UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

July 28, 1988

NRC INFORMATION NOTICE NO. 88-53: LICENSEE VIOLATIONS OF NRC REGULATIONS, WHICH LED TO MEDICAL DIAGNOSTIC MISADMINISTRATIONS

Addressees:

All manufacturers and distributors of radiopharmaceuticals for human use, nuclear pharmacies, and medical licensees.

Purpose:

This notice is to inform NRC licensees of enforcement action NRC took against a nuclear pharmacy which mislabeled vials of radiopharmaceuticals on six separate occasions, over a 16-month period. The mislabeling of vials with wrong chemical form resulted in diagnostic misadministrations at client hospitals. It is expected that licensees will review this notice, distribute it to appropriate personnel (including nuclear medicine physicians, responsible radiation safety officers, nuclear medicine staffs, and nuclear pharmacy staffs) and consider actions, as appropriate, to ensure that meticulous attention is paid to correctly labeling vials, vial shields, syringes, and syringe shields, and correctly assaying doses to prevent violations of the Commission requirements. This information notice does not constitute new NRC requirements, and no written response is necessary. It does however, convey a modification in the severity classification of violations of NRC requirements which have led to diagnostic misadministrations.

Description of Circumstances:

In a recent inspection of a nuclear pharmacy licensee, NRC found that the licensee incorrectly labeled vials containing radiopharmaceuticals on six separate occasions over a 16-month period. In turn, these mislabeled products were dispensed to patients at various hospitals and resulted in 14 diagnostic misadministrations. The hospitals reported these misadministrations to the NRC in accordance with 10 CFR Section 35.42 (Superseded Text) or 10 CFR Section 35.33(c), effective April 1, 1987.

In each case, the label placed on the vial of material provided the correct radionuclide and correct quantity (activity) of material, but the chemical form of the material was incorrect. Once such an error had been made, the

recipient hospital had no mechanism to verify the chemical form of the radiopharmaceutical. (The NRC license issued to the nuclear pharmacy required that certain checks be performed of the radioactive aspects of the radiopharmaceutical; i.e., the amount of radioactivity present. These checks were correctly performed.) Because different chemical forms are used to transport the radioactive material to different parts of the body, e.g., liver vs. brain vs. bone, etc., mislabeling can cause unnecessary radiation exposure to a part of the body other than that intended, as well as failure to produce the needed diagnostic information.

Nuclear pharmacies are required, as part of their license application, to submit labeling to the NRC. The labels must specify the radiopharmaceutical name (i.e., isotope and chemical form) in order to prevent errors that could lead to a misadministration, as indicated in "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses," Division 10, Task FC 410-4, August 1985 pp. 33-34. When the license is approved and issued by the NRC staff, the application is incorporated by reference as a license condition. The license in this case required the use of a label that identified the radiopharmaceutical by radionuclide and chemical form.

Hospitals are required to label syringes/syringe shields and vials/vial shields in accordance with 10 CFR Part 35.

After review of the violation and consultation with the Commission, the NRC issued a Notice of Violation classifying the mislabeling errors as a Severity Level III violation. Severity Level III violations can result in a civil penalty.

Discussion:

10 CFR Part 2, Appendix C, "General Statement of Policy and Procedure for NRC Enforcement Actions," (1988) (Enforcement Policy), Supplement VI provides that a violation involving the failure to report a diagnostic misadministration to the NRC constitutes an example of a Severity Level IV violation. The factors that cause diagnostic misadministrations often do not constitute violations of NRC requirements. As a result, there have been very few enforcement actions in the past in which errors causing diagnostic misadministrations are cited as violations. When such violations are cited, they generally have been categorized at Severity Level V, a level reserved for violations of minor safety significance.

The NRC has reconsidered the past practice of classifying violations involving diagnostic misadministrations and believes that, consistent with the example for classification at Severity Level IV of violations, involving a failure to report medical diagnostic misadministrations, a violation of the NRC's requirements which result in a medical diagnostic misadministration should also be classified at Severity Level IV. Additionally, a violation involving multiple errors of the same or similar root cause that results in several misadministrations over the inspection period (e.g., the inspection frequency for the license, i.e., two years for nuclear pharmacies and broad medical programs,

three years for specific medical licensees) or a recurrent violation from the previous inspection period that results in a misadministration, may be classified at a higher level to increase the licensee's sensitivity to this issue. Such sensitivity is especially important for labeling errors involving chemical forms, because these errors cannot be easily detected by the customer. Therefore, violations involving multiple errors or recurrent violations contributing to diagnostic misadministrations may constitute a significant failure to control licensed material and could be categorized at Severity Level III. Violations categorized at a Severity Level III may result in a civil penalty.

The NRC is proceeding to modify the existing Enforcement Policy to reflect the new categorization of violations in this area.

No specific action or written response is required by this information notice. If you have any questions about this matter, please contact the Regional Administrator of the appropriate NRC regional office or this office.

Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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Attachment: List of Recently Issued NRC Information Notices

LIST OF RECENTLY ISSUED
NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
88-52	Failure of Intrauterine Tandem of Fletcher Applicator Brachytherapy Devices During Patient Treatment	7/27/88	Medical licensees.
88-46, Supplement 1	Licensee Report of Defective Refurbished Circuit Breakers	7/26/88	All holders of OLs or CPs for nuclear power reactors.
88-51	Failures of Main Steam Isolation Valves	7/21/86	All holders of OLs or CPs for nuclear power reactors.
88-50	Effect of Circuit Breaker Capacitance on Availability of Emergency Power	7/18/88	All holders of OLs or CPs for nuclear power reactors.
88-49	Marking, Handling, Control, Storage and Destruction of Safeguards Information	7/18/88	All holders of OLs or CPs for nuclear power reactors and all other licensed activities involving a formula quantity of special nuclear material.
88-48	Licensee Report of Defective Refurbished Valves	7/12/88	All holders of OLs or CPs for nuclear power reactors.
88-47	Slower-Than-Expected Rod-Drop Times	7/14/88	All holders of OLs or CPs for PWRs.
88-46	Licensee Report of Defective Refurbished Circuit Breakers	7/8/88	All holders of OLs or CPs for nuclear power reactors.
88-45	Problems In Protective Relay and Circuit Breaker Coordination	7/7/88	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
CP = Construction Permit