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

Subj: NAVAL RADIOACTIVE MATERIALS PERMIT (NRMP) INFORMATION NOTICE 2007-02: 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. 06-03, September 2006
(b) U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, NUREG/BR-0117, No. 06-04, December 2006
(c) U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, NUREG/BR-0117, No. 07-01, May 2007
(d) U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, NUREG/BR-0117, No. 07-02, July 2007
(e) 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 occurred recently, and have been made public by the U.S. Nuclear Regulatory Commission (NRC) in references (a) through (d). 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) and BUMED (M3B42).

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 (e), the significant events reported by the NRC and appended as enclosure (1) may also be applicable to medical facilities within the Navy. In addition, a number of adverse events and incidents have also occurred 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 at 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 sometime later this year; the NRC will begin regulating naturally occurring and accelerator-produced radioactive material (NARM), which will be included in the definition of byproduct material. 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 incidents 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 at their facility. Many of these incidents have involved well-trained individuals that became complacent in their daily activities. Every staff member should be 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 CDR S. L. Gaiter, MSC, USN, Radiation Health Team Leader at DSN 377-0766 or (757)

953-0766, Fax (757) 953-0670, or by e-mail at schleurious.gaiter@med.navy.mil.

B. D. POMIJE
By direction

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

Copy to:
OPNAV (N455)
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Recent Medical Events and Other Significant Events Reported by the U.S. Nuclear Regulatory Commission

A. SIGNIFICANT MEDICAL EVENTS

1. **(Brachytherapy Overdose - Prostate Seed Implant)**: May 9, 2006; Bozeman, Montana.

Nature and Probable Causes: Licensee reported a medical event involving dose to an unintended site. The incident was identified during the post-implant CT scan of a prostate implant patient. A total of 88 Iodine-125 (I-125) seeds, with a total activity of 1.12 gigabecquerel (GBq)(30.3 millicuries (mCi)) were implanted. However, three seeds were recovered after the procedure. The CT scan confirmed that most of the seeds were located in an area surrounding the urethra instead of in the prostate. The licensee has estimated that the radiation dose to the unintended site was 14,500 centigray (cGy)(rad). The physician advised the patient of the possible side effects.

Actions Taken to Prevent Recurrence: Licensee had not yet taken corrective actions at the time the newsletter was printed.

2. **(Brachytherapy Underdose - High Dose Rate (HDR) Remote Afterloader)**: June 5, 2006; Oklahoma City, Oklahoma.

Nature and Probable Causes: Licensee reported an administration that was 68 percent less than prescribed during one of a series of brachytherapy doses to a patient. The patient received 116 cGy (rad) instead of the prescribed 360 cGy (rad). This was the first use of the new HDR modality mammosite treatment equipment. An Iridium-192 (Ir-192) source (Varian) with an activity of 222 GBq (6 Curies (Ci)) was used. The quality control (QC) on the instrument was performed before the patient treatment. The treatment plan was exported from the dosimetry computer to the HDR control computer. The computer, or personnel, chose the plan used for the QC and not the patient's plan. The computer interpreted the plan to mean that a particular amount of dose had already been given. Inspection of the computer records revealed that the exposure had been stopped during treatment. The licensee informed the patient of the discrepancy.

Actions Taken to Prevent Recurrence: Corrective actions taken by the licensee included performing the QC activity in a way that can't be confused with the therapy.

3. **(Brachytherapy Overdose - Prostate Seed Implant)**: July 10, 2006; Akron, Ohio.

Nature and Probable Causes: Licensee reported that a patient prescribed to receive a prostate seed implant procedure received seeds with 27 percent higher activity than intended. The licensee stated that the default seed strength of the computer planning system is specified in air kerma units; however, the activity of the seeds was entered in units of mCi. When the seeds for this patient were ordered, the activity was not changed to mCi. The patient was prescribed to receive 111 I-125 seeds, each with an activity of 14.58 megabecquerel (MBq) (0.394 mCi). The patient was implanted with the seeds that had an activity of approximately 18.5 MBq (0.5 mCi) each. The physician, patient, and State of Ohio were notified.

Actions Taken to Prevent Recurrence: Licensee had not yet taken corrective actions at the time the newsletter was printed.

4. **(Lost radioactive seeds)**: October 4, 2006; Spokane, Washington.

Nature and Probable Causes: The licensee reported two damaged shipping packages containing Cesium-131 (Cs-131) cancer therapy seeds. The shipping company discovered a flattened lead cap in its Spokane, Washington, terminal. A partial label on the cap indicated it came from one of two packages containing 63 Cs-131 seeds with a total activity of 12.2 GBq (330 mCi). The second package was found crushed, but essentially intact; all seeds were present and undamaged. Scraps from the first package were found on the runway and on the floor of an airport vehicle. Washington Department of Health (DOH) personnel responded to the scene, and the licensee also dispatched a team to the site. DOH personnel were able to recover three of the 63 seeds from the first package. Several areas of radioactive contamination and radiation exposure were located, with the highest level of contamination at 400 counts per minute, and the highest level of exposure at approximately 25 milliroentgen per hour (mR/hr) or 6.54×10^{-5} Coulombs per kilogram per hour ($C\text{-}kg^{-1}\text{-}hr^{-1}$).

Actions Taken to Prevent Recurrence: Washington DOH requested that the shipping company's management revise its hazardous material transportation-handling procedures and provide refresher training to staff.

5. **(Brachytherapy Medical Event Due to Error with Treatment Planning System)**: March 7, 2007; New York.

Nature and Probable Causes: The licensee reported a brachytherapy misadministration event to the New York State Department of Health. The event involved a 31 year old female patient with a history of vaginal cancer. The treatment involved the use of both Cesium-137 (Cs-137) and Ir-192 seeds. The licensee ordered 11 ribbons of Ir-192 seeds from Best Industries. Each ribbon contained 8 seeds with an activity of 1.855 milligram radium equivalent (3.19 mCi, or 118 MBq) per seed. The patient was to be administered a total dose of 2,500 cGy (rad) via interstitial brachytherapy, to be delivered to the 50 cGy (rad) isodose line for a total treatment time of 50 hours. On March 6, 2007, a Syed template was used to place the Ir-192 seeds into the patient, and the Cs-137 seeds were placed into the patient using a tandem applicator. Late in the morning of March 7, 2007, the medical physicist performed a manual check of the treatment plan calculations, and discovered that the hand calculations indicated a significantly higher dose rate than what was generated using the treatment planning software. The ensuing investigation, which took several hours, revealed that the original treatment plan was in error. At 5:30 p.m. on March 7, 2007, after 27 hours of treatment, the seeds were removed from the patient. The patient received an estimated dose of 4,590 cGy (rad) to the treatment site, rather than the intended 2,500 cGy (rad). The rectal dose was 7,300 cGy (rad). The radiation oncologist disclosed that the patient is at risk for radiation cystitis, rectal proctitis, and more importantly, fistula formation between the rectum and the vagina. The patient will be monitored closely over the next year by both her gynecologic oncologist and the radiation oncologist. The patient is being treated with broad spectrum antibiotics along with daily treatments in a hyperbaric oxygen chamber. The primary cause was the use of an inappropriate Dose Rate Factor (DRF) in the treatment planning system. The value used corresponded to the DRF for air kerma, however, the seed strength entered was in milligram radium equivalent. Other causes and/or contributing factors include: (1) Failure to check the treatment pre-plan before the seeds arrived although there was time to do so; failure to double check the calculations either prior to the implant or shortly thereafter; (2) the use of a treatment planning system that underwent acceptance testing for Cs-137 and I-125, but not Ir-192; and (3) lack of recent experience preparing a treatment using Ir-192. Neither the physicist nor the radiation oncologist had prepared a treatment using Ir-192 in six years. Due to their recent lack of experience, it would have been prudent to obtain additional review or outside review.

Actions Taken to Prevent Recurrence: Licensee had not yet taken corrective actions at the time the newsletter was printed.

6. **(Medical Event Involving Mammosite Treatment)**: March 19, 2007; Bakersfield, California.

Nature and Probable Causes: The licensee reported that a patient receiving mammosite treatment with a total prescribed dose of 3,400 cGy (rad) to be delivered in 10 fractions over the course of five days, only received 1,700 cGy (rad). The treatment was performed using a Nucletron HDR brachytherapy unit (model 105.999) and an Ir-192 source with an activity of 151.7 GBq (4.1 Ci). The first five fractions were delivered uneventfully. During the last five fractions, the radiation therapy technologist accidentally imported the wrong treatment plan, resulting in an under dose to the treatment area. The dwell position of the source was actually fully outside of the patient, so the tumor received effectively no dose. The licensee is calculating the skin and whole body dose to the patient. The patient and referring physician have been notified and retreatment has been scheduled. The incident was discovered upon review of the patient's chart when the patient returned for a follow-up exam.

Actions Taken to Prevent Recurrence: Licensee had not yet taken corrective actions at the time the newsletter was printed.

7. **(Overdose Due to Pharmacy Error)**: April 24, 2007; Ashville, North Carolina.

Nature and Probable Causes: The State of North Carolina was notified of an event that involved a mis-drawn and mislabeled dose from a pharmacy in Ashville, North Carolina. The written directive from the hospital was for 30 microcuries for a diagnostic thyroid scan, but 33.9 mCi was delivered labeled as 33.9 microcuries. The dose was administered on April 24, 2007, and the error was found on April 26, 2007. The patient and physician were notified, and the licensee is following up with the pharmacy. No information is available on any potential medical impact of the misadministration on the patient. The licensee missed the error because although the numbers were read, the units were not verified (microcuries vs. mCi).

Actions Taken to Prevent Recurrence: Licensee had not yet taken corrective actions at the time the newsletter was printed.

8. **(Exposure to Embryo/Fetus)**: May 29, 2007; St. Louis, Missouri.

Nature and Probable Causes: The licensee reported that cancer treatment to a patient using iodine-131 (I-131) resulted in a dose to an embryo/fetus. The patient was seen by her prescribing physician on May 22, 2007, concerning cancer treatment with I-131. The licensee conducted a pregnancy test on the patient with negative results. The patient was advised not to get pregnant prior to the treatment. On May 29, 2007, the treatment was using 4.64 GBq (125.5 mCi) of I-131. On May 30, 2007, the patient stated that she performed a home pregnancy test with positive results. The licensee performed another test on May 30, 2007, with positive results. Staff calculated a dose to the patient's uterus as an approximation for the dose received by the embryo/fetus. The dose was estimated to be between 25 and 34 cGy (rad). The risk to the embryo/fetus is being determined by the licensee. The possible effects will be discussed with the patient at a future date.

Actions Taken to Prevent Recurrence: Licensee had not yet taken corrective actions at the time the newsletter was printed.

B. SIGNIFICANT ENFORCEMENT ACTIONS

1. **(Failure to Implement Written Procedures for Written Directives)**: July 10, 2006; IUPUI/Indiana University Medical Center.

Summary of Violation: A Notice of Violation (NOV) was issued for a Severity Level III violation involving the licensee's failure to develop, implement, and maintain written procedures to provide high confidence that each administration of NRC-licensed materials is in accordance with the written directive of an authorized user (AU) physician, as required by 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive."

2. **(Failure to Implement Written Procedures for Written Directives and Failure to Notify NRC)**: July 10, 2006; Community Hospitals of Indiana, Inc.

Summary of Violation: A NOV was issued for a Severity Level III problem involving the failure to develop written procedures to provide high confidence that each administration was in

accordance with a written directive. Specifically, the licensee's written procedure for High Dose Rate (HDR) brachytherapy did not describe that the HDR metal interface connector was to be attached during treatment simulation to determine appropriate location of the sources within the patient. In addition, the licensee did not notify the NRC Operations Center by the next calendar day after discovery of the patient medical event.

3. **(Loss-of-Control of Radioactive Material and Failure to Perform Surveys):** July 12, 2006; Southside Community Hospital.

Summary of Violation: A NOV was issued for a Severity Level III violation involving the failure to perform surveys, or secure from unauthorized removal, or limit access to six vials, at least two of which contained I-131. The vials were subsequently disposed of as non-radioactive waste.

4. **(Failure to Implement Written Procedures for Written Directives):** July 21, 2006; Hospital Andres Grillasca, Inc.

Summary of Violation: A NOV was issued for a Severity Level III violation, involving the failure to implement written procedures to provide high confidence that each patient treatment is in accordance with the treatment plan and written directive, and that both manual and computer-generated dose calculations are verified. As a result of the failure to verify that an HDR treatment was administered in accordance with the written directive, a dose was calculated and delivered to a depth of 1 centimeter (cm) rather than the prescribed 2 cm depth, resulting in an underdose of 57 percent.

5. **(Failure To Have Written Directive Prior to Administration Of I-131):** October 20, 2006; St. Joseph Health Center.

Summary of Violation: A NOV was issued for a Severity Level III violation involving the administration of greater than 30 microcuries of I-131 sodium iodide without a written directive that was signed and dated by an authorized user. Specifically, a technologist administered 5.4 mCi of I-131 sodium iodide to a patient that was scheduled to receive 15 microcuries of I-131 sodium iodide, without a written directive that was dated and signed by an authorized user before administering the I-131 sodium iodide dose.

6. **(Failure to Secure Licensed Material)**: November 30, 2006; St. Peter's University Hospital.

Summary of Violation: A NOV was issued for a Severity Level III violation involving the failure to secure licensed material from unauthorized removal or access, and/or maintain constant surveillance of licensed material that was stored in a controlled or unrestricted area. Specifically, on August 2, 2006, an High Dose Reloader (HDR) unit containing Ir-192 was left unsecured and unattended in that the door to the room housing the HDR was open and no staff member was in the immediate vicinity to maintain constant surveillance, contrary to 10 CFR 20.1801 and 10 CFR 20.1802.

7. **(Failure to Secure Licensed Material)**: April 4, 2007; Milton A. Hershey Medical Center.

Summary of Violation: A NOV was issued for a Severity Level III violation involving the failure to secure from unauthorized removal or limit access to radioactive material located in the nuclear medicine department hot lab, which is a controlled area. In addition, the licensee did not control and maintain constant surveillance of this licensed material.

8. **(Failure to Secure a High Dose Rate Afterloader)**: April 5, 2007; Mercy Hospital.

Summary of Violation: A NOV was issued for a Severity Level III violation involving the failure to secure from unauthorized removal or limit access to a HDR Afterloader. The device was stored in a treatment room, and access to which was not restricted as required.

9. **(Submittal of Inaccurate Information to NRC)**: April 30, 2007; Englewood Hospital and Medical Center.

Summary of Violation: A NOV and Proposed Imposition of Civil Penalty in the amount of $3,250 was issued for a Severity Level III problem involving the submittal of inaccurate information to the NRC in support of a request to amend the license to add an individual as an Authorized Medical Physicist.

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

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