

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIAL AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, D.C. 20555-0001

July 19, 2007

NRC INFORMATION NOTICE 2007-25: SUGGESTIONS FROM THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES FOR CONSIDERATION TO IMPROVE COMPLIANCE WITH SODIUM IODIDE I-131 WRITTEN DIRECTIVE REQUIREMENTS IN 10 CFR 35.40 AND SUPERVISION REQUIREMENTS IN 10 CFR 35.27

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

The U.S. Nuclear Regulatory Commission (NRC) is issuing this Information Notice (IN) to underscore the requirement in 10 CFR 35.40 that the administration of sodium iodide iodine-131 (I-131) in dosages greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)) requires a written directive signed and dated by an authorized user (AU). In this connection, this IN is being issued to emphasize the need for administering technologists to verify the existence of written directive and/or the dosage with an AU prior to administration of sodium iodide I-131. Another purpose of the IN is to remind licensees of their responsibility under 10 CFR 35.27(a) to instruct the supervised individual in written directive procedures and to require supervised individuals to follow the instruction of the supervising AU. This IN contains the Advisory Committee on the Medical Use of Isotopes' (ACMUI's) suggestions for ensuring compliance in using written directives and improving communication between the AU and the individual performing the administration. Recipients should review the information contained in this IN 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 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.

BACKGROUND

Between February, 2004, and May, 2005, NRC received eleven medical event reports involving oral administrations of sodium iodide I-131 at activity levels that required written directives. The NRC requested that the ACMUI examine these medical events identify root causes and ways of reducing the occurrence of these types of medical events. In April, 2006, the ACMUI, presented NRC with its conclusions and recommendations. The NRC incorporated the ACMUI recommendations in this IN for distribution and consideration by the medical community.

The dosage activity in seven of the eleven sodium iodide I-131 administrations exceeded the minimum dosage activity that required a written directive (i.e., greater than 1.11 MBq (30 μ Ci)), but a written directive had not been issued. Nine of the medical events resulted in over-dosages.

Although the details of the medical events varied, the primary cause for most of the events was the licensee's failure to verify all sodium iodide I-131 dosages greater than 30 μ Ci against a written directive prior to administration.

The NRC notes that there is evidence that this failure continues to be a cause for medical events. Specifically, since the ACMUI performed its review, there have been 8 additional medical events involving sodium iodide I-131 (not included in the examples below) that also involved the failure to verify that there was a written directive for sodium iodide I-131 dosages greater than 30 μ Ci. These additional events underscore the continuing need to increase awareness of the written directive requirements in 10 CFR 35.40 and corresponding supervision requirements in 10 CFR 35.27(a).

DESCRIPTION OF CIRCUMSTANCES

There were no written directives for eight of the eleven administrations reviewed by the ACMUI, because five prescribed dosages were for less than 30 μ Ci of sodium iodide I-131 (two of these included verbal orders), one was for a different radionuclide (I-123), one had no prescribed dosage, and one for greater than 30 μ Ci was only made verbally. The absence of written directives for sodium iodide I-131 dosages greater than 30 μ Ci should have alerted the administering technologist to seek a written directive and, if one was not found, to verify the dosage with the AU prior to administration.

The three remaining medical events involved written directives which were not followed. These three events were primarily due to human errors (i.e., lack of attention to detail and failure to follow procedures) compounded by the staff's failure to follow a written directive. Reviewing the written directive or contacting the AUs prior to administering the dosages could have prevented these errors.

Cases in which No Written Directive was issued - Eight Cases:

Pharmacy Errors

- A contaminated pipette in the radiopharmacy raised the desired dosage of 20 μ Ci, to 0.9 millicurie (mCi). The dosage was correctly labeled as 0.9 mCi. The activity displayed on the radiopharmacy dose calibrator of "0.915 mCi" was misinterpreted by the radiopharmacy technologist as "9.15 μ Ci." The nuclear medicine technologist misread the 0.9 mCi on the label as 9 μ Ci and administered the dosage. This resulted in an administered dosage of 915 μ Ci rather than the requested dosage of 5 to 20 μ Ci.
- The radiopharmacy prepared a dosage of 980 μ Ci instead of the prescribed dosage of 15 μ Ci. The dosage of 980 μ Ci was administered to a patient by a technologist at the medical facility without verification of the dosage. This mistake could have been

prevented by verifying the dosage and recognizing that a written directive is required for all sodium iodide I-131 administrations exceeding 30 μ Ci.

Pharmacy Error Compounded by a Verbal Order

- The AU gave a verbal order for 2.0 mCi without providing the required written directive. The nuclear pharmacy inadvertently prepared and sent a 2.8 mCi dosage, which was then administered by the technologist at the medical facility.

Verbal Order

- The technologist misunderstood the verbal orders of the AU and ordered 500 μ Ci of sodium iodide I-131 instead of 5 μ Ci. The patient was administered 535 μ Ci instead of the intended 5 μ Ci. The technologist did not verify the existence of a written directive, which is required for all sodium iodide I-131 administrations exceeding 30 μ Ci.

Misunderstood request/written order

- The technologist misunderstood the referring physician's request (the report does not specify the form of the request) and administered 3 mCi of sodium iodide I-131 rather than the intended 25 μ Ci. Approval of the dosage was not obtained from the AU prior to administration.
- The AU intended to prescribe 12 mCi but instead wrote 12 μ Ci by mistake on the prescription. The technologist did not realize that the AU had written 12 μ Ci and ordered and administered a dose of 12mCi which the technologist thought was what the AU had intended; however, this administration did not comply with the written directive, and therefore constituted a medical event. This event was caused by the failure to compare a dosage greater than 30 μ Ci with the AU's written instruction and lack of communication between the technologist and the AU.

Wrong Patient

- The individual received a 2 mCi I-131 dosage instead of the intended 200 μ Ci I-123 dosage because the patient incorrectly responded affirmatively to being the patient that was supposed to receive the I-131 dosage.

No Order

- The technologist administered a 4 mCi dosage that was left over from a previous "no show" patient without a written directive under the assumption that the prescribing physician would complete the written directive at a later time. After administering the 4 mCi dosage, the technologist discovered that the AU had intended to prescribe 150 mCi. As there had been no written directive, the technologist could not verify the prescribed dosage against the dosage about to be administered.

Failure to Follow a Written Directive - Three Cases:

- Two different medical events resulted in administered dosages of 5.2 mCi and 15 mCi instead of the prescribed 2 mCi dosages. One was attributed to lack of attention to

detail and the other to failure to follow procedures.

- The technologist confused the dosages of three patients who were scheduled to receive I-131 treatments on the same day and administered 100 mCi to a patient who was scheduled to receive 17.3 mCi.

DISCUSSION

As outlined in the DESCRIPTION OF CIRCUMSTANCES, most of the medical events were caused primarily by failure to recognize that dosages greater than 30 μ Ci of sodium iodide I-131 require a written directive and should have been verified against a prescribed dosage in a written directive. With the exception of the patient misidentification, these events could have been preventable if procedures had been established and followed for checking dosages about to be administered against a prescribed dosage contained in a written directive. The ACMUI developed four suggestions that the medical community may consider to improve compliance with the regulations.

- 1) Licensees are required to have a written directive before the administration of greater than 30 μ Ci of sodium iodide I-131 (10 CFR 35.40) and to provide instructions in written directive procedures to supervised individuals (10 CFR 35.27). The ACMUI suggests that licensees reemphasize these requirements to their staff so that the staff is aware that a written directive is required for dosages of sodium iodide I-131 greater than 30 μ Ci and verifies that there is a written directive before administering these dosages. Licensees also should remind staff that verbal orders are only acceptable under specific situations and, even then, must be followed up with a written directive (10 CFR 35.40(a)(1) and 35.40(c)(1)).
- 2) Licensees are required to determine and record the activity of each dosage before medical use (10 CFR 35.63). The ACMUI recognizes that licensees are not required to perform a direct measurement of a unit dosage in a dose calibrator prior to administration, if it is received from a drug manufacturer or commercial nuclear pharmacy. However, the ACMUI believes that it is a good standard of practice to make direct measurements of therapeutic dosages in dose calibrators. The ACMUI also suggests that licensees have the written directive readily available while determining the dosage prior to administration to verify and ensure that the dosage to be administered conforms with the written directive.
- 3) The licensee is required to have written procedures to provide high confidence that the patient's identity is verified before each administration (10 CFR 35.41(a)(1)). The ACMUI suggests that licensees evaluate their identity verification procedures to prevent patient misidentification. Although not required by the regulations, the ACMUI suggests that licensees consider confirming positive patient identification by two separate methods prior to dosage administration. The ACMUI suggests following a patient identification procedure similar to that required for a blood administration.
- 4) The ACMUI suggests that licensees seek to improve communication between AUs and the individuals performing the administration. The AUs should consider reviewing plans for the treatment with the administering technologists. In addition, licensee management should foster a culture at the licensee's facility that encourages technologists to freely ask questions of the AUs regarding written directives.

NRC licensees must ensure that their staff fully understand and adhere to the requirements contained in the regulations. NRC, in coordination with the ACMUI, has developed this IN to convey the above suggestions drawn from a study of medical events involving the oral administration of sodium iodide I-131. Unless specifically addressed in 10 CFR Part 35, these suggestions are not NRC requirements. The ACMUI believes consideration of these suggestions will improve compliance with the regulations and minimize the likelihood of medical events.

CONTACT

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

/RA/

Janet R. Schlueter, Director
Division of Materials
and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

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Enclosure:
"List of Recently Issued FSME/NMSS
Generic Communications"

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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 <i>Code of Federal Regulations</i> (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 <i>Code of Federal Regulations</i> (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 <i>Code of Federal Regulations</i> (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. |
| 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. |

| Date | GC No. | Subject | Addressees |
|----------|----------------------|--|--|
| 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