

NOTICE OF VIOLATION

Nuclear Diagnosis, Inc.
Springfield, Missouri

License No. 24-17561-01
Docket No. 030-12966

During an NRC inspection conducted on March 4, 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:

1. 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 are described in the application dated June 21, 1994.

Item 10.4 of the June 21, 1994, application states that the licensee will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2.

- a. Item 1. of Appendix I, Reg. Guide 10.8, requires that laboratory coats or other protective clothing be worn at all times in areas where radioactive materials are used.

Contrary to the above, on March 4, 1994, a technologist did not wear a laboratory coat or other protective clothing while using radiopharmaceuticals in the licensee's hot lab.

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

- b. Item 4. of Appendix I, Reg. Guide 10.8, requires that syringe shields be used for routine preparation of multi-dose vials.

Contrary to the above, on March 4, 1994, a technologist did not use a syringe shield while preparing radiopharmaceutical multi-dose vials.

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

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.

49 CFR 172.403(a) requires that unless exempted from labeling by 49 CFR 173.421 through 173.425 of this subchapter (Subpart E- Labeling), each package of radioactive material must be labeled as provided in the section.

49 CFR 172.403(g) requires that the following applicable items of information must be entered in the blank spaces on the Radioactive label by legible printing (manual or mechanical), using a durable weather resistant means of marking:

- (1) Contents. The name of the radionuclides . . .
- (2) Activity.

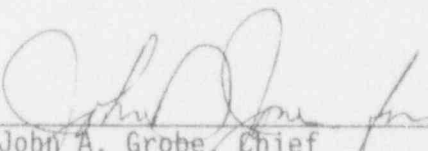
Contrary to the above, on March 4, 1994, the licensee shipped a package containing radioactive material with a label affixed to the package and failed to enter in the blank spaces on the Radioactive label (white I) the radioactive contents of the package and the activity of the radioactive contents of the package.

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

Pursuant to the provisions of 10 CFR 2.201, Nuclear Diagnosis, 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 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. Where good cause is shown, consideration will be given to extending the response time.

MAR 23 1994

Dated _____



John A. Grobe, Chief
Nuclear Materials Inspection
Section 2