APPENDIX B

U. S. NUCLEAR REGULATORY COMMISSION
REGION IV

NRC Inspection Report: 30-28679/85-01

Docket: 30-28679 Category: G

Licensee: Community Hospital
West Second Street & Lincoln
Elk City, Oklahoma 73644

Facility Name: Community Hospital

Inspection At: Elk City, Oklahoma

Inspection Conducted: August 27-28, 1985

Inspector: _____ 10/10/85
R. Wise, Radiation Specialist, Nuclear Materials Safety Section Date

Approved: _____ 10/10/85
R. J. Everett, Chief, Nuclear Materials Safety Section Date

Inspection Summary

Inspection Conducted August 27-28, 1985 (Report: 30-28679/85-01)

Areas Inspected: An unannounced inspection for the purpose of reviewing activities authorized by NRC Byproduct Material License 35-23180-01 and to investigate allegations of misadministrations of radiopharmaceuticals, unqualified nuclear medicine technicians, conducting nuclear medicine in the absence of an authorized user, and that physicians named on the license had not applied or given their consent for the use of their name in the application.

The inspection involved 6 inspector-hours onsite by one NRC inspector.

Results: Within the areas inspected, one violation was identified. The allegations were not substantiated.

DETAILS

1. Persons Contacted

*Talton L. Francis, Administrator
*Norman E. Walters, Assistant Administrator
*Charles E. Elliott, M.D., Radiation Safety Officer
*Leonard J. Weaver, Nuclear Medicine Technician
Kay Cross, Laboratory Supervisor

*Denotes attendance at exit meeting.

2. Background

Community Hospital was issued a NRC Byproduct Material License on July 8, 1985, which authorized the use of byproduct material listed in Groups I, II, and III of Schedule A, Section 35.100 of 10 CFR 35. The licersee had not previously been inspected by the NRC.

The NRC Region IV Office was notified by telephone on August 7 and August 8, 1985, of concerns regarding the nuclear medicine practices at Community Hospital. These allegations included: misadministration of radiopharmaceuticals, unqualified nuclear medicine technicians, conducting nuclear medicine in the absence of an authorized user, and that physicians named in the license had not given their consent for the use of their names in the license application.

3. Management, Organization and Training

The NRC inspector reviewed the organizational structure existing at the time of the inspection and determined that the organizational structure was as outlined in the licensee's license application, with the following exceptions. The authorized users named in the license were no longer affiliated with the facility; however, another physician, currently named as an authorized user on another NRC license had been hired. A request for an amendment to the material license had been submitted on August 17, 1985, changing the name of the authorized user, designating him as the radiation safety officer, and adding Groups IV and V to the list of authorized materials. See Paragraph 5.c.

One nuclear medicine technician was on staff at the time of the inspection and the NRC inspector was informed that a registered nuclear medicine technologist would be on staff effective September 3, 1985. The licensee employs an outside consultant to review NRC license and regulatory compliance. The consultant routinely visits this facility to conduct audits, perform instrumentation calibrations, provide training of staff as may be required, and to serve as a member of the Radiation Safety Committee.

The NRC inspector interviewed the nuclear medicine technician in regard to his training and qualifications. The NRC inspector was informed that the technician had spent 3 days in another hospital's nuclear medicine department in training and 5 days of additional training with the radiopharmaceutical supplier and scanning equipment supplier. See Paragraph 5.b.

No violations or deviations were identified.

4. Facilities, Equipment, and Materials

The NRC inspector reviewed the nuclear medicine laboratory (isotope preparation area), injection and scanning area, and waste storage. The facility was as described in the license application.

The NRC inspector observed from records review that the licensee started using Mo-99/Tc-99m generators on July 13, 1985. Also noted in records review was that patient doses administered on July 16, 1985, were assayed on the dose calibrator which was not completely calibrated. Failure to conduct quarterly linearity tests, accuracy checks, and geometric variation tests and failure to maintain records which includes graphs of such tests prior to assaying patient doses was identified as examples of a violation of License Condition 16.

5. Allegation Review

a. The allegation that misadministrations of radiopharmaceuticals had occurred was reviewed.

Two misadministrations of radiopharmaceuticals had occurred on July 24, 1985. The licensee had filed a written report, dated July 31, 1985, which was received by the NRC Region IV office on August 5, 1985. The report contained all of the information required for compliance with 10 CFR 35.43.

No further action is required of the licensee in this area.

b. The allegation that the nuclear medicine technician was unqualified was reviewed.

The nuclear medicine technician on staff at the time of the inspection had received training at another medical facility in nuclear medicine. Additional training was provided by the radiopharmaceutical supplier and the nuclear medicine equipment vendor. The total time spent in training was approximately eight days. The NRC has not established any qualification requirements for nuclear medicine technicians.

No further action is required in this area.

c. The allegation that nuclear medicine was being conducted without an authorized use present at the facility was reviewed.

The users named in the license were no longer affiliated with the facility effective August 2, 1985, however; a physician named on another NRC license was on staff effective August 1, 1985. License Condition 14, states, in part, that a visiting physician is authorized to use licensed material under the terms of the license for a period not to exceed sixty days in any calendar year. An amendment requesting the deletion of the previous users and naming this physician as the authorized user was submitted on August 17, 1985.

No further action is required in this area.

d. The allegation that physicians named on the license had not applied nor given their consent for the use of their name in the application was reviewed.

The physicians named in the license as authorized users were working under contract to the hospital as radiologists with responsibilities in nuclear medicine. That contract for these physicians was terminated on August 2, 1985.

No further action is required in this area.

No violations or deviations were identified. The allegations were not substantiated.

6. Radiation Exposure Control

The NRC inspector reviewed the vendor film badge reports for July 1985. The NRC inspector noted that film badge and TLD finger ring results indicated minimal exposures for that period.

No violations or deviations were noted.

7. Independent Measurements and Waste Disposal

The NRC inspector obtained radiation measurements along the walls of areas adjacent to those rooms where licensed material was being used or stored and found all readings to be ≤0.3 mR/hr. The NRC inspector also observed that the general working area within the nuclear medicine laboratory was ≤0.5 mR/hr.

During the inspection, the NRC inspector was informed that spent Mo-99/Tc-99m generators had been returned to the supplier. The licensee uses a vendor-supplied shipping carton, shipping documents and proper labels for shipments. All other wastes generated are being stored for decay and eventual disposal as normal trash.

8. Exit Meeting

The NRC inspector met with licensee representatives listed in paragraph 1 on August 28, 1985, to summarize the purpose and findings of the NRC inspection. The licensee acknowledged his understanding of the inspection findings.