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DEPARTMENT OF THE NAVY
NAVY ENVIRONMENTAL HEALTH CENTER
2510 WALMER AVENUE
NORFOLK, VIRGINIA 23513-2617

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23 Oct 1990

From: Commanding Officer, Navy Environmental Health Center
To: Distribution List

Subj: NAVY RADIOACTIVE MATERIAL PERMIT PROGRAM

Encl: (1) NRC Information Notice Number 90-59: Errors in the use of Radioactive Iodine 131
(2) NRC IE Information Notice Number 85-61: Supplement One Misadministrations to Patients Undergoing Thyroid Scans

1. Enclosures (1) and (2) are forwarded for review by your Radiation Safety Officer, Radiation Safety Committee and all authorized users. As discussed in enclosure (1), it is recommended that your Nuclear Medicine Department procedures include provisions for questioning female patients about the possibility of pregnancy or lactation and discussing positive responses with the authorized user.

2. Point of contact is LCDR G. I. Snyder, MSC, USN, Radiation Health Department, AUTOVON: 564-4657 or Commercial: (804) 444-4657, Ext. 266.

P. J. DURFEE
By direction

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

September 17, 1990

NRC INFORMATION NOTICE NO. 90-59: ERRORS IN THE USE OF RADIOACTIVE IODINE-131

Addressees:

All medical licensees.

Purpose:

This information notice is intended to emphasize to medical use licensees the potential radiation dose levels resulting from errors in the administration of iodine-131 to humans. This issue was previously addressed in IE Information Notice No. 85-61, Suppliment 1: Misadministrations To Patients Undergoing Thyroid Scans (attached). Due to the significance and frequency of recurrence of these errors, NRC believes this issue should be readdressed. It is expected that licensees will review this information for application to their own procedures for the administration of iodine-131, distribute the notice to those responsible for radiation safety and quality assurance, and consider actions, if appropriate, to establish procedures to preclude the misadministration of iodine-131 at their facilities. However, suggestions contained in this notice do not constitute any new U.S. Nuclear Regulatory Commission (NRC) requirements, and no 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 a result of the administration of radioactive iodine:

Case 1: A patient with a history of thyroid cancer was scheduled for her yearly whole-body scan. Before the scan, the patient underwent a pregnancy test, with negative results. After the pregnancy test results were received, the technologist began to complete a departmental questionnaire to obtain information from the patient relative to the requested procedure. The questionnaire addressed the possibilities of pregnancy and lactation. However, before completing the questionnaire, the technologist was called away and did not return to complete the form before administration of the iodine-131. As a result, the patient was given the intended dosage of 4.89 millicuries of iodine-131. Approximately 48 hours later when the patient was scanned, there was considerable iodine-131 uptake in her breasts. When questioned by the physician, the patient indicated that she had given birth to a female infant two weeks earlier and had been nursing this infant for approximately the last 36 hours. The total body dose to the infant was estimated to be 17 rads, and the radiation dose to the infant's thyroid was estimated to be 30,000 rads. A synthetic thyroid hormone replacement has been prescribed for the child, with scheduled periodic follow-ups. The unintended dose to the mother's breasts was estimated to be 8.9 rads.

Case 2: A patient to be scheduled for a thyroid scan was administered 3 millicuries of iodine-131 instead of the intended dosage of 300 microcuries of iodine-123. The patient's physician called in the request for a thyroid scan to the secretary of the nuclear medicine department, who inadvertently scheduled a whole-body scan. No written request from the physician was required. The dosage at this facility for a whole-body scan is 3 millicuries of iodine-131, whereas the dosage for a thyroid scan is 300 microcuries of iodine-123. The estimated dose to the patient's thyroid gland due to this error was 4700 rads.

Case 3: A patient was scheduled for an ectopic thyroid evaluation, with an intended dosage of 100 microcuries of iodine-131. In completing the Nuclear Medicine department referral sheet, the referring physician incorrectly requested a post-thyroidectomy neck scan. As a result, the patient was administered 1 millicurie of iodine-131, with an estimated dose to the thyroid of 1300 rads.

Case 4: A patient was scheduled for an ectopic thyroid evaluation, with an intended dosage of 50 to 100 microcuries of iodine-131. The technologist consulted the department procedure manual that listed prescribed dosages for specific scans, and the dosage was incorrectly listed as 4.5 millicuries. As a result, the patient was administered 4.3 millicuries. The estimated dose to this patient's thyroid gland was 4300 rads.

Case 5: A patient was administered a dosage of 15 microcuries of iodine-131. Almost immediately following the administration, the patient indicated to the technologist that she was approximately 4 to 5 weeks pregnant. The technologist failed to ask the patient if she was pregnant before the administration. The patient had arrived at the department with a baby in her arms, and the technologist assumed that the patient was not pregnant. The total body dose to the fetus was estimated to be 2 to 4 millirem. Since the fetal thyroid is incapable of concentrating iodine-131 until approximately 12 weeks of gestation, it was estimated that there was no additional dose to the fetal thyroid.

DISCUSSION:

All licensees are reminded of the importance of ensuring the safe performance of licensed activities, in accordance with NRC regulations, requirements of their licenses, and accepted medical practice. The forementioned cases illustrate: the lack of familiarity with appropriate thyroid studies and dosages; the necessity of consistently following quality control procedures; and a need to understand the significance of radiation doses that result from the administration of millicuries versus microcuries of radiopharmaceuticals containing radioiodine. Specifically, the radiation dose to the thyroid, resulting from a dosage of one millicurie rather than one microcurie of

iodine-131, is a one thousand-fold increase. In addition, the radiation dose received from an activity of iodine-131 is approximately 100 fold greater than the dose from the same activity of iodine-123. The following table illustrates the relationship between microcurie versus millicurie quantities of iodine-131, as well as the radiation dose differential between iodine-123 and iodine-131, for three different age groups, with a thyroid uptake of 15 percent.

TABLE: A Comparison of Isotopes and Radiation Doses for Various Age Groups Assuming 15% Uptake by the Thyroid*

	Rads per uCi		Rads per mCi	
	I-123	I-131	I-123	I-131
1 year old	0.07	7.40	70.3	7400
5 years old	0.04	4.07	40.0	4070
Adult	0.007	0.78	7.0	777

* Based on information from ICRP Publication No. 53

All workers should have a clear understanding of the significance of errors in scale when calculating and preparing diagnostic dosages versus therapeutic dosages of radiopharmaceuticals containing radioiodine. The threshold at which a diagnostic dosage becomes a therapeutic dosage is low, and depends on the age of the patient and the percent uptake by the patient's thyroid gland. Consequently, the potential for causing a significant, undesired radiation dose to a patient's thyroid gland must always be kept in mind when administering iodine radiopharmaceuticals.

Licensees are reminded that the package inserts provided by the manufacturers contain information pertinent to both proper dosages and radiation doses, and may be valuable resources when reviewing imaging policies and procedures for errors and inconsistencies. Nuclear medicine department procedures should include provisions for questioning female patients about the possibility of pregnancy or lactation. By attention to detail, and adherence to departmental policy and procedures, many incidents involving radioactive iodine-131 may be avoided.

No specific written response is required by this information notice. If you have any questions regarding this matter, please contact the appropriate regional office or this office.

Glen L Sjoblom

Richard Cunningham, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical Contact: Sally Merchant, NMSS
(301) 492-0637

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:
90-50	Minimization of Methane Gas in Plant Systems and Radwaste Shipping Containers	08/08/90	All holders of operating licenses or construction permits for nuclear power reactors
90-44	Dose-Rate Instruments	06/29/90	All NRC licensees
90-38	Requirements for Processing Financial Assurance Submittals for Decommissioning	05/29/90	All fuel facility and materials
90-35	Transportation of Type A Quantities of Non-Fissile Radioactive Materials	05/24/90	All U.S. Nuclear Regulatory Commission (NRC) Licensees
90-31	Update on Waste Form and High Integrity Container Topical Report Review Status, Identification of Problems with Cement Solidication, and Reporting of Waste Mishaps	05/04/90	All holders of operating licenses or construction permits for nuclear power reactors, fuel cycle licenses, and certain byproduct materials licenses
90-27	Clarification of the Recent Revisions to the Regulatory Requirements for Packaging of Uranium Hexafluoride (UF_6) for Transportation	04/30/90	All Uranium Fuel Fabrication and Conversion Facilities
90-24	Transportation of Model SPEC 2-T Radiographic Exposure Device	04/10/90	All NRC licensees authorized to use, transport, or operate radiographic exposure devices and source changers
90-20	Personnel Injuries Resulting from Improper Operation of Radwaste Incinerators	03/22/90	All NRC licensees who process or incinerate radioactive waste

LIST OF RECENTLY ISSUED
NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
90-58	Improper Handling of Ophthalmic Strontium-90 Beta Radiation Applicators	9/11/90	All NRC medical licensees.
90-57	Substandard, Refurbished Potter & Brumfield Relays Misrepresented As New	9/5/90	All holders of OLs or CPs for nuclear power reactors.
90-56	Inadvertent Shipment of A Radioactive Source In A Container Thought To Be Empty	9/4/90	All U.S. Nuclear Regulatory Commission (NRC) licensees.
90-55	Recent Operating Experience on Loss of Reactor Coolant Inventory While In A Shutdown Condition	8/31/90	All holders of OLs or CPs for nuclear power reactors.
83-44 Supp. 1	Potential Damage to Redundant Safety Equipment As A Result of Backflow Through the Equipment and Floor Drain System	8/30/90	All holders of OLs or CPs for nuclear power reactors.
90-54	Summary of Requalification Program Deficiencies	8/28/90	All holders of OLs or CPs for nuclear power reactors.
89-18 Supp. 1	Criminal Prosecution of Wrongdoing Committed by Suppliers of Nuclear Products or Services	8/24/90	All holders of OLs or CPs for nuclear power reactors.
90-53	Potential Failures of Auxiliary Steam Piping and the Possible Effects on the Operability of Vital Equipment	8/16/90	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
CP = Construction Permit

SSINS No: 6835
IN 85-61
Supplement No. 1

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT
WASHINGTON, D.C. 20555

April 15, 1987

IE INFORMATION NOTICE NO. 85-61, SUPPLEMENT 1: MISADMINISTRATIONS TO PATIENTS UNDERGOING THYROID SCANS

Addressees:

All licensees authorized to use byproduct material for human applications.

Purpose:

This notice supplements IE Information Notice 85-61 (attached). It is expected that licensees will review this supplemental information for applicability to their activities and consider actions, if appropriate, to preclude further iodine-131 misadministrations. However, suggestions contained in this information notice do not constitute NRC requirements; therefore, no specific actions or written response is required.

Description of Circumstances:

Since the original notice was issued on July 22, 1985, the NRC has reviewed 14 additional iodine-131 misadministrations. The probable causes of these misadministrations are as follows:

- The cause of 8 of the 14 misadministrations can be ascribed to the referring physician's order being misinterpreted or to a miscommunication to the technologists.

- The cause of three other misadministrations can be ascribed to the technologists not being sufficiently familiar with the iodine-131 dosage requirements for thyroid scan procedures that involve scanning the chest area to ensure that the proper dosage was used.

- The cause of the remaining three misadministrations can be ascribed to miscellaneous factors: a patient's identity was not verified before administering the iodine-131 dosage; the technologist selected the wrong iodine-131 capsule from the isotope laboratory and did not assay it to ensure proper dosage before administering it to the patient; and the nuclear medicine physician or radiologist was not aware that part of the patient's thyroid was intact before prescribing the amount of iodine-131 for administration to the patient for a whole-body iodine-131 scan.

Discussion:

Licensees that have experienced such misadministrations have found that the following corrective actions have been effective in preventing iodine-131 misadministrations.

- Provide periodic refresher training for nuclear medicine personnel involved in the performance of thyroid studies that emphasizes the effects on patients resulting from misadministrations involving iodine-131. Maintain records of such training.

- For licensees conducting infrequent or nonroutine nuclear medicine procedures involving the administration of iodine-131, ensure that the authorized user, and any physicians under the supervision of the authorized user, as well as the technologists involved are sufficiently familiar with these procedures so that they will be properly conducted.

- Establish a manual that contains the proper procedures for each of the nuclear medicine studies (i.e., thyroid uptake, thyroid uptake and scan, thyroid neck and chest, thyroid whole-body scan, etc.).

- Ensure that all thyroid studies referred to the nuclear medicine department involving the administration of iodine-131 will be in written form and the authorized user, or any physicians under the supervision of the authorized user, will prescribe an appropriate thyroid study for the particular patient conditions. For example, interview the patient, obtain additional information from the referring physician if needed, examine the patient, and sign the iodine-131 thyroid study prescription.

- Instruct all personnel involved in the performance of iodine-131 studies to request clarification from the prescribing physician if any element of a prescription or procedure is unclear, ambiguous, or apparently erroneous.

- Before each administration to a patient (adult or child), always calculate the required dosage for the prescribe procedure, and then ensure the correct dosage is prepared by calibrating that dose in the dose calibrator.

- Ensure compliance with 10 CFR 35.53, measurement of radiopharmaceutical dosages, §35.60, syringe shields and labels, and §35.61, vial shields and labels prior to administration of iodine-131, and maintain records of dosage disposition.

No specific written response is required by this information notice. If you have any questions regarding this matter, please contact the Regional Administrator of the appropriate NRC regional office or this office.

Glen L Godlow for

James G. Partlow, Director
Division of Inspection Programs
Office of Inspection and Enforcement

Technical Contact: H. Karagiannis, IE
(301) 427-9030

Attachments:
1. IE Information Notice No. 85-61
2. List of Recently Issued IE Information Notices

SSINS No.: 6835
IN 85-61

Attachment 1
IN 85-61 Supplement 1
April 15, 1987

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT
WASHINGTON, D.C. 20555

July 22, 1985

IE INFORMATION NOTICE NO. 85-61: MISADMINISTRATIONS TO PATIENTS UNDERGOING THYROID SCANS

Addressees:

Licensees authorized to use byproduct material for human applications.

Purpose:

This information notice is intended to alert recipients of potentially significant problems pertaining to human applications of byproduct material. In four recent cases, because of errors, patients received significant, unnecessary radiation exposures. It is expected that licensees will review the information in this notice for applicability to their facilities and consider actions, if appropriate, to preclude similar problems occurring at their facilities. However, suggestions contained in this information notice do not constitute NRC requirements; therefore, no specific action or written response is required.

Description of Circumstances:

In the first case, a referring physician telephoned the hospital to request a "radioactive iodine scan" for his patient. The written request was to be forwarded to the nuclear medicine department at a later date. When the patient arrived at the nuclear medicine department, the written request had not arrived. The nuclear medicine physician did not review the patient's history to evaluate the need for this scan or direct which isotope to use. The nuclear medicine technologist had interpreted the physician's telephone order as a total-body iodine-131 scan and administered a 5 millicurie dosage of iodine-131 to the patient. When the written request arrived at the hospital the next day, the request was for a "thyroid scan," which required a 5 millicurie dosage of technetium-99m. As a result of the misadministration, the patient received a dose of from 6500 to 9000 rads to the thyroid instead of the 0.7 rads that would have resulted from the use of technetium-99m.

In the second case, a 5 millicurie dosage of iodine-131 was administered to the wrong patient. The patient's identification was not verified and the iodine-131 was administered to a patient that was supposed to receive a 5 millicurie dosage of technetium-99m.

In the third case, because of incorrect patient scheduling, a 10 millicurie dosage of iodine-131 was administered to a patient instead of the intended 400 microcurie dosage of iodine-123. The nuclear medicine physician had not reviewed the patient's previous history and had not approved the nuclear medicine procedure and related dosage.

In the fourth case, a patient, who was scheduled for a thyroid uptake and scan, received a dose of 1000 microcuries of iodine-131 instead of the intended 100 microcuries of iodine-131. The hospital staff reported that this misadministration occurred because the involved personnel were unfamiliar with this clinical procedure, which was not frequently performed.

Discussion:

Checking the patient's identification and previous history before approving nuclear medicine procedures is very important, especially where a high dose to the patient will result from the procedure. It also is important for licensees to establish written procedures for dosage preparation and administration and to check the referring physician's written request before administering the dosage.

No specific action or written response is required by this information notice. If you have any questions regarding this matter, please contact the Regional Administrator of the appropriate NRC regional office or this office.

James G. Partlow, Director
Division of Inspection Programs
Office of Inspection and Enforcement

Contact: Harriet Karagiannis, IE
(301) 492-9655

Attachment:
List of Recently Issued IE Information Notices

Attachment
IN 85-61
July 22, 1985

LIST OF RECENTLY ISSUED
IE INFORMATION NOTICES

Information Notice No.	Subject	Date of Issue	Issued to
85-60	Defective Negative Pressure Air-Purifying, Fuel Facepiece Respirators	7/17/85	All power reactor facilities holding an OL or CP
85-59	Valve Stem Corrosion Failures	7/17/85	All power reactor facilities holding an OL or CP
85-58	Failure Of A General Electric Type AK-2-25 Reactor Trip Breaker	7/17/85	All power reactor facilities designed by B&W and CE holding an OL or CP
85-57	Lost Iridium-192 Source Resulting In The Death Of Eight Persons In Morocco	7/16/85	All power reactor facilities holding an OL or CP; fuel facilities; and material licensees
85-56	Inadequate Environment Control For Components And Systems In Extended Storage Or Layup	7/15/85	All power reactor facilities holding an OL or CP
85-55	Revised Emergency Exercise Frequency Rule	7/15/85	All power reactor facilities holding an OL or CP
85-54	Teletheraphy Unit Malfunction	7/15/85	All NRC licensees authorized to use teletheraphy units
85-53	Performance Of NRC-Licensed Individuals While On Duty	7/12/85	All power reactor facilities holding an OL or CP
85-52	Errors In Dose Assessment Computer Codes And Reporting Requirements Under 10 CFR Part 21	7/10/85	All power reactor facilities holding an OL or CP

OL = Operating License
CP = Construction Permit

Attachment 2
IN 85-61 Supplement No. 1
April 15, 1987

LIST OF RECENTLY ISSUED
IE INFORMATION NOTICES

Information Notice No.	Subject	Date of Issue	Issued to
87-19	Perforation and Cracking of Rod Cluster Control Assemblies	4/9/87	All Westinghouse power PWR facilities holding an OL or CP
87-18	Unauthorized Service on Teletherapy Units by Nonlicensed Maintenance Personnel	4/8/87	All NRC licensees authorized to use radioactive material in teletherapy units
87-17	Response Time of Scram Instrument Volume Level Detectors	4/7/87	All GE BWR facilities holding an OP or CP
87-16	Degradation of Static "O" Ring Pressure Switches	4/2/87	All LWR facilities holding an OL or CP
87-15	Complaince with the Posting Requirements of Subsection 223b of the Atomic Energy Act of 1954, as Amended	3/25/87	All power reactor facilities holding a CP and all firms supplying components or services to such facilities
87-14	Actuation of Fire Suppression System Causing Inoperability of Safety-Related Ventilation Equipment	3/23/87	All power reactor facilities holding an OL or CP
86-106 Sup. 2	Feedwater Line Break	3/18/87	All power reactor facilities holding an OL or CP
87-13	Potential for High Radiation Fields Following Loss of Water from Fuel Pool	2/24/87	All power reactor facilities holding an OL or CP except Fort St. Vrain.
86-106 Sup. 1	Feedwater Line Break	2/13/87	All power reactor facilities holding an OL or CP
87-12	Potential Problems With Metal Clad Circuit Breakers, General Electric Type AKF-2-25	2/13/87	All power reactor facilities holding an OL or CP

OL = Operating License
CP = Construction Permit