NOTICE OF VIOLATION

Medical Consultants Imaging Co. Cleveland, Ohio License No. 34-26286-01 Docket No. 030-32080

During an NRC inspection conducted on February 24, 1994, 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:

 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for the review of supervised individual's use of byproduct materials are described in letter dated September 1, 1992 and letter received October 8, 1992, and were approved by License Condition No. 20, Amendment No. 2 dated June 25, 1993.

The letter dated September 1, 1992 states in Item 4 that authorized users will review supervised individual's use of byproduct materials and consist of a confirmatory review of the use of materials with regard to patient examination, radiopharmaceutical selection, dose administration, compliance with procedure control and record keeping. Item 3 of letter received October 8, 1992 states that the review of supervised individual's use of byproduct materials will be conducted at least monthly.

Contrary to the above, from inception of the requirement in June 1993 to the date of this inspection, the licensee through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, the licensee's only active authorized user (and RSO) failed to perform monthly reviews of supervised individuals' use of material with regard to patient examination, compliance with procedure control and record keeping.

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 CFK 173.421 excepts radioactive materials in certain limited quantities, defined therein, from the specification packaging, shipping paper and certification, marking, and labeling requirements of subpart H, 49 CFR Part 173.

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49 CFR 173.421-1(a) requires, in part, that a "limited quantity" of radioactive material, shipped as excepted from specification packaging, shipping paper and certification, marking, and labeling requirements, be certified as being acceptable for transportation by having a notice enclosed in or on the package, included with the packing list, or otherwise forwarded with the package. This notice must include the name of the consignor or consignee and the statement: "This package conforms to the conditions and limitations specified in 49 CFR 173.421 for excepted radioactive material, limited quantity, n.o.s., UN2910."

Contrary to the above, in 1993 to the date of this inspection, the licensee routinely transported technetium-99m contaminated solid wastes and cesium-137 dose calibrator check sources in its mobile nuclear medicine vans, as "limited quantities," excepted from specification packaging, shipping paper and certification, marking, and labeling requirements, and did not have a notice enclosed in or on the package, included with the packing list, or otherwise forwarded with the package, with the required statement concerning the consignor or conformance of the packages.

- b. 49 CFR 173.475 requires, in part, that prior to each shipment of any radioactive materials package, the shipper insure by examination or appropriate test that the external radiation and contamination levels are within allowable limits specified in 49 CFR Parts 171-177.
- Contrary to the above, in 1993 to the date of this inspection, the licensee routinely transported technetium-99m contaminated solid wastes and cesium-137 check sources in its mobile nuclear medicine vans as "limited quantity" shipments, without insuring that package radiation and contamination levels did not exceed limits prescribed by 173.421.

These are Severity Level IV violations (Supplement V).

Pursuant to the provisions of 10 CFR 2.201, Medical Consultants Imaging Co. 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

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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.

APR 1 1994

Dated

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B. J. Holt, Chief ' Nuclear Materials Inspection Section 1