UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, D.C. 20555

February 2, 2007

NRC INFORMATION NOTICE 2007- 03: REPORTABLE MEDICAL EVENTS INVOLVING PATIENTS RECEIVING DOSAGES OF SODIUM IODIDE IODINE-131 LESS THAN THE PRESCRIBED DOSAGE BECAUSE OF CAPSULES REMAINING IN VIALS AFTER ADMINISTRATION

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical use licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

PURPOSE

NRC is issuing this information notice (IN) to alert addressees about events in which patients were administered dosages of sodium iodide, iodine-131 (I-131) that were less than the prescribed dosages, because of sodium iodide I-131 capsules that remained in vials, containing multiple capsules, after administration. These occurrences resulted in medical events because the patients did not receive the prescribed dosages. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action or written response is required. NRC is providing this IN to the Agreement States for their information and for distribution to their medical licensees as appropriate.

DESCRIPTION OF CIRCUMSTANCES

In September 2006, one licensee performed administrations incorrectly on two separate occasions. In each case, only one sodium iodide I-131 capsule was administered to the patient, rather than the two capsules containing the total dose. Consequently, the patients did not receive the dosages prescribed in the written directives. Before these events, the licensee had received the total prescribed dose of I-131 in a single capsule. In the case of these two events, instead of the expected single capsule, the commercial radiopharmacy dispensed two capsules containing the prescribed dose. The licensee measured the radioactivity in each vial containing capsules, before administration, to ensure the proper dosage amount. When the content of each of the vials was emptied, for administration, one of the two capsules remained in the vial. Each vial was placed back into its shipping container and returned to the pharmacy. Each of the two patients was released, having received only a portion of the prescribed dosage.

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Over the last 10 years, there have been 12 reported events of this type (i.e., events in which patients were administered dosages of sodium iodide I-131 that were less than the prescribed dosages, because capsules remained in vials after administration). In some of these cases, the patients were administered one of multiple capsules contained in a single vial. In other cases, patients were administered two of three capsules, where two capsules were placed in one vial by the commercial pharmacy, and the third capsule was placed in a separate vial.

There were a few instances where the errors were discovered shortly after the patients had been released, and the patients returned to the licensees to receive the remaining portions of the prescribed dosages. Notwithstanding that in these cases the patients returned to receive the remaining portions of the prescribed dosages, NRC concludes that the total dose, for purposes of determining whether the medical event reporting criteria had been met, is the dose received by the patients at the time when they were released from the licensee's control (i.e., following administration of the first capsule). Since, at the time of the patients' release, the delivered dosages differed from the prescribed dosages by more than 20 percent and the thyroid dose reductions resulting from the reduced dosages exceeded the 0.5 sieverts (50 rem) to an organ, the events required reporting as medical events under 10 CFR 35.3045(a)(1)(ii).

DISCUSSION

NRC regulations, in 10 CFR 35.63, do not require licensees to perform a direct measurement of a unit dosage in a dose calibrator before administration, if the unit dosage is corrected for decay based on the activity determined by an appropriately licensed manufacturer, preparer or licensee (e.g., commercial pharmacy). However, as a measure for prevention of these types of medical events, a licensee could assay the vial containing I-131 capsules, after administration of the dosage, to assure that no capsules remain in the vial. To keep occupational doses as low as reasonably achievable, assay measurement of the vial post-administration is preferred over visual verification of the content of the vial.

Precautions can also be taken before administration, and include reviewing the packing slip before administration, to verify the number of capsules shipped by the pharmacy. Further, assaying the activity before administration could identify that the total dose was not in the vial and that missing capsule(s) may, for example, have been placed in another vial of the shipment.

Besides resulting in a medical event, another negative consequence of a capsule remaining in a vial is that the licensee may incorrectly mark and label the vial for transport back to the commercial radiopharmacy. For example, the vial may be placed back into the original container and shipped back to the commercial pharmacy with the marking and labeling of a package that is assumed to be empty, when in fact, it is not. This could result in a violation of the requirements in 10 CFR 71.5, "Transportation of Licensed Material." Another example of an adverse consequence of a capsule remaining in the vial is that this might result in the inadvertent disposal of the vial containing I-131 in "non-radioactive" waste. This could lead to a violation of the requirements for waste disposal, or the requirements for storage and control of licensed material in 10 CFR Part 20, "Standards for Protection Against Radiation."

CONTACT

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

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Enclosure:
"List of Recently Issued NMSS Generic Communications"

Recently Issued FSME/NMSS Generic Communications

Date	GC No.	Subject	Addressees
12/7/06	RIS-06-26	TRAINING AND EXPERIENCE AND GRANDFATHER PROVISIONS FOR AUTHORIZED MEDICAL PHYSICISTS UNDER 10 CFR PART 35	All NRC medical licensees and Radiation Control Program Directors.
12/7/06	RIS-06-25	Requirements For The Distribution And Possession Of Tritium Exit Signs And The Requirements In 10 CFR 31.5 AND 32.51a	All U.S. Nuclear Regulatory Commission (NRC) licensees distributing tritium exit signs and those possessing a tritium exit sign under a general license.
11/15/06	RIS-06-22	Lessons Learned From Recent 10 CFR PART 72 Dry Cask Storage Campaign	All Title 10 *Code of Federal Regulations* (10 CFR) Part 72 specific licensees and certificate holders and holders of operating licenses for nuclear power reactors (including those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel) that are not 10 CFR Part 72 specific licensees.
09/22/06	RIS-06-14	Enforcement Discretion for Facility Changes Under 10 CFR 70.72(c)(2)	All fuel cycle licensees regulated under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, Subpart H.
09/14/06	RIS-06-20	Guidance for Receiving Enforcement Discretion When Concentrating Uranium at Community Water Systems	All community water systems (CWSs), in U.S. Nuclear Regulatory Commission (NRC) non-Agreement States, that during the treatment of drinking water, may accumulate and concentrate naturally-occurring uranium in media, effluents, and other residuals, above 0.05 percent by weight.
09/14/06	RIS-06-19	Availability of Guidance on Radioactive Seed Localization	All NRC medical licensees.
08/31/06	RIS-06-18	Requesting Exemption from the Public Dose Limits for Certain Caregivers of Hospital Patients	All NRC medical licensees.
08/15/06	RIS-06-16	Transfer of the Management Oversight Of Certain NRC Region I Licensees in Mississippi To the NRC Region IV Office	All NRC materials licensees.
07/20/06	RIS-06-11	Requesting Quality Assurance Program Approval Renewals Online by Electronic Information Exchange	All 10 CFR Part 71 quality assurance program and certificate holders.
04/23/06	RIS-06-10	Use of Concentration Control for Criticality Safety	All licensees authorized to possess a critical mass of special nuclear material.

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 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.
11/14/06	IN-06-25	Lessons Learned From NRC Inspection Of Control And Accounting Of Special Nuclear Material At Commercial Nuclear Power Reactors	All power reactors, category I fuel cycle facilities, independent spent fuel storage installations, conversion facility, and gaseous diffusion plants. Note that the information notice contains physical security information and is, therefore, being withheld from public disclosure in accordance with 10 CFR 2.390
11/7/06	IN-06-23	Events Involving Potential Tampering Or Malfeasance By Persons Granted Unescorted Access	All power reactors, category I fuel cycle facilities, independent spent fuel storage installations, conversion facility, and gaseous diffusion plants. Note that the information notice contains physical security information and is, therefore, being withheld from public disclosure in accordance with 10 CFR 2.390
07/10/06	IN-06-13	Ground-Water Contamination Due to Undetected Leakage of Radioactive Water	All holders of operating licenses for nuclear power and research and test reactors including those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor and those authorized by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 72 licenses to store spent fuel in water-filled structures.
07/06/06	IN-06-12	Exercising Due Diligence When Transferring Radioactive Materials	All materials licensees.

Date	GC No.	Subject	Addressees
06/12/06	IN-06-11	Applicability of Patient Intervention in Determining Medical Events for Gamma Stereotactic Radiosurgery and Other Therapy Procedures	All medical licensees.
03/31/06	IN-06-07	Inappropriate Use of a Single-parameter Limit as a Nuclear Criticality Safety Limit	All licensees authorized to possess a critical mass of special nuclear material.
03/21/06	IN-02-23, Supl. 1	Unauthorized Administration of Byproduct Material for Medical Use	All medical licensees.
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.