U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Information Notice No. 93-04: Investigation and Reporting of Misadministrations by the Radiation Safety Officer

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

January 7, 1993

Information Notice No. 93-04: INVESTIGATION AND REPORTING OF MISADMINISTRATIONS BY THE RADIATION SAFETY OFFICER

Addressees

All U.S. Nuclear Regulatory Commission medical licensees.

Purpose

The NRC is issuing this information notice to provide guidance to licensees on the investigation of events surrounding a misadministration. On January 27, 1992, the "Quality Management Program and Misadministrations" rule became effective. The current (1992) 10 CFR 35.33(a)(2) requires that a report of a misadministration must be submitted to NRC and must include, in part, why the event occurred. This superseded the previous requirement in 10 CFR 35.33(c) that the Radiation Safety Officer (RSO) should promptly investigate the cause of a diagnostic misadministration and make a record for NRC review. Furthermore, in 10 CFR 35.21(b)(1), the RSO is required, in part, to investigate overexposures and misadministrations, and implement corrective action, as necessary. Information contained in this notice does not constitute a new requirement, and no written response is required.

Description of Circumstances

The following case of a diagnostic misadministration reported to the NRC involved inaccurate information provided by the licensee and a failure of the RSO to adequately investigate the incident.

A diagnostic misadministration report (DMR), submitted by the licensee, stated that a nuclear medicine technologist, called in from vacation to administer a dose of I-131 sodium iodide for a thyroid uptake study, inadvertently administered 112 microcuries instead of the intended dose of 10 microcuries. The DMR indicated that the error occurred because the technologist incorrectly read the dose calibrator as 11.2 microcuries instead of 112 microcuries. This implies that the technologist assayed a single iodine capsule, which she subsequently administered to the patient. The DMR also stated that, instead of five capsules for a total of 100 microcuries, an order was placed for five capsules of 100 microcuries each. No explanation was provided for the order of five 20 microcurie capsules for a diagnostic procedure utilizing

10 microcuries. During the inspection, the technologist indicated that she had assayed five capsules at the same time and then mathematically determined the activity of a single capsule. Thus the measured activity expressed on the dose calibrator would have read 560 microcuries instead of 112 microcuries as reported in the licensee's report. This inaccuracy of the DMR obscured a

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violation of 10 CFR 35.53 involving a failure to assay each dosage before administration, which very likely contributed to the misadministration. The RSO was also on vacation at the time of the incident and was not made aware of it until his return. There were inconsistencies between the DMR and verbal explanations of the misadministration event given by the licensee's technologists during an NRC inspection. The RSO indicated that he performed an investigation, but he did not personally make a report or maintain any records of the investigation, and his efforts did not uncover the fact that the DMR, which was prepared by the Chief Technologist, was inaccurate and inconsistent. Thus, the violation of 10 CFR 35.53 remained uncorrected, and could have resulted in future misadministrations.

Discussion:

Although this event occurred before January 27, 1992, and therefore was defined as a misadministration under the old rule, it would continue to meet the definition of a misadministration under the "Quality Management Program and Misadministrations" rule. Of greater importance, however, is the lack of complete and accurate information in the misadministration report and the failure of the RSO to identify and investigate the cause of the misadministration and implement the necessary corrective action.
10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee or information required by the Commission's regulations to be maintained by the licensee must be complete and accurate in all material respects.

Currently, 10 CFR 35.33(a)(2) requires, in part, that the licensee submit a written report within 15 days after the discovery of a misadministration to include a brief description of the event, why the event occurred, effect on the patient, necessary improvements to prevent recurrence, and actions taken to prevent recurrence as well as other information. 10 CFR 35.21(a) states, in part, that the licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. Furthermore, 10 CFR 35.21(b)(1) requires, in part, that the RSO shall investigate misadministrations, and implement corrective action, as necessary. An investigation may include: 1) talking to all persons involved in the misadministration, to include the technologists, authorized user, and patient (if acceptable to the referring physician and necessary to the investigation), in order to determine the correct details and sequence of events; 2) reviewing the records associated with the procedure including the requesting physician's order(s) and/or the written directive; 3) performing an independent assessment of the dose delivered to the patient; and 4) reviewing any other circumstances associated with the incident. This information would be used to identify the best course of corrective action. If there appear to be any discrepancies, the RSO should reexamine all the available information to resolve these discrepancies and make the best determination of the root cause of the misadministration.

Licensees should ensure that the RSO at their facility is aware of and understands the requirements to: 1) conduct a thorough investigation .

following a misadministration; 2) determine improvements needed to prevent recurrence; 3) implement any necessary corrective action; 4) submit a written report of the investigation as stated above; and 5) retain a record for five years of the written report and any other records required by 10 CFR 35.33. Furthermore, it is essential that the RSO provide sufficient time and attention to fulfill properly his/her radiation safety program responsibilities, including all of the requirements in 10 CFR 35.21.

This information notice requires no specific action or written response. If you have any questions about the information in this notice, please contact the technical contact listed below, or the appropriate NRC regional office.

ORIGINAL SIGNED BY

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Office of Nuclear Material Safety
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Attachments:
1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices
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