonic exit interview with the staff members noted in Section 1 on October 17, 1990. The specific findings as noted in this report were reviewed. The discussion also focused on the need for effective management control and the need for prompt and effective corrective actions for the problems identified.