APPENDIX B

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

NRC Inspection Report: 030-02927/89-01 License: 35-13435-01

Docket: 030-02927

Licensee: Hillcrest Health Center
2129 South 59th Street
Oklahoma City, Oklahoma 73119

Inspection At: Oklahoma City, Oklahoma

Inspectors: Selvan Rajendran 1/31/90
Selvan Rajendran, Radiation Specialist Date
Nuclear Materials Inspection Section

for Selvan Rajendran 1/31/90
Linda L. Kasner, Health Physicist, Nuclear Date
Materials Inspection Section

Approved: Charles L. Cain 1/31/90
Charles L. Cain, Chief, Nuclear Materials Date
Inspection Section

Inspection Summary

Inspection Conducted October 30, 1989, and January 5, 1990
(Report 030-02927/89-01)

Areas Inspected: Routine, unannounced safety inspection of institutional diagnostic nuclear medicine program including licensee action on previous violations; organization, management, and training; facilities and equipment; dose calibrator use; external dosimetry; and waste disposal.

Results: This inspection identified six violations involving program management, facilities, equipment, and radiation surveys. Two of the violations, involving the failure to secure areas where licensed materials were stored and failure to adequately test and evaluate dose calibrators, were repeat violations from the previous inspection conducted in 1986.

The inspection also revealed a significant dependence by the Radiation Safety Officer (RSO) and by other members of management upon the licensee's consulting

medical physicists to perform specific tasks, audits, and evaluations related to the radiation safety program. This dependence, combined with a lack of familiarity with some NRC regulations and the failure of both the Radiation Safety Committee (RSC) and RSO to become actively involved in program audits, contributed to their failure to recognize that some of their procedures were in conflict with written commitments made in the license application.

In the area of program management, one violation was identified in regard to failure to conduct RSC meetings quarterly (Section 3).

In the area of facilities and equipment, three violations were identified including failure to secure licensed materials against unauthorized removal, a repeat violation (Section 4); use of facilities not authorized by the license (Section 4); and failure to post a radioactive materials area (Section 4).

In the area of surveys and evaluations, two violations were identified. One involved the failure to properly perform dose calibrator constancy, linearity, and accuracy tests (Section 5). This also was a repeat violation. The second involved the failure to adequately evaluate and document radiation surveys (Section 4).

DETAILS

1. Persons Contacted

*Dr. T. H. Molskness
*Wanda Lewellan, Administrator
*Lois Canfield, R.T., Director of Radiology
*Kathy Tash, Technologist

*Denotes those present during exit meeting.

2. Followup on Previous Inspection Findings

(Open) (30-02927/8601) Violation of 10 CFR 20.207: Failure to secure licensed materials in an unrestricted area from unauthorized removal. The inspectors determined that there were no locks on the door to the nuclear medicine laboratory which could prevent an unauthorized removal of byproduct material.

(Open) (30-02927/8601) Violation of License Condition 14: Failure to perform dose calibrator constancy checks each day, linearity tests every 3 months, and an annual accuracy test. The inspectors determined by record review that these tests had not been performed.

(Closed) (30-02927/8601) Violation of License Condition 15: Failure to conduct weekly wipe tests. The inspectors determined by review of records that weekly wipe tests had been performed.

(Closed) (030-02927/8601) Violation of License Condition 14: Failure of the Radiation Safety Committee (RSC) to perform an annual review of the radiation safety program. The inspectors determined by review of RSC minutes that annual reviews had been performed as required.

(Closed) (030-02927/8601) Violation of 10 CFR 20.205: Failure to perform surveys of incoming packages. The inspectors determined by review of records that package surveys had been performed.

3. Organization, Management, and Training

The licensee is authorized to use radiopharmaceuticals for uptake, dilution, and excretion studies in accordance with 10 CFR 35.100, as well as for imaging and localization studies under 10 CFR 35.200. The licensee has had two physicians/authorized users and one nuclear medicine technician. One of the users has served in the capacity of Radiation Safety Officer (RSO). The licensee has not authorized any visiting physicians since the last inspection conducted on May 22, 1986.

The licensee has used only unit doses of Tc-99m and the capsule form of I-131 for thyroid uptake studies. There have been approximately

80 diagnostic procedures per month, and the licensee has contracted unit-dose service with a local radiopharmacy.

The inspectors determined that virtually all of the radiation safety program of the nuclear medicine department had been delegated by the RSO to the nuclear medicine technician. The consultant, who had been performing many of the dose calibrator checks and overseeing the radiation safety program, had been ill for over a year and had just passed away recently. Subsequently, the licensee has employed the services of two new consultants to assist in management of their radiation safety program.

The RSC consisted of the RSO, the nuclear medicine technician (NMT), the Director of Radiology, a representative of the nursing staff, and the consultant; therefore, RCS membership was found to be in compliance with 10 CFR 35.22. The RSC meetings were not held from July 25, 1986, through April 30, 1987; and from November 17, 1988, through May 17, 1989. This was identified as a violation of 10 CFR 35.22(a)(2) which requires that the RSC meet quarterly.

The inspectors reviewed the radiation safety training received by the NMT and ancillary personnel. The Director of Radiology stated that all new employees are given training as soon as possible after their date of hire. The annual training has been administered by their consultant, and the NMT has been working with the licensee for approximately 9 years.

The licensee had one misadministration during this inspection period that occurred on January 19, 1989. The Director of Radiology notified the NRC, in writing, on January 30, 1989. The licensee did not have any other events requiring notifications to NRC as required by 10 CFR 35.14, 10 CFR 20.402, 10 CFR 20.403, or 10 CFR 20.405.

One violation was identified.

4. Facilities and Equipment

On October 30, 1989, an inspector toured the licensee's nuclear medicine department and observed a briefcase containing radiopharmaceuticals being delivered by a representative of a commercial nuclear pharmacy. The licensed materials were left in the nuclear medicine laboratory which had no locks installed on its doors and was unattended after the materials were delivered. This failure to secure licensed materials while in storage in an unrestricted area was identified as a repeat violation of 10 CFR 20.207.

The licensee stated that this facility is a new laboratory and that locks have not yet been installed. The previous nuclear medicine laboratory had been converted to offices, and the current laboratory was an old x-ray room. The licensee has added a nuclear medicine laboratory that was not approved in the license. This was identified as a violation of 10 CFR 35.13(e) which requires that a licensee obtain a license amendment

before it adds to or changes the areas of use identified in the application or on the license.

The room where the byproduct material was stored and used was appropriately posted in accordance with 10 CFR 19.11, but was not posted with a sign or signs bearing the radiation caution symbols and the words: "Caution Radioactive Materials." Failure to have the room so posted was identified as a violation of 10 CFR 20.203(e).

The inspectors observed the technologist administer a dose to a patient. The technologist followed the guidelines outlined in Appendix G of Regulatory Guide 10.8, Revision 1, regarding wearing laboratory coats and disposable gloves; using syringe shields; assaying the patient dose prior to administration; wearing personnel monitoring devices (film badges); wearing thermoluminescent dosimeter (TLD) finger badges during preparation, assay, and inspection of radiopharmaceuticals; and disposing of radioactive waste only in specially designated and properly shielded receptacles.

The inspectors reviewed the licensee's available survey instrumentation. The licensee possessed a Picker Model CDV-700 with a maximum range of 50 mR/hr. The survey instrument had been calibrated annually by the consultant.

Surveys of incoming and outgoing packages had sometimes been performed by the nuclear pharmacy couriers. A review of these records of package surveys confirmed compliance with NRC requirements. A review of the records of recent package surveys conducted by the licensee's staff confirmed compliance with NRC requirements as well.

The records of various surveys of areas within the department required by 10 CFR 35.70, and described in the license application, were examined by the inspectors and determined to be inadequate. The licensee had conducted radiation surveys at the appropriate intervals using the Picker CDV-700 survey meter. The results of these surveys had been recorded indicating millirems per hour or counts per minute, but the records did not show a diagram of the areas surveyed. Additionally, the licensee had failed to determine the efficiency of the survey instrument and was uncertain if it met the required sensitivity to detect 200 dpm per 100 square centimeter sample as specified in their procedure. This was identified as a violation of License Condition 14 which references procedures described in the license application. The application specifies that procedures described in Appendix I of Regulatory Guide 10.8, Revision 1, will be used to conduct area surveys.

The only sealed calibration source the licensee possessed was an 88-microcurie Cs-137 source used for the dose calibrator constancy checks. This source is exempt from leak testing requirements.

Four violations were identified.

5. Dose Calibrator Use

The inspectors reviewed the testing and use of the licensee's dose calibrator with individuals who work in the nuclear medicine laboratory. The individuals stated that they assay each dose that they administer and that they receive their radiopharmaceuticals from a commercial nuclear pharmacy.

During the inspection conducted on October 30, 1989, the inspector reviewed the records of checks of linearity, accuracy, and geometrical variation as well as daily constancy checks of the dose calibrator. He noted that the log for the daily constancy checks did not provide the technologist with the information necessary to determine whether the instrument's response was within 5 percent of the expected response. The inspector asked the technologist how she could ascertain that the daily checks using the cesium-137 check source were acceptable. She was uncertain how to make this determination. Licensee representatives stated that this procedure would be modified to ensure that the expected activity of the cesium-137 source is decay-corrected to enable the technologist to determine whether the result of the daily measurement of this source is acceptable.

During September 1-18, 1989, when the regular technologist was on vacation, the daily constancy checks were not performed. The licensee's application dated August 28, 1986, references Appendix D, Section 2, of Regulatory Guide 10.8 (Revision 1), which commits the licensee to perform daily constancy checks of the dose calibrator and to determine whether the instrument is reading within 5 percent of the expected response.

On the first date of this inspection, the inspector noted that a linearity test was last performed on October 18, 1989, and the last accuracy test had been performed in May 1986. From May 4, 1987, through August 2, 1988, and from November 2, 1988, through May 16, 1989, no linearity tests were performed. The linearity tests that were performed did not verify if instrument performance was within 5 percent of the expected value. Appendix D requires that the licensee perform linearity tests quarterly, that the linearity be evaluated to be within 5 percent of the calculated activity, and that the accuracy test be performed annually.

Failure to perform the required tests for instrument constancy, linearity, and accuracy was identified as a repeat violation of License Condition 14 which references the license application.

The inspectors noted, on January 5, 1990, that the licensee had implemented methods to evaluate daily constancy and linearity checks and that the results of tests performed during the interval from October 1989 until the date of the inspection in January 1990 had met the acceptable standards.

One violation was identified.

6. External Dosimetry

The inspectors reviewed the licensee's records of whole body film badge reports and extremity TLD reports from 1986 to the present. No doses in excess of regulatory limits were noted. The maximum quarterly whole body and extremity doses received by nuclear medicine personnel were 150 mrem and 225 mrem, respectively. The average doses were 25 mrem and 40 mrem, respectively. The inspectors observed that the personnel working in the restricted areas wore the required dosimetry.

Radiation levels in the nuclear medicine department were measured by the inspectors using a Xetex 305B, S/N 011756. In the hot lab, readings were 0.3 mR/hr around the storage area where the waste and the doses are stored, and the general area around the hot lab was 0.2 mR/hr. All other areas in the vicinity of the nuclear medicine department were 0.1 mR/hr.

No violations were identified.

7. Waste Disposal

The licensee's waste disposal procedures, surveys, and records were reviewed and found to be adequate. Most radwaste has consisted of syringes, needles, gloves, and paper contaminated with technetium-99m. Waste products have been sent back to the vendor with the spent unit doses.

No violations were identified.

8. Exit Interview

The inspectors met with the licensee representatives denoted in Section 1 at the conclusion of the inspection. They summarized the scope and findings of the inspection. The inspectors expressed their concern about the violations identified and that two had recurred since the previous inspection. They further reviewed the responsibilities of both management and the RSO with regard to the radiation safety program.

The licensee's representatives stated that their former consultant had been extremely ill and had just passed away recently. They also confirmed that they had hired two consultants to help with the nuclear medicine program. These individuals are expected to perform quarterly audits of the radiation safety program.