NOTICE OF VIOLATION

Youngstown Associates
In Radiology, Inc.
Youngstown, Ohio

License No. 34-16621-01
Docket No. 030-11343

During an NRC inspection conducted on December 15, 1993 with continuing NRC review through December 23, 1993, 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, the violations are listed below:

1. 10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

   Pursuant to 35.32(a)(1), the quality management program must include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131.

   10 CFR 35.2 defines, in part, a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical.

   Pursuant to 10 CFR 35.32(a)(2), the quality management program must include written policies and procedures to meet the objective that, prior to each administration, the patient's identity is verified by more than one method.

   Contrary to the above, as of December 15, 1993, the licensee's quality management program did not include a written procedure to meet the objective that: (1) a written directive is prepared prior to administering sodium iodide-131 in quantities greater than 30 microcuries and that the written directive be signed and dated by the authorized user; and (2) patient identity is verified by more than one method. Specifically, the licensee's quality management program dated January 13, 1992 requires that written directives be prepared prior to administering 30 millicuries of sodium iodide-131 rather than 30 microcuries, and does not require patient identification by more than one method or that the authorized user sign and date the written directive.

   In addition, on March 13, 1992 and August 24, 1992, the licensee administered sodium iodide-131 in quantities greater than 30 microcuries, and failed to prepare written directives before dose administration. Furthermore, on March 2, March 30, and November 30, 1992, written directives prepared for sodium iodide-131 administrations in excess of 30 microcuries, did not include the date and the authorized user's signature.

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

2. 10 CFR 35.51(a) requires, in part, that for survey instruments used to show compliance with 10 CFR Part 35, the licensee calibrate two separated readings with a radiation source on all scales with readings up to 1000 millirem per hour.

   Contrary to the above, the calibrations of the licensee's Victoreen Model 290 survey instrument performed on June 30, 1992 and August 4, 1993 were not performed on all scales with readings up to 1000 millirem per hour, and the licensee used this instrument to show compliance with 10 CFR Part 35. Specifically, although capable of measuring radiation levels up to 1000 millirem per hour, the survey instrument calibration range did not extend beyond 80 millirem per hour.

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

3. 10 CFR 35.50(b)(4) requires, in part, that a licensee test its dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used.

   Contrary to the above, the licensee did not test its dose calibrator for geometry dependence at the time of installation at its new (West Boulevard) facility on approximately June 16, 1993.

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

4. 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.

   49 CFR 173.457(i) requires that, prior to each shipment of any package, the shipper insure by examination or appropriate test that the external radiation and contamination levels are within allowable limits.

   Contrary to the above, the licensee routinely shipped (returned) spent radiopharmaceutical doses to a radiopharmacy supplier as "limited quantity," without insuring that the radiation level at any point on the external surface of the package did not exceed 0.5 millirem per hour, as prescribed by 173.421.

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

5. 10 CFR 19.11(a) and (b) require, in part, that the licensee post current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments and operating procedures; or that the licensee post a notice describing these documents and where they may be examined.

Contrary to the above, on December 15, 1993, the licensee did not have any of the required documents posted.

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

Pursuant to the provisions of 10 CFR 2.201, Youngstown Associates In Radiology, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois, 60532-4351, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

FEB 24 1994

Dated

Roy J. Caniano, Chief
Nuclear Materials Safety Branch