UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

Report No: 52-17273-01/87-01

Licensee: Caguas Sono-Nuclear and Vascular Center
P. O. Box 6960
Caguas, PR 00626

Docket No: 030-12438 License No: 52-17273-01

Inspection Date: November 18, 1987

Inspector: Mark Elliott 12/8/87
Mark Elliott, Radiation Specialist Date Signed

Approved by: John Potter 12/8/87
J. P. Potter, Chief, Nuclear Materials Safety Section, Nuclear Materials Safety and Safeguards Branch, Division of Radiation Safety and Safeguards Date Signed

Scope: This routine unannounced inspection of activities conducted under License No. 52-17273-01 included the topics identified in the enclosed Report Details.

Results: Eleven violations were identified.

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REPORT DETAILS

1. Licensee Employees Contacted

Dr. Carmen Caballero, President and Radiation Safety Officer
Dr. James Scott-Cora, Nuclear Medicine
Grisel Alejandro, Certified Nuclear Medicine Technologist (CNMT)

2. Exit Interview

The inspection scope and findings were summarized with Dr. J. Scott-Cora and G. Alejandro. Dr. Caballero was not available at the time of the inspection. Also, a telephone call was made on November 25, 1987, from Mr. J. Potter of NRC to Dr. Scott-Cora, concerning the Confirmation of Action letter that was sent to you on December 2, 1987.

3. Licensing and Inspection History

NRC License No. 52-17273-01 was issued on February 14, 1977. An initial NRC inspection was conducted on August 2, 1978. During the initial inspection, one violation was identified: the failure to post Form NRC-3. A 591 violation was issued at the time of inspection and acknowledged by Dr. Caballero. A routine unannounced inspection was conducted on January 12, 1982. Two violations were identified: The failure to perform daily surveys of elution and preparation areas and the failure to maintain records of surveys conducted upon receipt of incoming radioactive material packages. A Notice of Violation was issued on February 2, 1982. A routine unannounced inspection was conducted on January 23, 1985. Three violations were identified: the failure to conduct contamination level surveys at two-week intervals, failure to perform wipe tests of source containers received by the licensee, and failure to perform leak tests of sealed sources. A Notice of Violation was issued on February 18, 1985.

4. Organization

The inspector reviewed the licensee's organization against the license conditions. The organization and assignment of responsibility was found to be as stated in the license application. Key personnel include:

Dr. Carmen Caballero, President and Radiation Safety Officer
Dr. James Scott-Cora, Nuclear Medicine
Dr. Iraida Romero, Nuclear Medicine (not currently listed on license, all work approved by an authorized user)
Grisel Alejandro, CNMT

No violations were identified on this program area.

5. Diagnostic and Therapeutic Uses of Radionuclides

The licensee is authorized to use radionuclides identified in 10 CFR 35.100, 35.200 (except aerosols and gases), 35.300, and 35.500. The Nuclear Medicine Department performs an average of forty procedures

per week. The licensee has a standing order to receive a 200-millicurie Tc-99m generator each week. Iodine 131 therapies are performed using 5-6 millicurie capsules. The inspector determined through discussion with licensee representatives and review of records that one ventilation study was performed on October 15, 1987, using Tc-99m DTPA aerosol. The licensee was not currently authorized to use this material. The inspector reviewed selected elution records. On three different occasions (April 23, May 1, and June 19, 1987), the licensee's records show that elutions were used containing amounts of Mo-99 in excess of the limits specified in 10 CFR 35 (no more than 0.15 µCi Mo-99/mCi Tc-99m).

Two violations were identified in this program area.

6. Radiation Protection Procedures

The licensee's radiation protection practices were reviewed. The inspector determined that no written procedures for the safe use of radioactive material were available. Such procedures are required by 10 CFR 35.21. Syringe shields are used by the licensee when injecting patients with radioactive materials. Radiation level surveys and wipe tests are performed in all areas where radioactive materials are used or stored and in unrestricted areas. Surveys of incoming packages of radioactive materials are made. Pursuant to the requirements of 10 CFR 35.21, no written procedures were available describing these surveys. The licensee possesses sealed sources of Co-57, Co-60, Cs-137, Ba-133, and I-125, which have been properly leak tested every six months. The inspector noted that these sealed sources had not been inventoried at the required quarterly frequency. The inspector also reviewed the Radiation Safety Officer's involvement in day-to-day activities of the Radiation Safety Program. 10 CFR 35.21(b)(3) requires the Radiation Safety Officer to brief management once each year on the byproduct material program. Contrary to this, no information concerning the Radiation Safety Program had been developed or transmitted to management.

Three violations were identified in this program area.

7. Facilities and Instrumentation

The inspector determined that the imaging area and hot lab were as described in the application of July 31, 1987. Caution signs were properly posted. NRC Form 3 was posted, but no copies of Parts 19 and 20 or the license were posted, nor was a notice describing their availability.

The licensee possesses a dose calibrator in which each dose is evaluated before injection. License conditions require that accuracy tests be performed at least annually. The licensee has not performed these tests since the last inspection in January 1985. The license conditions also require that linearity tests be performed at least quarterly. The licensee failed to perform these tests during the fourth quarter of 1985

and during the third and fourth quarter of 1986. License conditions specify that geometrical variation tests are to be performed upon installation or after any maintenance and/or repair. The licensee representative indicated that these geometrical variation tests had never been performed; also, there were no records to indicate otherwise. The dose calibrator is checked daily for constancy using Co-60, Co-57, Cs-137, and Ba-133 sealed sources. One Picker instrument (model 655-186) is available for performing surveys, and is calibrated annually by a consultant.

Four violations were identified in this program area.

8. Training of Personnel

Based on interviews with personnel and a review of records, it was determined that procedures require all personnel working in nuclear medicine to have received training. Periodic refresher training is given by a consultant on selected topics, and records are available.

No violations were identified in this program area.

9. ALARA Program

10 CFR 35.20(a) states that each licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses ALARA. The licensee did not have a written Radiation Protection Program that includes provisions for keeping doses ALARA as required by 10 CFR 35.20(a).

One violation was identified in this program area.

10. Personnel Monitoring

All occupationally exposed personnel wear whole body film badges and extremity TLDs are provided. Badges are exchanged on a monthly basis. The inspector reviewed exposure records between March 1985 and September 1987. The maximum quarterly whole body exposure for nuclear medicine personnel was 100 millirems and the maximum quarterly extremity exposure was 1920 millirems. The inspector reviewed the licensee's program for internal exposure control. 10 CFR 35.20(a) states that a licensee that administers radioactive aerosols shall do so in a room with a system that will keep airborne concentrations within the limits prescribed in 20.103 and 20.106. Also, 10 CFR 20.201(b) states that each licensee shall make surveys to show compliance with 20.103 and 20.106. Contrary to this, the licensee did not perform surveys before, during, or after the aerosol use on October 15, 1987, to show compliance with 20.103 and 20.106.

One violation was in this program area.

11. Waste Disposal

All radioactive waste is held in storage for decay prior to disposal. Records of all surveys and disposal were available and complete.

No violations were identified in this program area.

12. Misadministration, Incidents, Notifications and Reports

The licensee system for reporting events and making notification was evaluated. Based on a review of licensee records and statements made by licensee representatives, there is no indication that misadministrations, incidents, overexposures, thefts or losses of material have occurred.

No violations were identified in this program area.