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Ser OEM/000773
12 APR 2005

From: Commanding Officer, Navy Environmental Health Center

Subj: NAVAL RADIOACTIVE MATERIALS PERMIT (NRMP) INFORMATION NOTICE 2005-01: RECENT MEDICAL EVENTS AND OTHER ADVERSE EVENTS AND INCIDENTS

Ref: (a) U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, NUREG/BR-0117, No. 04-01, March 2004
(b) U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, NUREG/BR-0117, No. 04-02, June 2004
(c) U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, NUREG/BR-0117, No. 04-04, December 2004
(d) Title 10, Code of Federal Regulations (CFR), Part 35

Encl: (1) Recent Medical Events and Other Significant Events Reported by the U.S. Nuclear Regulatory Commission
(2) Recent Incidents and Adverse Events Under the NRMP Program

1. This information notice is issued to make NRMP permittees aware of the various medical events and other adverse events and incidents that have recently occurred, and have been made public by the U.S. Nuclear Regulatory Commission (NRC) in references (a) through (c). In addition, NRMP permittees also need to be aware of significant adverse events and incidents that have occurred at medical facilities within the Navy under the NRMP program. The dissemination of this information notice has been authorized by the Naval Radiation Safety Committee, OPNAV (N455).

2. It should be noted that even though there have been no recent "medical events" within the Navy, as defined by the NRC in reference (d), the significant events reported by the NRC and appended as enclosure (1) are also applicable to medical facilities within the Navy. In addition, a significant number of adverse events and incidents have also occurred within the Navy, with only one being reportable to the NRC. However, many of these had the potential to be much more severe and could have also been reportable to the NRC. A listing of significant adverse events under the NRMP program is appended as enclosure (2).

3. Each permittee's Radiation Safety Committee (RSC) shall review enclosures (1) and (2) and determine applicability to their facility. In addition, policies and procedures shall be reviewed to ensure that they are adequate to prevent such an incident from occurring. Appropriate training shall also be conducted to ensure that staff members are knowledgeable of the types of incidents that have occurred, and how to prevent them from occurring. Note that many of these incidents have involved well-trained individuals that have become complacent in their daily activities.

Note that every staff member is held accountable for ensuring that policies and procedures are followed, and that every patient should be given the best and most appropriate care.

4. Permittee's shall document their RSC's review of this Information Notice, as well as applicable training of their staff. No formal reply is required.

5. For additional information, please contact LCDR Brian D. Pomije, MSC, USN, Radiation Health Team Leader, at DSN 377-0766 or (757) 953-0766, Fax (757) 953-0685, or e-mail at pomijeb@nehc.med.navy.mil.

B. D. POMIJE
By direction

Distribution:
All Medical NRMP Permittees
NSHS, Portsmouth, VA (Attn: Clinical Nuclear Medicine School)

Copy to:
BUMED (M3F71)
OPNAV (N455)

Recent Medical Events and Other Significant Events Reported by the U.S. Nuclear Regulatory Commission

A. MEDICAL EVENTS CAUSED BY FAILURE TO PROPERLY MEASURE THE RADIOACTIVITY OF SAMARIUM-153 DOSAGES

1. Seven medical events were reported to the U.S. Nuclear Regulatory Commission (NRC), between November 2003 and January 2004, each involving licensee failure to properly measure the radioactivity of samarium-153 dosages with dose calibrators. One medical event occurred when both a nuclear pharmacy and a medical licensee failed to properly measure the radioactivity of a samarium-153 unit dosage. During initial measurement of the dosage radioactivity, the nuclear pharmacy erroneously multiplied the dose-calibrator displayed radioactivity by a "10 factor." However, the dose calibrator was set to display the actual radioactivity. Therefore, the nuclear pharmacy labeled the dosage vial to indicate 10 times the actual radioactivity before transfer to a medical licensee. When the medical licensee measured the dosage, it noted that the radioactivity displayed on its dose calibrator was approximately one-tenth of that on the vial label and the prescribed radioactivity on the written directive. The medical licensee contacted the nuclear pharmacy to discuss the discrepancy between the radioactivity measured with its dose calibrator and that indicated on the label. The nuclear pharmacy informed the technologist that a "10 factor" had to be applied to the radioactivity measured by the dose calibrator to obtain the actual radioactivity. The medical licensee applied the factor provided by the nuclear pharmacy and erroneously determined that the dosage contained the prescribed radioactivity, before administering it to a patient. As a result, the patient received approximately one-tenth of the prescribed samarium-153 radioactivity.

2. Six other medical events occurred because a medical licensee used an incorrect dose calibrator potentiometer setting during measurement of the radioactivity in samarium-153 dosages. As a result, the administered radioactivities were approximately 30 percent less than prescribed.

3. On June 12, 2002, the NRC issued Information Notice (IN) 2002-19, "Medical Misadministrations caused by Failure to Properly Perform Tests on Dose Calibrators for Beta- and Low-Energy Photon- Emitting Radionuclides." The IN described the circumstances of medical misadministrations that occurred as a result of inaccurate radioactivity measurement of samarium-153 dosages and some of the potential sources of errors in measurement of beta- and low-energy gamma emitters. Based on the recent medical events described above, licensees/permittees are encouraged to review the IN and to verify that the radioactivities of beta- and low-energy gamma-emitting dosages are properly measured. This IN can be found on NRC's website at http://www.nrc.gov/reading-rm/doc-collections/gencomm/info-notices/2002/in02019.pdf.

B. SIGNIFICANT MEDICAL EVENTS

1. **(Dose to Fetus):** November 20, 2003; Hillcrest Hospital, Mayfield Heights, Ohio

***Nature and Probable Causes*:** The Ohio Bureau of Radiation Protection reported that a 19-year-old female patient was administered 5.18 gigabecquerel (140.1 millicurie) of Iodine-131 for thyroid carcinoma as prescribed. The patient did not believe that she was pregnant and completed the required forms indicating that she was not pregnant before the dose was

administered. On December 5, December 8, and December 11, 2003, quantitative tests confirmed that the patient was pregnant. The results were provided to her endocrinologist, who recommended that a fetal dose calculation be performed. The licensee's consultant informed the endocrinologist that the fetus would have received a whole body dose of 19.6 centigray (rad). The endocrinologist sent the results to the Center for Human Genetics at the University Hospital in Cleveland, Ohio, where an assessment determined that the pregnancy could safely continue.

***Actions Taken to Prevent Recurrence*:** Licensee: The licensee has implemented pregnancy testing for child-bearing-age female patients receiving radiation therapy.

2. **(Overdose of Radioiodine):** January 29, 2004, Department of Veterans Administration, Boston, Massachusetts

***Nature and Probable Causes*:** The licensee reported that a patient was administered 19.8 megabecquerel (MBq)(535 microcurie (μCi)) of Iodine-131 (I-131), instead of the prescribed 0.19 MBq (5 μCi). The verbal order from the authorized user for a 0.19 MBq (5 μCi) dose was misunderstood and an 18.5 MBq (500 μCi) dose was ordered. After the event was discovered, the patient was given a thyroid blocking solution. Based on the patient's resultant thyroid uptake, the licensee computed a dose to the thyroid of approximately 86 centisievert (rem). The root causes of this event included: (1) inadequate procedures (the licensee's procedures did not include the use of I-131 for this procedure because I-123 is normally used); (2) the failure of the nuclear medicine technologist to follow procedures for studies requiring a written directive; and (3) the failure to communicate the dose order clearly.

***Actions Taken to Prevent Recurrence*:** Licensee: Corrective actions include procedure modification and a review of the education and competency training for nuclear medicine technologists.

3. **(Dose to Fetus):** April 20, 2004, Department of Veterans Affairs, North Little Rock, Arkansas

***Nature and Probable Causes*:** The licensee reported an event involving a dose to a fetus at the Veterans Affairs Medical Center in Birmingham, Alabama. The patient signed a form stating that she was not pregnant and a blood sample was obtained for a serum pregnancy test. However, when the licensee retrieved the pregnancy test result, the result from a test performed two months previously was erroneously retrieved; that test result was negative for pregnancy. The patient was then orally administered 0.222 megabecquerel (6 microcuries) of Iodine-131 sodium iodide on April 20, 2004. On April 21, 2004, the patient was intravenously administered 0.444 gigabecquerel (12 millicuries) of Technetium-99m pertechnetate. After both dosages were administered, the licensee discovered that the patient was pregnant. An ultrasound test was used to determine gestation was at 9 to 11 weeks. The dose to the fetal thyroid was estimated to be 6.6 centisieverts (rem) if the thyroid was functioning, or 0.5 to 1 centisieverts (rem) if the thyroid was not functioning. The most likely dose to the fetus and fetal thyroid was estimated at less than 1 centisievert (rem), based on a fetal age of 10 weeks. The root cause was the failure to follow procedures and/or inadequate procedures.

Actions Taken to Prevent Recurrence: Corrective actions include retraining nuclear medicine staff and requiring authorization by the radiation safety officer before administering any therapeutic dose to female patients of childbearing age. In addition, procedures will be modified to require a staff nuclear medicine physician to acknowledge pregnancy test results and give approval in writing.

4. **(Dose to Wrong Patient):** May 10, 2004; University Hospital, Cincinnati Ohio

Nature and Probable Causes: The licensee reported that a patient was administered 74 megabecquerel (2 millicuries) of Iodine-131 (I-131) instead of the prescribed dose of 7.4 megabecquerel (200 microcuries) of Iodine-123 (I-123). The patient scheduled to receive the I-123 dose responded affirmatively to being the patient that was scheduled to receive the I-131 dose. The mistake occurred because the technologist did not follow procedures regarding proper patient identification. An investigation by the Ohio Department of Health occurred on May 11-12, 2004. The licensee's corrective actions were deemed adequate.

Actions Taken to Prevent Recurrence: Corrective actions included modification of the Quality Management Program to delete visual recognition of patients as a means of patient identification, and replacing this with verification via photo identification. Another action included reemphasis of the need to thoroughly check patient identification using two approved methods.

5. **(Overdose of Radioiodine):** August 10, 2004; Northeast Alabama Regional Medical Center, Birmingham, Alabama

Nature and Probable Causes: The licensee reported that a patient received 111 megabecquerel (3 millicuries) of Iodine-131 (I-131) for the assessment of metastatic thyroid disease instead of the prescribed dose of 0.93 megabecquerel (25 microcuries). The imaging technologist misunderstood the referring physician's order and the authorized user did not approve the dose. The referring physician and patient were notified of the event. As a result of the dose, the patient could eventually become hypothyroid.

Actions Taken to Prevent Recurrence: Corrective measures included re-instructing personnel and ensuring that the authorized user approves all procedures.

C. SIGNIFICANT EVENTS RESULTING IN NRC VIOLATIONS

1. **(Brachytherapy):** March 19, 2004; Guthrie Healthcare System (EA-04-025)

Summary of Violation: A Notice of Violation was issued for a Severity Level III violation. This involved the failure to follow the requirements of the licensee's written Quality Management Plan. This required developing a second radiation dosimetry plan, based on actual distribution of prostate implant sources, relative to the prostate gland, as seen by localization radiographs, for 26 out of 30 patients treated with prostate implants, between January 2001 and January 2002.

2. **(RAM Security):** April 7, 2004; Department of Veterans Affairs (EA-04-019)

***Summary of Violation*:** A Notice of Violation was issued for a Severity level III violation involving the failures: (1) to secure from unauthorized removal, or limit access to, licensed material [5.55 gigabecquerel (GBq) (approximately 150 millicuries(mCi) of molybdenum-99 in a molybdenum-99/technetium-99m generator; 4.14 GBq (112 mCi) in four cesium-137 sealed sources; and 4.33 GBq (117 mCi) in two strontium-90 sealed sources] in a controlled area; and (2) to control and maintain constant surveillance of this licensed material.

3. **(RAM Security):** April 23, 2004; Department of the Navy - National Naval Medical Center (NNMC), Bethesda (EA-04-075)

***Summary of Violation*:** A Notice of Violation was issued for a Severity Level III violation involving the failures: (1) to secure from unauthorized removal, or limit access to, licensed material [999 megabecquerel (approximately 27 millicuries (mCi) total activity included in iridium-192 seeds] in a controlled area; and (2) to control and maintain constant surveillance of this licensed material.

Enclosure (2) has intentionally been removed from this document.

For a copy of Enclosure (2),
please contact Navy Environmental Health Center (NAVENVIRHLTHCEN).