NOTICE OF VIOLATION

Shared Medical Technology, Inc. License No. 48-17543-01

As a result of the inspection conducted on September 13-14, 1989, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, (1989) (Enforcement Policy) the following violations were identified:

1. 10 CFR 35.50(b)(3) requires that the dose calibrator linearity test be performed over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

   Contrary to the above, as of September 14, 1989, dose calibrator linearity tests were not performed over the range of its use between the highest dosage that will be administered to a patient, 30 millicuries, and 10 microcuries. Specifically, dose calibrator tests on dose calibrators Serial Nos. 25219 and 11424B performed since April 1987, and the tests performed since January 17, 1988, on the dose calibrator Serial No. 17774A did not cover the range to 10 microcuries.

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

2. 10 CFR 71.5(a) requires that licensees who transport licensed material outside the confines of their plants or deliver licensed material to a carrier for transport comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Part 170-189.

   a. 49 CFR 172.203(d)(iv) requires that each shipping paper describing a radioactive material contain the category of label applied to each package in the shipment.

      Contrary to the above, the licensee failed to list on shipping papers describing radioactive material the category of label applied to each package of radioactive material transported by the licensee during 1988 and to the day of the inspection, September 14, 1989.

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

   b. 49 CFR 172.403 requires that each package of radioactive material, unless excepted from labeling by §173.421 or §173.422, be labeled, as appropriate, with a RADIOACTIVE WHITE-I, a RADIOACTIVE YELLOW-II, or a RADIOACTIVE YELLOW-III label.

      Contrary to the above, during 1988, and to the day of the inspection, September 14, 1989, the licensee transported packages of radioactive materials to various hospitals in Minnesota and Wisconsin without affixing the appropriate RADIOACTIVE WHITE-I or RADIOACTIVE YELLOW-II labels to packages that were not excepted from labeling by §173.421 or §173.422.

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

c. 49 CFR 173.415(a) requires that each shipper of a Specification 7A package must maintain on file for at least one year after the latest shipment, and shall provide to DOT on request, a complete documentation of tests and an engineering evaluation or comparative data showing that the construction methods, packaging design, and materials of construction comply with that specification.

Contrary to the above, the licensee failed to maintain on a file to the day of the inspection, September 14, 1989, a complete documentation of tests and engineering evaluation or comparative data showing that the construction methods used in the licensee's shipping containers, packaging design, and materials of construction comply with 7A specifications.

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

d. 49 CFR 178.350-3 requires that packaging that meets Specification 7A be marked "USA DOT 7A TYPE A" on the outside of each packaging. In addition, 49 CFR 172.310(a)(2) requires each package to radioactive material which conforms to the requirements of Type A packaging must be plainly and durably marked on the outside of the package with the words, "Type A."

Contrary to the above, on the day of the inspection, September 14, 1989, the NRC inspector observed two containers prepared for transport as radioactive material Type A, and the containers were not marked "USA DOT 7A TYPE A" on the outside of the containers.

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

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each violation: (1) the corrective steps that have been taken and the results achieved; (2) the corrective steps that will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

September 29, 1989
Dated

I. L. Jamnicon for
D. J. Sreniawski, Chief
Nuclear Materials Safety
Section 2