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

May 7, 1993

NRC INFORMATION NOTICE 93-36: NOTIFICATIONS, REPORTS, AND RECORDS OF MISADMINISTRATIONS

Addressees

All U.S. Nuclear Regulatory Commission medical licensees.

Purpose

NRC is issuing this information notice to alert addressees to numerous failures to satisfy all of the notification, reporting and recordkeeping requirements in 10 CFR Part 35, "Medical Use of Byproduct Material," section 35.33, "Notifications, reports, and records of misadministrations," particularly as they relate to notification of patients. It is expected that recipients will review the information for applicability to their facilities, or past required notifications with respect to misadministrations, and consider appropriate actions to avoid or correct similar problems. However, information contained in this notice does not constitute new requirements, and therefore, no specific action or written response is required.

Description of Circumstances

The requirement to notify a patient of a misadministration has been part of 10 CFR Part 35 since the NRC promulgated the "Misadministration Reporting Requirements" in 1980. The statements of consideration for the 1980 rule declared that "patients have a right to know when they have been involved in a serious misadministration, unless this information would be harmful to them." In promulgating the patient notification requirement, the Commission gave explicit recognition to the fact that informing the patient might affect his or her ability to assert legal rights. Over the years, the rule has varied in certain respects, e.g., the types of misadministrations for which notification to the patient is required and the types of records to be retained, as well as the retention periods for records. However, the patient notification requirement has been retained in the rulemakings modifying 10 CFR Part 35.

On January 27, 1992, the "Quality Management Program and Misadministrations" (QM) rule became effective. In addition to requiring the licensee to establish and maintain a written quality management program, this rule modified the definition of misadministration and the requirements for notifications, reports, and records of misadministrations. On January 7, 1993, Information Notice (IN) 93-04 was sent to all NRC medical licensees on the investigation and reporting of misadministrations by the Radiation Safety Officer. IN 93-04 emphasized that information licensees provide to the Commission, regarding misadministrations, must be complete and accurate in all material aspects.

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Since that time, NRC staff conducted a survey of data on therapeutic misadministrations occurring at NRC licensed facilities over the past three years (CY90-92). It revealed that, although the referring physician was notified in 97 percent of misadministrations, the patient was verbally notified in only 72 percent of misadministrations. A medical judgment by the referring physician that "informing the patient would be harmful" was only cited in 32 percent of the misadministrations in which the patient was not notified. In the remaining 68 percent, licensees provided other reasons for not informing the patient such as, "no adverse effects expected," or that "the dose was within acceptable clinical limits." These reasons are not part of the exception to the requirement to notify the patient; therefore, the patient should have been notified. Furthermore, in cases where the patient was notified verbally, a written report was provided to the patient only 56 percent of the time. Written reports to patients significantly increased from 46 percent before January 27, 1992, to 76 percent after that date, which may reflect a change in the rule language to emphasize the requirement for the licensee to provide a written report to the patient.

Discussion

The following discussion is to remind licensees of the specific requirements contained in 10 CFR 35.33.

- 10 CFR 35.33(a)(1) requires that NRC licensees notify by telephone the NRC Operations Center of a misadministration no later than the next calendar day after discovery. Before January 27, 1992, licensees were required to notify the appropriate NRC regional office within 24 hours after discovery of a therapeutic misadministration.

- 10 CFR 35.33(a)(2) requires that the licensee submit a written report to the appropriate NRC Regional Office within 15 days after discovery of the misadministration. This written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient" for the purpose of this information notice) and if not, why not; and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.

- 10 CFR 35.33(a)(3) requires that, for a misadministration, the licensee notify the referring physician and the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the patient or that, based on medical judgment, telling the patient would be harmful.

The referring physician may make a decision that, based on medical judgment, informing the patient would be harmful. In this circumstance, the patient's responsible relative or guardian should be notified. The regulatory history of the misadministration rule suggests that the referring physician may also consider whether, <u>based on medical judgment</u>, telling the responsible relative (or guardian) would be harmful to that individual. Thus, there could be situations in which the licensee is not required to notify the patient <u>or</u> responsible relative (or guardian) because the referring physician has personally informed the licensee that, <u>based on medical judgment</u>, telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, or both. However, this does not include other reasons for not informing the patient, such as: "no adverse effects were expected"; "dose was within acceptable clinical limits"; "no medical benefit to the patient"; "not in the patient's best interest"; or "the patient has died." Although the Commission's regulations do not define the terms "responsible relative" or "guardian," in the absence of a definition, the terms should be given their ordinary meanings: "responsible relative" is the relative who makes decisions regarding a patient when the patient cannot (e.g., patient is a minor; patient is unconscious or incapable of comprehending the information; or the patient has died), usually the next-of-kin; and "guardian" is that person legally responsible for the patient. These ordinary definitions should be applied regardless of whether the patient is living or deceased. If there is any confusion as to the identity of the responsible relative (or guardian), the licensee has the responsibility to determine the identity of that person.

There is no basis in the language of 10 CFR 35.33 for the belief that the misadministration reporting requirements cease to apply upon the death of the patient. The purposes of the rule are not limited to enabling the patient or responsible relative (or guardian) to give informed consent for further medical treatment, but include informing the patient or responsible relative (or guardian) about a misadministration so that they may assert the patient's legal rights with regard to the misadministration. Therefore, if the patient has died, the family, in the person of the responsible relative (or guardian), is still entitled to have the information contained in the misadministration report.

- 10 CFR 35.33(a)(4) requires that, if the patient was notified, the licensee furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either: i) a copy of the report submitted to NRC; or ii) a brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the NRC can be obtained from the licensee. This written report is required whether the patient was notified by the licensee or the referring physician. If the referring physician notifies the patient, the licensee is still required to inform the NRC as to what information was provided to the patient.

- 10 CFR 35.33(b) requires the licensee to retain a record of each misadministration for five years. This record must contain: 1) the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician); 2) the patient's social security number or identification number if one has been assigned; 3) a brief description of and reason for the misadministration; 4) the effect on the patient; and 5) actions and improvements taken to prevent recurrence. Although not required in 10 CFR 35.33(b), the licensee also may choose to maintain a copy of the written report that was sent to the patient, if the patient was notified.

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. The licensee must ensure, therefore, that the written report required by 10 CFR 35.33(a)(2) contains all the required information, including what information was provided to the patient.

The licensee is reminded of the importance of the requirement to notify the patient so that the patient, in consultation with their personal physician, is allowed to make timely decisions regarding remedial and prospective health care. In the future, licensees should be aware that failure to provide notification of a misadministration to the referring physician, patient, or patient's responsible relative (or guardian), will be considered for escalated enforcement action including possible civil penalties. The NRC considers failure to make the required notifications of a misadministration to be a significant regulatory concern. This information notice provides the opportunity for licensees to review records of any past misadministrations and assure that all appropriate notifications have been made.

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.

Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards

Technical contact: Janet R. Schlueter, NMSS
(301) 504-2633

Attachments:
1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

LIST OF RECENTLY ISSUED NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
93-31	Training of Nurses Responsible for the Care of Patients with Brachytherapy Implants	04/13/93	All U.S. Nuclear Regulatory Commission medical licensees.
93-30	NRC Requirements for Evaluation of Wipe Test Results; Calibration of Count Rate Survey Instruments	04/12/93	All U.S. Nuclear Regulatory Commission medical licensees.
93-19	Slab Hopper Bulging	03/17/93	All nuclear fuel cycle licensees.
93-18	Portable Moisture-Density Gauge User Responsibilities during Field Operations	03/10/93	All U.S. Nuclear Regulatory Commission licensees that possess moisture-density gauges.
93-14	Clarification of 10 CFR 40.22, Small Quantities of Source Material	02/18/93	All Licensees who possess source material.
93-10	Dose Calibrator Quality Control	02/02/93	All Nuclear Regulatory Commission medical licensees.
93-07	Classification of Transportation Emergencies	02/01/93	All Licensees required to have an emergency plan.
93-05	Locking of Radiography Exposure Devices	01/14/93	All Nuclear Regulatory Commission industrial radiography licensees.
93-04	Investigation and Reporting of Misadministrations by the Radiation Safety Officer	01/07/93	All U.S. Nuclear Regulatory Commission medical licensees.

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
93-35	Insights from Common-Cause Failure Events	05/12/93	All holders of OLs or CPs for nuclear power plants (NPPs).
93-34, Supp. 1	Potential for Loss of Emergency Cooling Function Due to A Combination of Operational and Post-Loca Debris in Containment	04/06/93	All holders of OLs or CPs for nuclear power reactors.
93-34	Potential for Loss of Emergency Cooling Function Due to A Combination of Operational and Post-Loca Debris in Containment	04/26/93	All holders of OLs or CPs for nuclear power reactors.
93-33	Potential Deficiency of Certain Class 1E Instrumentation and Control Cables	04/28/93	All holders of OLs or CPs for nuclear power reactors.
93-32	Nonconservative Inputs for Boron Dilution Event Analysis	04/21/93	All holders of OLs or CPs for pressurized water reactors (PWRs).
93-31	Training of Nurses Responsible for the Care of Patients with Brachytherapy Implants	04/13/93	All U.S. Nuclear Regulatory Commission medical licensees.
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OL = Operating License
CP = Construction Permit

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*See previous concurrence OE: JL Heberman 05/07/93 Tech Ed: EKraus 03/01/93

OFC	IMAB		IMAB*	E	IMAB*	E	IMOB*	
NAME	JRSchlueter		LWCamper		JEGlenn		FCombs	
DATE	05/07/93		03/09/93		03/15/93		03/18/93	

OFC	OGC*		D/IMNS		DD/NMSS		D/NMSS	
NAME	STreby		RECunningham		GArlotto		RMBernero	
DATE	05/05/93		05/07/93		05/07/93		05/07/93	

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The licensee is reminded of the importance of the requirement to notify the patient so that the patient, in consultation with their personal physician, is allowed to make timely decisions regarding remedial and prospective health care. In the future, a focus of NRC inspections will be to ensure that licensees comply with all notification requirements in the event of a misadministration. This information notice provides the opportunity for licensees to review records of any past misadministrations and assure that all appropriate notifications have been made.

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DATE	04/ /93		03/09/93		03/15/93		03/18/93	

OFC	OGC		D/IMNS		TechEd*			
NAME	STreby		RECunningham		EKraus			
DATE	04/5/93		05/ /93		03/01/93			

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

Technical contact: Patricia K. Holahan, Ph.D., NMSS
(301) 504-2694

Enclosure: filed in jacket.
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*See previous concurrence

OFC	IMAB	E	IMAB*		IMAB*		IMOB	
NAME	PKHolahan		LWCamper		JEGlenn		FComb	
DATE	03/17/93		03/09/93		03/15/93		03/18/93	

OFC	OGC		D/IMNS		TechEd			
NAME	STreby		RECunningham		EKraus			
DATE	03/ /93		03/ /93		03/01/93			

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OFC	IMAB	E	IMAB	E	IMAB	E	IMOB	
NAME	PKHolahan		LWCamper		JEGlenn		FCombs	
DATE	03/9/93		03/9/93		03/15/93		03/ /93	

OFC	OGC		D/IMNS		TechEd			
NAME	STreby		RECunningham		EKraus			
DATE	03/ /93		03/ /93		03/01/93			

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