NOTICE OF VIOLATION

Caguas Sono - Nuclear and Vascular Center
Caguas, Puerto Rico

Docket No. 030-12483
License No. 52-17273-01

During the Nuclear Regulatory Commission (NRC) inspection conducted on November 18, 1987, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1987), the violations are listed below:

A. License Condition 14 of the license amendments which were in effect prior to renewal in its entirety on August 26, 1987, states that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the application dated December 28, 1981.

1. Items I.b and II.a.1 of the written ALARA program contained in the application dated December 28, 1981, state that the Radiation Safety Officer shall perform an audit once each year of the Radiation Safety Program.

   Contrary to the above, the Radiation Safety Officer has not performed an annual audit of the Radiation Safety Program for the years of 1986 and 1985.

   This is a Severity Level IV violation (Supplement VI).

2. Item 10 of the application dated December 28, 1981, states that the licensee shall test each dose calibrator for linearity at least quarterly.

   Contrary to the above, the licensee failed to perform linearity tests during the 4th quarter of 1985 and during the 3rd and 4th quarters of 1986.

   This is a Severity Level IV violation (Supplement VI).

3. Item 10 of the application dated December 28, 1981 and 10 CFR 35.50(b)(2) state that the licensee shall test each dose calibrator for accuracy upon installation and at least annually thereafter.

   Contrary to the above, the licensee has not performed accuracy tests on the dose calibrator since the last inspection on January 23, 1985.

   This is a Severity Level IV violation (Supplement VI).

4. Item 10 of the application dated December 28, 1981, and 10 CFR 35.50(b)(4) state that the licensee shall perform a geometrical variation test on the dose calibrator upon installation and after any maintenance and/or repair.

   Contrary to the above, as of the time of the inspection, the licensee had never performed a geometrical variation test on the dose calibrator.

   This is a Severity Level IV violation (Supplement VI).

B. 10 CFR 35.21(b)(2) states that the Radiation Safety Officer shall establish, collect in one binder or file, and implement written policy and procedures for receiving and opening packages of byproduct material and for using byproduct material safely.

   Contrary to the above, at the time of the inspection, the licensee did not have procedures for receiving and opening packages of byproduct material nor for using byproduct material safely.

   This is a Severity Level IV violation (Supplement VI).

C. 10 CFR 35.204(a) states that a licensee may not administer to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.

   Contrary to the above, the licensee administered radiopharmaceuticals containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m, on May 1, 1987 (0.167 uCi Mo-99/mCi Tc-99m), June 19, 1987 (0.178 uCi Mo-99/mCi Tc-99m), and April 23, 1987 (0.166 uCi Mo-99/mCi Tc-99m).

   This is a Severity Level IV violation (Supplement VI).

D. 10 CFR 35.59(g) states that a licensee shall conduct a quarterly physical inventory of all sealed sources in its possession.

   Contrary to the above, the licensee failed to conduct a quarterly physical inventory of all sealed sources during the 3rd quarter of 1987.

   This is a Severity Level IV violation (Supplement VI).

E. 10 CFR 35.20(a) states that each licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses as low as reasonably achievable.

   Contrary to the above, at the time of the inspection the licensee did not have a written Radiation Protection Program that includes provisions for keeping doses as low as reasonably achievable.

   This is a Severity Level IV violation (Supplement VI).

F. License Conditions 6.b and 7.b state that the licensee is not authorized to possess or use technetium-99m in aerosol form.

Contrary to the above, the licensee did possess and use technetium-99m DTPA in aerosol form on October 15, 1987.

This is a Severity Level IV violation (Supplement VI).

G. 10 CFR 35.205(a) states that a licensee who administers radioactive aerosols shall do so in a room with a system that will keep airborne concentrations within the limits prescribed by 10 CFR 20.103 and 20.106.

10 CFR 20.201(b) states that each licensee shall make or cause to be made such surveys as may be necessary for the licensee to comply with the regulation in this part.

Contrary to the above, the licensee did not perform surveys to show compliance with 10 CFR 20.103 or 20.106 before, during, or after the administration of a radioactive aerosol in an open room on October 15, 1987.

This is a Severity Level IV violation (Supplement IV).

H. 10 CFR 19.11 requires a licensee to post current copies of certain documents near or in a licensed activity location. These documents include 10 CFR Parts 19 and 20, the license complete with amendments, referenced documents, and operating procedures. If posting is not practicable, the licensee may post a notice that describes the documents and where they may be examined. The licensee is also required to post Form NRC-3, "Notice to Employees," to permit individuals who frequent any portion of a "restricted area" to observe the form.

Contrary to the above, at the time of inspection, the licensee had not posted 10 CFR Parts 19 and 20, the license complete with amendments, referenced documents, operating procedures, or a notice of where these documents might be examined. In addition, the licensee had not posted Form NRC-3 in or near a restricted area.

This is a Severity Level V violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Caguas Sono - Nuclear and Vascular Center is hereby required to submit a written statement or explanation to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, Region II, within 30 days of the date of the letter transmitting this Notice. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) admission or denial of the violation, (2) the reason for the violation if admitted, (3) the corrective steps which have been taken and

the results achieved, (4) the corrective steps which will be taken to avoid further violations, and (5) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending the response time. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken.

FOR THE NUCLEAR REGULATORY COMMISSION

/s/ J. Philip Stohr

J. Philip Stohr, Director
Division of Radiation Safety
and Safeguards

Dated at Atlanta, Georgia
this 21st day of December 1987