UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555-0001

March 21, 2006

NRC INFORMATION NOTICE 2002-23, Supplement 1: UNAUTHORIZED ADMINISTRATION OF BYPRODUCT MATERIAL FOR MEDICAL USE

ADDRESSEES

All medical licensees.

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to underscore the requirement in 10 CFR 35.27 that appropriate authorization be obtained before administration of byproduct material for medical use, and to re-emphasize the seriousness of deliberate misconduct. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action nor written response is required.

BACKGROUND

NRC previously issued IN 2002-23, "Unauthorized Administration of Byproduct Material for Medical Use" on July 16, 2002, informing licensees of the importance of appropriate authorization before administration of byproduct material for medical use. (Note: IN 2002-23 may be viewed at the NRC website at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/2002/in02023.pdf). The cases described in IN 2002-23 involved the deliberate unauthorized administration of licensed material to humans. Since the issuance of IN 2002-23, NRC has become aware of additional cases involving the deliberate unauthorized administration of licensed material to humans. The unauthorized administrations in each of these additional cases involved licensee employees or students and did not involve patients.

DESCRIPTION OF CIRCUMSTANCES

In April 2004, a nuclear medicine technologist (NMT) at a teaching institution deliberately directed a student technologist to administer a dose of technetium-99m to the NMT for a scan of her brain knowing that she did not have the approval of a physician authorized user. The student technologist performed the brain scan as directed by the NMT. Licensee management notified NRC when they discovered the unauthorized administration. As a result of NRC enforcement action, the licensee in this case has taken several corrective actions to prevent recurrence, including providing orientation for new students and employees regarding these events, discussing this issue at external meetings, and communicating this issue via articles to be published in professional journals.

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In another case, an NMT at a medical institution was administered a dose of technetium-99m for a renal scan in July 2003 by an individual with the NMT's knowledge that there was no approval by a physician authorized user. The NRC Office of Investigation found that the individual was another NMT at the medical institution; however, the NRC did not make a final determination regarding the willfulness of the violation. As in the first case, licensee management notified NRC when it discovered the unauthorized administration.

The licensee in this case has also taken several corrective actions to prevent recurrence including providing training to employees regarding these events, implementing quarterly audits/inspections of the Nuclear Medicine Department, and reviewing policies and procedures for areas of improvement.

DISCUSSION

The deliberate unauthorized medical administration of byproduct material involves violations of 10 CFR 35.27, "Supervision" and 10 CFR 30.10, "Deliberate Misconduct."

The NRC's requirements regarding the medical use of byproduct material are contained in 10 CFR Part 35, "Medical Use of Byproduct Material," and provide that only a physician authorized user or someone under the supervision of an authorized user, may administer licensed material. Specifically, Section 35.27(a)(2), "Supervision," requires that an individual, under the supervision of an authorized user, follow the instructions of the supervising authorized user regarding medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, and all applicable NRC regulations and license conditions.

In addition,10 CFR 30.10 (a)(1), which is applicable to medical users, provides in part that any licensee, certificate of registration holder, or applicant; or contractor or subcontractor of these entities, who knowingly provides goods or services related to the licensee's, certificate holder's, or applicant's activities in Part 30, may not engage in deliberate misconduct that causes or would have caused if not detected, a licensee, certificate of registration holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission. Under these provisions, persons who have reasonable knowledge that their actions are related to an activity subject to NRC regulations, and deliberately engage in misconduct that causes or would have caused a violation have violated section 30.10, and may be subject to enforcement action. Such deliberate violations are significant in that they pose a distinct threat to public health and safety.

Violations caused by the deliberate actions of a licensee and/or its employees are of serious concern to the NRC. Deliberate violations on the part of licensees can seriously undermine the public's trust in the NRC's ability to effectively carry out its mission to protect the health and safety of the public and radiation workers. Therefore, NRC has authority to impose significant enforcement action for such violations, and will consider imposing significant sanctions when assertions of deliberate misconduct are substantiated.

NRC expects its licensees to ensure that their staff fully understand and adhere to the requirements associated with the medical administration of licensed material. NRC will consider enforcement actions for both licensees and individual staff members when NRC requirements are determined to have been deliberately violated. In the cases described above, the licensees and some of the involved individuals were issued Notices of Violation. NRC enforcement actions may be viewed at http://www.internal.nrc.gov/OE/.

This IN requires no specific action nor written response. If you have any questions about the information in this notice, please contact the technical contact listed below or the appropriate regional office.

Patricia Holahan for/RA/

Charles L. Miller, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical Contact: Joseph Nick, RI
610-337-5056
E-mail: jln@nrc.gov

Attachment: List of Recently Issued NMSS Generic Communications

Recently Issued NMSS Generic Communications

Date	GC No.	Subject	Addressees
01/26/06	RIS-02-15, Rev. 1	NRC Approval of Commercial Data Encryption Products For the Electronic Transmission Of Safeguards Information	All authorized recipients and holders of sensitive unclassified safeguards information (SGI).
01/24/06	RIS-06-01	Expiration Date for NRC-Approved Spent Fuel Transportation Routes	The U.S. Nuclear Regulatory Commission (NRC) licensees who transport, or deliver to a carrier for transport, irradiated reactor fuel (spent nuclear fuel (SNF)).
01/13/06	RIS-05-27, Rev. 1	NRC Regulatory Issue Summary 2005-27, Rev. 1, NRC Timeliness Goals, Prioritization of Incoming License Applications and Voluntary Submittal of Schedule for Future Actions for NRC Review	All 10 CFR Parts 71 and 72 licensees and certificate holders.
01/19/06	IN-06-02	Use of Galvanized Supports and Cable Trays with Meggitt Si 2400 Stainless- Steel-jacketed Electrical Cables	All holders of operating licenses for nuclear reactors except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel; and fuel cycle licensees and certificate holders.

Note: NRC generic communications may be found on the NRC public website at http://www.nrc.gov, under Electronic Reading Room/Document Collections.