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

April 16, 1999

NRC INFORMATION NOTICE 99-11: INCIDENTS INVOLVING THE USE OF RADIOACTIVE IODINE-131

Addressees:

All medical use licensees.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to alert addressees to recent incidents involving the use of radioactive iodine-131. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific actions nor written response is required.

Description of Circumstances:

The following cases are recent events, reported to NRC, that have resulted in unintended radiation doses to humans, as the result of the administration of radioactive iodine:

Case 1: A patient was scheduled for a thyroid ablation after removal of a cancerous thyroid. Before the ablation dose was given to the patient, she was interviewed by both a nuclear medicine technologist and an authorized-user physician. The interview included discussion of pregnancy and breast-feeding status; the patient emphatically denied either circumstance. As a result, the patient was administered 5.75 gigabecquerels (155.2 millicuries) of iodine-131. Unbeknownst to the licensee, the patient's referring physician had ordered a pregnancy test, in the belief that such a test was standard practice. Four hours after the administration of the radioiodine dosage, the results of the pregnancy test were forwarded to the nursing station. The test was positive and a subsequent ultrasound determined that the patient was approximately 13.5 weeks pregnant, with twins, at the time of the administration. The total effective dose equivalent to each fetus was estimated to be 0.38 gray (38 rads) and the committed dose equivalent to each of the fetal thyroids was estimated at 2000 gray (200,000 rads). Before the ablation, the patient also underwent a metastatic scan, using 100 megabecquerels (2.7 millicuries) of iodine-131, and two thyroidectomy surgeries, each within the period of time that she was pregnant. As in the ablation procedure, licensee staff collected the patient's history, including most recent menses. And in each case, the patient emphatically denied the possibility

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of pregnancy. NRC determined that this case did not constitute a misadministration, since the patient received the intended dosage, and the licensee had taken reasonable steps to ascertain the medical status of the patient, prior to the administration of radioiodine.

Case 2: A patient was scheduled to receive a dosage of iodine-131 for the treatment of thyroiditis, in accordance with an authorized user's written directive. Before the treatment, licensee staff interviewed the patient regarding pregnancy status and the patient certified that she was not pregnant and signed an informed consent form. The patient was administered 341 megabecquerels (9.2 millicuries) of iodine-131. A month after the treatment, the patient discovered that she had been approximately 4 months pregnant at the time of the treatment, and notified the licensee. The licensee estimated that the dose to the fetal thyroid was 88 gray (8800 rads) committed dose equivalent. As in the case above, NRC determined that this incident did not constitute a misadministration, since the patient received the intended dosage, and the licensee had taken reasonable steps to ascertain the medical status of the patient, before the administration of radioiodine.

Case 3: A patient was scheduled to receive a dosage of 370 megabecquerels (10 millicuries) of iodine-131 for the treatment of hyperthyroidism, in accordance with an authorized user's written directive. A second physician, not familiar with the patient, administered this dosage. The physician went to the patient's room, verified his name and administered the dosage. However, at that time, the hospital had two patients with the exact same name, and the physician failed to verify the patient's identity through a second means. The event was discovered in time to allow the administration of a thyroid-blocking agent, KI, to limit the uptake of iodine by the patient's thyroid. This incident, which constituted a misadministration because it involved the wrong patient, resulted in a committed dose equivalent of approximately 1.4 gray (140 rads) to the thyroid.

Case 4: A referring physician orally requested a nuclear medicine department to give his patient 370 megabecquerels (10 millicuries) iodine-131 for a whole body scan. The nuclear medicine technologist questioned the procedure, during a telephone conversation with the referring physician. However, the technologist subsequently gave the dosage ordered by the referring physician to the patient, without a written directive. Later consultation between the authorized user and the referring physician determined that the patient should have received a thyroid uptake and scan, involving 740 kilobecquerels (20 microcuries) of iodine-131. This incident, which constituted a misadministration because the administered dosage exceeded the intended dosage by more than 20 percent, resulted in a committed dose equivalent of approximately 270 gray (27,000 rads) to the patient's thyroid.

Case 5: Two patients were scheduled to receive therapeutic dosages of iodine-131, in accordance with written directives prepared by an authorized user. One patient was to receive 296 megabecquerels (8 millicuries) and the other 1.11 gigabecquerels (29.9 millicuries). After assaying the vials containing the dosages, the technologist reversed the lids on the vial shields.

The lids contained the dosage information. Because of the reversal of the lids, the technologist inadvertently administered the larger dosage to the first patient, which exceeded the prescribed dosage by 370 percent.

Discussion:

Cases one and two, although not misadministrations, are included in this information notice to illustrate the significant unintended consequences that can result from the administration of radioiodine to a female patient whose pregnancy status has not been conclusively determined. Although there is no NRC requirement that licensees perform pregnancy tests on female patients of child-bearing age, NRC believes that cases one and two offer information that could be significant to its licensees, and thereby warrant inclusion in this information notice. In particular, case one points out the need for communication and coordination between the authorized-user and the referring physician. Cases three, four, and five illustrate the importance of verifying correct dosages and patient identity before administration; -- ensuring that all referring physician requests for administrations involving greater than 1.11 megabecquerels (30 microcuries) of iodine-131 are followed by a written directive, prepared by an authorized-user physician, before administration.

Although errors involving the use of radioiodine seldom occur, when they do, the consequences can be significant because of the high radiation doses involved. Licensee procedures for the safe handling and use of radioiodine must address the objectives of the quality management rule contained in 10 CFR 35.32. The objectives, for the administration of iodine-131 in excess of 1.11 megabecquerels (30 microcuries), include: (1) preparing a written directive before administration; (2) verifying the patient's, or human research subject's identity, by more than one method, as the individual named in the written directive; (3) ensuring that each administration is in accordance with the written directive; and (4) ensuring that unintended deviations from the written directive are identified and evaluated. Cases three, four, and five illustrate why licensee employees who administer licensed materials, including radioiodine, under the supervision of an authorized user physician, must receive instruction in the licensee's written quality management procedures, and must follow those instructions. Licensees are reminded that they are responsible for ensuring that the instructions are given to the appropriate employees, and for ensuring that the employees can and will follow those instructions. By paying attention to detail, and adhering to established departmental policy and procedures, many incidents involving radioiodine may be avoided.

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
99-09	Problems Encountered when manually EditingTreatment Data on the Nucletron misroselectron-HDR (New) Model 105-999	3/24/99	All medical licensees authorized to conduct high-dose-rate (HDR) remote after loading brachytherapy treatments
99-06	1998 Enforcement Sanctions as a Result of Deliberate Violations of	3/19/99	All U. S. Nuclear Regulatory Commission licensees.
99-05	Inadvertent Discharge of Carbon Dioxide Fire Protection System and Gas Migration	3/8/99	All holders of licenses for nuclear power, research, and test reactor, and fuel cycle facilities
99-04	Unplanned Radiation Exposures to Radiographers, Resulting from failures to follow Proper Radiation Safety Procedures	3/8/99	All radiography licensees.
99-03	Exothermic Reactions Involving Dried Uranium Oxide Powder (Yellowcake)	1/29/99	All operating uranium recovery facilities that produce oxide powder (U_3O_8) (yellowcake)
99-02	Guidance to Users on the Implementation of a New Single-Source Dose-Calculation Formalism and Revised Air-Kerma Strength Standard for Iodine-125 Sealed Sources	1/21/99	All medical licensees authorized to conduct brachytherapy treatments.
99-01	Deterioration of High-Efficiency Particulate Air Filters in a Pressurized Water Reactor Containment Fan Cooler Unit	1/20/99	All holders of licences for nuclear power, research and test reactors; and fuel cycle facilities.
98-33 Regulatory	NRC Regulations Prohibit Agreements that Restrict or Discourage an Employee from Participating in Protected Activities	8/28/98	All holders of a Nuclear Commission license
98-30	Effect of the Year 2000 Computer Problem on NRC Licensees and Certificate Holders	8/12/98	All material and fuel cycle licensees and certificate holders

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Information Notice No.	Subject	Date of Issuance	Issued to
97-15, Sup 1	Reporting of Errors and Changes inLarge-Break/Small-Break Loss-of-Coolant Evaluation models of Fuel Vendors and Compliance with 10 CFR 50.46(a)(3)	4/16/99	All holders of operating licensees for nuclear power reactors, except those who have permanently cease operations and have certified that fuel has been permanently removed from the reactor
99-10	Degradation of Prestressing Tendon Systems in Prestressed Concrete Containments	4/13/99	All holders of OIs for nuclear power reactors
99-09	Problems Encountered When Manually Editing Treatment Data on The Nucletron Microselectron-HDR (New) Model 105.999	3/24/99	All medical licensees authorized to conduct high-dose-rate (HDR) remote after loading brachytherapy treatments
99-08	Urine Specimen Adulteration	4/1/99	All holders of operating licensees For nuclear power reactors and licensees authorized to possess or use formula quantities of strategic special nuclear material (SSNM)
99-07	Fire Protection Preaction Sprinkler System Deluge Valve Failures and Potentials Testing Deficiencies	3/22/99	All NRC licensees
99-06	1998 Enforcement Sanctions as a Result of Deliberate Violation on NRC Employee Protection Requirements	3/19/99	All U.S. Nuclear Regulatory Commission licensees

OL = Operating License
CP = Construction Permit

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Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical Contact: Jamnes Cameron, RIII
(630) 829-9833
E-mail: jlc@nrc.gov

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