

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT
WASHINGTON, D.C. 20555

October 3, 1986

IE INFORMATION NOTICE NO. 86-85: ENFORCEMENT ACTIONS AGAINST MEDICAL
LICENSEES FOR WILLFULL FAILURE TO
REPORT MISADMINISTRATIONS

Addressees:

All NRC medical licensees.

Purpose:

This notice is provided to alert all NRC medical licensees of enforcement actions taken by NRC against medical licensees who willfully failed to report misadministrations. It is suggested that addressees review this notice and disseminate it to their employees. However, suggestions contained in this information notice do not constitute NRC requirements; therefore, no specific action or written response is required.

Description of Circumstances:

NRC recently has taken escalated enforcement action against two hospitals as described below.

In the first case, several violations of NRC requirements were identified during an NRC inspection at a hospital. An Enforcement Conference was conducted with the licensee to discuss the violations. Subsequent to that conference and as a result of an investigation conducted by the NRC's Office of Investigations, NRC established that four diagnostic misadministrations had occurred before the NRC's inspection and were not reported to the NRC as required by 10 CFR 35.43. Two hospital employees stated to NRC investigators that the Radiation Safety Officer (RSO), who also was the Director of the Nuclear Medicine Department, instructed them to inform NRC inspectors that diagnostic misadministrations had not occurred. It also appeared that the RSO willfully concealed a film of a nuclear medicine misadministration scan and thus impeded NRC's inspection into whether misadministrations had occurred. As a result, on April 22, 1986, the NRC issued an Order to the hospital (1) to remove the RSO from that position and from all involvement in the performance or supervision of NRC-licensed nuclear medicine activities, and (2) to suspend all licensed activities at the hospital until the licensee demonstrates that a qualified individual has been appointed as the RSO and authorized by the NRC.

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In the second case, an allegor stated that the Chief Nuclear Medicine Technologist (CNMT) of a hospital did not report a misadministration to either the NRC or the patient's referring physician as required by 10 CFR 35.43. During an interview conducted by the NRC's Office of Investigations, the CNMT admitted performing a diagnostic misadministration and not being truthful with NRC inspectors. The CNMT explained that the hospital RSO, who is also the Medical Director of Radiology, instructed her via a hospital radiologist not to report the misadministration. During an interview with an NRC investigator, the RSO admitted that although he was aware of the NRC requirement, he did not report the misadministration because he did not think the incident was that serious.

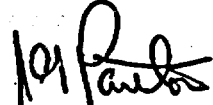
As a result, on June 17, 1986 the NRC issued an Order to show cause why the license should not be modified to prohibit these individuals from any further involvement in the performance or supervision of licensed activities. Consideration was given to removing the CNMT from NRC-licensed activities by an immediately effective Order. However, this was not considered necessary because the CNMT had already left the hospital. In addition, although the violations occurred because of the deliberate, irresponsible actions of the two individuals, the NRC was concerned that hospital management did not aggressively pursue an investigation of the alleged misadministration when informed of it during the NRC inspection, but rather awaited the initiation of the NRC investigation. Thus, the NRC issued a proposed Imposition of a Civil Penalty in the amount of five thousand dollars (\$5000).

Discussion:

NRC requires the submittal of all misadministrations pursuant to 10 CFR 35.43 since some misadministrations can have health effects on the patient. For example, IE Information Notice 85-61 describes four diagnostic misadministrations in which the patient received an unplanned significant dose of radiation. In one of those misadministrations, the patient received an estimated dose of 6500 to 9000 rads to the thyroid instead of the 0.7 rads that would have resulted from the planned diagnostic procedure.

Normally, failure to report a medical diagnostic misadministration would be characterized as a Severity Level IV violation. However, escalated enforcement actions were taken in these two cases because the failure to report the misadministration was willful and willful material false statements were made to NRC inspectors regarding the misadministrations. All licensee personnel should be aware of the importance of being truthful with NRC inspectors and of complying with NRC regulations. NRC has the authority to order the immediate removal of personnel (such as RSOs or technologists) involved in willful material false statements from NRC-licensed activities if the NRC determines that licensee personnel have misled NRC inspectors and/or there is no longer reasonable assurance that they can be relied on to comply with NRC requirements.

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



James G. Partlow, Director
Division of Inspection Programs
Office of Inspection and Enforcement

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Attachment: List of Recently Issued IE Information Notices

LIST OF RECENTLY ISSUED
IE INFORMATION NOTICES

Information Notice No.	Subject	Date of Issue	Issued to
86-84	Rupture Of A Nominal 40-Millicurie Iodine-125 Brachytherapy Seed Causing Significant Spread Of Radioactive Contamination	9/30/86	All NRC medical institution licensees
86-83	Underground Pathways Into Protected Areas, Vital Areas, Material Access Areas, And Controlled Access Areas	9/19/86	All power reactor facilities holding an OL or CP; fuel fabrication and processing facilities
86-82	Failures Of Scram Discharge Volume Vent And Drain Valves	9/16/86	All power reactor facilities holding an OL or CP
86-81	Broken Inner-External Closure Springs On Atwood & Morrill Main Steam Isolation Valves	9/15/86	All power reactor facilities holding an OL or CP
86-80	Unit Startup With Degraded High Pressure Safety Injection System	9/12/86	All power reactor facilities holding an OL or CP
86-79	Degradation Or Loss Of Charging Systems At PWR Nuclear Power Plants Using Swing-Pump Designs	9/2/86	All power reactor facilities holding an OL or CP
86-78	Scram Solenoid Pilot Valve (SSPV) Rebuild Kit Problems	9/2/86	All BWR facilities holding an OL or CP
86-77	Computer Program Error Report Handling	8/28/86	All power reactor facilities holding an OL or CP and nuclear fuel manufacturing facilities
86-76	Problems Noted In Control Room Emergency Ventilation Systems	8/28/86	All power reactor facilities holding an OL or CP

OL = Operating License
CP = Construction Permit

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