DEPARTMENT OF THE NAVY
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From: Commanding Officer, Navy Environmental Health Center

Subj: NAVAL RADIOACTIVE MATERIALS PERMIT (NRMP) INFORMATION NOTICE 2006-01: 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. 05-01, March 2005
(b) U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, NUREG/BR-0117, No. 05-02, June 2005
(c) U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, NUREG/BR-0117, No. 05-03, September 2005
(d) U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, NUREG/BR-0117, No. 05-04, December 2005
(e) U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, NUREG/BR-0117, No. 06-01, March 2006
(f) U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, NUREG/BR-0117, No. 06-02, June 2006
(g) Title 10, Code of Federal Regulations, Part 35 (10 CFR 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 (f). These and other quarterly newsletters can be accessed online at http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0117/. 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 (g), 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 recently within the Navy, but none were reportable to the NRC. However, many of these had the potential to be more severe and could have also been reportable to the NRC. The NRC's enforcement program can be accessed via the NRC's homepage [http://www.nrc.gov/] under "What We Do," and documents to cases can be accessed under "Electronic Reading Room," "Documents in

ADAMS." A listing of significant adverse events under the Navy's NRMP program is appended as enclosure (2). These events were self-identified by each command, and reported to the Navy Environmental Health Center.

3. It should be noted that beginning in 2007, the NRC will begin regulating accelerator-produced radioactive material (NARM) in addition to byproduct material, as well as certain discrete sources of naturally occurring radioactive material (NORM). This means that certain medical events and incidents may require reporting to the NRC in the near future.

4. Each permittee's Radiation Safety Committee (RSC) should review enclosures (1) and (2) and determine applicability to their facility. In addition, policies and procedures should be reviewed to ensure that they are adequate to prevent such an incident from occurring. Appropriate training should 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. Many of these incidents have involved well-trained individuals that became complacent in their daily activities. 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.

5. 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.

6. 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 Use NRMP Permittees
NSHS, Portsmouth, VA (Attn: Clinical Nuclear Medicine School)

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

A. SIGNIFICANT MEDICAL EVENTS

1. **(Unintended Brachytherapy Doses):** February 23, 2004; Saint Joseph Regional Medical Center

***Nature and Probable Causes*:** Licensee reported that five patients who received brachytherapy treatments for endometrial cancer, received radiation doses to the wrong location. The 1st patient was treated in January 2004; the 2nd and 3rd patients in February 2004; and the 4th and 5th patients in March 2004. A new Wang vaginal applicator was used during the procedures. The tandem device was loaded with Cs-137 sources manufactured by Amersham. The tandem device was designed to use 3M brachytherapy sources, and not the Amersham sources. The Amersham sources were too small for use in the tandem device, causing the sources to slide out of position and irradiate the inner thigh whenever the patients moved into a more up-right position. Approximately 2 weeks after treatment, three patients developed ulcerations on the skin of the inner thigh. Dose calculations indicated unintended doses ranging from 1500 and 2000 centigray (cGy) [rad]. Despite the unintended doses to the inner thigh, the licensee believed that the patients received the respective prescribed doses to the treatment areas based on clinical observations. All patients were notified of the error.

***Actions Taken to Prevent Recurrence*:** Licensee retrained personnel and replaced the applicator with one that will accept both source sizes.

2. **(Infant Overexposure and Written Directive Violation):** March 9, 2005; St. Johns Mercy Hospital Center

***Nature and Probable Causes*:** Licensee reported that a 5 month-old infant was prescribed 18.5 megabecquerel (MBq) (0.5 millicuries (mCi)) of Tc-99m myoview sulfur colloid, but instead received 414.4 MBq (11.2 mCi). Personnel did not look at the label when measuring the dose to be administered. The whole body dose to the infant was calculated to be between 5.2 and 10 centisievert (cSv) [rem]. The physician had informed the infant's parents.

***Actions Taken to Prevent Recurrence*:** Licensee's corrective actions included counseling the technologist, revising procedures, and retraining staff.

3. **(Dose to Fetus):** November 16, 2004; Riverside Methodist Hospital

***Nature and Probable Causes*:** Licensee reported that a pregnant patient was administered 7.59 MBq (205 microcuries (μCi)) of I-123 radioiodine on November 2, 2004, during an uptake study pursuant to a diagnosis of hyperthyroidism. On November 16, 2004, the patient was administered 469.9 MBq (12.7 mCi) of I-131 radioiodine as treatment. Before this administration, the patient had been counseled regarding pregnancy and acknowledged in writing that she was not and could not be pregnant at that time. A pregnancy test was not performed to confirm this declaration. Later, the patient saw her physician because of abdominal pain. A radiograph of the abdomen revealed the pregnancy. A prenatal specialist determined that the fetus was 17 weeks old at the Time of the I-131 administration. The fetal whole body dose was estimated at 2.04 cGy [rad] and the thyroid dose at 22,400 cGy [rad]. It was subsequently

determined that the licensee had followed all required procedures. The fetus was carried full term; however, the fetus did suffer hyperthyroidism and required treatments in-utero to mitigate the effects of hyperthyroidism.

***Actions Taken to Prevent Recurrence*:** Licensee has implemented a policy of performing a serum pregnancy test and receiving the results within 80 hours of administration of therapeutic amounts of I-131. This test will be performed on all women 13 to 50 years of age, unless the women have been surgically sterilized.

B. SIGNIFICANT ENFORCEMENT ACTIONS

1. **(Lack of Program Oversight and Control):** March 31, 2005; Good Samaritan Regional Medical Center

***Summary of Violation*:** A Notice of Violation (NOV) was issued for a Severity Level III problem involving twelve violations indicating a lack of appropriate oversight and control of the brachytherapy program, including a programmatic weakness in the implementation of written directives.

2. **(Unintended Brachytherapy Doses):** September 23, 2005; Saint Joseph Regional Medical Center

***Summary of Violation*:** An NOV and proposed civil penalties in the amount of $19,200 was issued for three Severity Level II problems, one Severity Level II violation, and two Severity Level IV violations, associated with brachytherapy treatments that resulted in unintended radiation doses to five patients. Because three of the patients suffered significant health consequences, each of those events is categorized as a separate Severity Level II problem in accordance with NRC enforcement policy. In addition, the licensee became aware that three medical events had occurred and did not notify the NRC until more than a day after they were discovered, contrary to 10 CFR 35.3045(c), which requires notification no later than the next calendar day.

3. **(RAM Security):** September 21, 2005; Mountainside Hospital

***Summary of Violation*:** An NOV was issued for a Severity Level III violation involving the failure to maintain constant surveillance and control of a nuclear imaging camera containing NRC licensed material while in transit. Specifically, the licensee shipped a Siemens Model ECAM without removing the sealed sources from their protective housings inside the camera prior to shipping. A Severity Level IV violation was also cited based on the licensee's failure to provide the required packaging for transport of the camera.

4. **(RAM Security):** September 02, 2005; Boone Hospital Center

***Summary of Violation*:** An NOV and proposed civil penalty in the amount of $3,250 was issued for a Severity Level III violation involving the failure to control and maintain constant surveillance of iodine-125 in a controlled area. Specifically, a cartridge containing iodine-125

seeds was transferred to an unauthorized/untrained licensee employee who subsequently transferred the cartridge to a second unauthorized/untrained licensee employee, who in turn, opened the cartridge and inadvertently lost control of some of the seeds.

5. **(Infant Overexposure and Written Directive Violation):** August 25, 2005; St. John's Mercy Medical Center

***Summary of Violation*:** An NOV was issued for a Severity Level III problem involving a violation of NRC regulations and the licensee's license conditions. Specifically, the NOV cited: (1) the licensee's administration of a dosage in excess of 30 mCi (1.12 MBq) and more than 20 percent different from the prescribed dose, to an infant; and (2) the licensee's failure to check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering the dosage to the patient.

6. **(Submission of Inaccurate Information):** January 27, 2006; Digirad Imaging Solutions, Inc.

***Summary of Violation*:** An NOV for a Severity Level III violation with no civil penalty and an immediately effective Confirmatory Order was issued to confirm commitments made as part of a settlement agreement concerning submission of inaccurate information to the NRC. The settlement agreement was reached as a result of an Alternative Dispute Resolution session, held at the request of the licensee. In addition to the NOV, the licensee has changed its procedures to ensure that any information it submits to the NRC will be complete and accurate, and the RSO will submit articles to various medical and health physics journals describing the incident to provide an opportunity for other licensees in the industry to learn from the incident.

7. **(RAM Security):** January 17, 2006; South Jersey Healthcare

***Summary of Violation*:** An NOV was issued for a Severity Level III violation involving the failure to secure from unauthorized removal, or limit access to, a package containing licensed material which was stored in a mail room (awaiting inter-office transfer). The mail room was an unrestricted area, and the licensee failed to control and maintain constant surveillance of this licensed material.

8. **(RAM Security):** December 13, 2005; Danville Regional Medical Center

***Summary of Violation*:** An NOV was issued for a Severity Level III violation involving the failure to secure from unauthorized removal or access, and/or maintain constant surveillance of licensed material stored in a controlled or unrestricted area. Specifically, a High-Dose-Rate Remote Afterloader (HDR) unit was left unsecured and unattended in the HDR treatment room.

9. **(RAM Security):** October 28, 2005; Crozer-Chester Medical Center

***Summary of Violation*:** Same violation as above for Danville Regional Medical Center.

10. **(Radiopharmaceutical Administration Without the Knowledge nor Approval of an Authorized User):** October 14, 2005; Hershey Medical Center

***Summary of Violation*:** An immediately effective Confirmatory Order was issued to confirm commitments made as part of a settlement agreement concerning three separate occasions where the licensee's staff were injected with radiopharmaceuticals without the authorization of an Authorized User (AU). The settlement agreement was reached as a result of an Alternate Dispute Resolution session, held at the request of the licensee. As part of the agreement reached, a NOV at a Severity Level III, with no civil penalty, was issued to the facility. In addition, the licensee has expanded its training program addressing NRC regulatory requirements, and the Chief of Nuclear Medicine, the RSO, and the Chief Technologist will prepare articles, for various medical and health physics journals, that address, among other topics, the need to establish an environment and culture that promote regulatory compliance through the implementation of controls and procedures.

11. **(Radiopharmaceutical Administration Without the Knowledge nor Approval of an Authorized User):** February 15, 2005; Washington Hospital Center

***Summary of Violation*:** An NOV was issued for a willful Severity Level III violation involving the use of licensed radioactive material in humans by an individual who was not an AU and who was not under the supervision of an AU. The violation occurred when a Nuclear Medicine Technologist was injected with a diagnostic dosage of Tc-99m without the knowledge nor approval of a physician or AU. An NOV was also issued directly to the Nuclear Medicine Technologist for a Severity Level III violation based on his deliberate activities.

12. **(RAM Security):** May 04, 2006; Washington Hospital Center

***Summary of Violation*:** An NOV was issued for a willful Severity Level III violation involving deliberate failure to secure, from unauthorized removal, and failure to maintain constant surveillance over licensed material. Specifically, the lock on the door to the hot lab, a controlled area containing licensed material, had been deliberately disabled with tape to allow ease of access, and the hot lab was left unattended with the door lock disabled.

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

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