

## OFFICE OF RADIATION SAFETY SERVICES (ORSS) – NEWARK CAMPUS

It is expected that all Human Use Licensees will review the following information for applicability to their licensed operations and consider actions, as appropriate, to avoid similar problems discovered at different institutions. However, suggestions contained in this newsletter are not new requirements; therefore, no specific action is required. The following medical events or non-compliance items were discovered by the Nuclear Regulatory Commission (NRC).

### DOSE TO FETUS:

**Date and Place: November 20, 2003; Hillcrest Hospital, Mayfield Heights, Ohio**

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

The licensee has implemented pregnancy testing for child-bearing-age female patients receiving radiation therapy.

### DOSE TO FETUS:

**Date and Place: April 20, 2004; Department of Veterans Affairs, North Little Rock, Arkansas**

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.

## DOSE TO FETUS

**Date and Place: November 16, 2004, Riverside Methodist Hospital, Cleveland, Ohio**

A pregnant patient was administered radioactive iodine. The patient was administered 7.59 Megabecquerel (205 microcuries) of Iodine-123 (I-123) on November 2, 2004, during an uptake study pursuant to a diagnosis of hyperthyroidism. On November 16, 2004, the patient was administered 469.9 Megabecquerel (12.7 millicuries) of Iodine-131 (I-131) as treatment. Before this administration, the patient was 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 dose estimate for the fetus was 2.0432 centigray (rad) to the whole body and 22,400 centigray (rad) to the fetal thyroid from both the I-123 and I-131 administrations. The Ohio Department of Health investigated the licensee on January 28, 2005, and determined that the licensee followed all required procedures. The patient will carry the fetus to term. The prenatal specialist has performed a blood test on the fetus and has confirmed that the fetus has hypothyroidism. An ultrasound test on the fetus showed no abnormalities in fetal development. The prenatal specialist will perform treatments in-utero to mitigate the effects of hypothyroidism.

### **Actions Taken to Prevent Recurrence**

Licensee: The 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.

## DOSE TO WRONG PATIENT:

**Date and Place: May 10, 2004; University Hospital, Cincinnati Ohio**

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.

## OVERDOSE OF RADIOIODINE:

**Date and Place: August 10, 2004; Northeast Alabama Regional Medical Center, Birmingham, Alabama**

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.

### **MEDICAL EVENT AT THE DEPARTMENT OF VETERANS ADMINISTRATION**

**Date and Place: January 29, 2004, Boston, Massachusetts**

A patient was administered 19.8 MegaBecquerel (MBq) (535 microcurie ( $\mu\text{Ci}$ ) of Iodine-131 (I-131), instead of the prescribed 0.19 MBq (5  $\mu\text{Ci}$ ). The verbal order from the authorized user for a 0.19 MBq (5  $\mu\text{Ci}$ ) dose was misunderstood and an 18.5 MBq (500  $\mu\text{Ci}$ ) 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.

### **MEDICAL EVENT AT ST. JOSEPH REGIONAL MEDICAL CENTER**

**Date and Place: February 23, 2004, South Bend, Indiana**

Five patients who received brachytherapy treatments for endometrial cancer, received radiation doses to the wrong location. The first patient was treated in January 2004; the second and third patients in February 2004; and the fourth and fifth patients in March 2004.

A new Wang vaginal applicator was used during the procedures. The tandem device was loaded with Cesium-137 sources, and the sources were manufactured by Amersham. The tandem device was designed to use 3M brachytherapy sources; however, Amersham sources were used. 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, the third, fourth and fifth patients developed ulcerations on the skin of the inner thigh. The licensee's initial calculations estimated the skin doses to be below 50 centisieverts (cSv) (rem). However, the third patient exhibited recurring skin ulcerations, prompting the licensee to reevaluate the calculated doses. The licensee's revised calculations determined that the third patient received an unintended dose to a small area of the skin on the upper thigh of approximately 2000 centigray (cGy) (rad). The fourth patient received an unintended dose to a similar area of the thigh of approximately 1500 to 2000 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. A NRC Region III inspection will review the circumstances surrounding the event and an NRC medical consultant will provide an independent medical evaluation of the probable deterministic effects of the radiation exposures.

### **Actions Taken to Prevent Recurrence**

The licensee retrained personnel and replaced the applicator with one that will accept both source sizes.

### **MEDICAL EVENT AT SADDLEBACK MEMORIAL HOSPITAL**

**Date and Place: January 24, 2005, Laguna Hills, California**

A medical event involving a breast cancer patient treated with a Varian Medical Systems remote high dose rate (HDR) afterloading unit (model VS2000) and Iridium -192 (Ir-192) source with an activity of 277.5 gigabecquerels (7.5 curies). Ten fractional treatments were administered from January 24 to January 28, 2005. The

prescribed dose was 350 centigray (cGy) (350 rad) per fraction at 1 centimeter (cm) from the surface of the balloon, at two fractions per day, for a total of 3500 cGy (rad). The patient returned on March 18, 2005, complaining of pain on her breast. A moist desquamation was noted on the breast surface at the point the catheter had entered the breast. Reevaluation of the treatment plan revealed that the wrong catheter length parameter (source travel distance) was used during the treatment. The Ir-192 source was implanted 8 cm short of its planned location, near the catheter breast entry point. Dosimetry reconstruction indicated that the maximum dose delivered to a tissue area of 2.5 by 2.1 by 0.5 cm, at the entrance port was 7000 cGy (rad).

#### **Actions Taken to Prevent Recurrence**

Corrective actions included instituting a quality assurance checklist requiring two persons to verify and document treatment parameter determinations and correct treatment computer inputs, to include the catheter length parameter. Also, normal catheter length parameters for standard treatments will be documented and checked before treatments. Staff will be trained in these new procedures before using the HDR unit.

### **MEDICAL EVENT AT ST. JOHNS MERCY HOSPITAL CENTER**

#### **Date and Place: March 9, 2005, St. Louis, Missouri**

A 5 month-old infant was prescribed 18.5 megabecquerel (MBq) [0.5 millicuries (mCi)] of Technetium-99m (Tc-99m) myoview sulfur colloid, but instead received 429.2 MBq (11.6 mCi) of Tc-99m myoview sulfur colloid. 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 centisieverts (rem). The physician has informed the infant's parents.

#### **Actions Taken to Prevent Recurrence**

The licensee is determining corrective actions to prevent recurrence.

### **VIOLATIONS ISSUED BY NRC DURING ROUTINE INSPECTIONS**

#### **Washington Hospital Center (EA-04-157)**

A Notice of Violation was issued to Washington Hospital Center for a willful Severity Level III violation involving the use of licensed radioactive material in humans by an individual who was not an authorized user and who was not under the supervision of an authorized user. The violation occurred when a Nuclear Medicine Technologist was injected with a diagnostic dosage of technetium-99m without the knowledge nor approval of a physician or authorized user.

#### **University of Sciences (EA-04-219)**

A Notice of Violation was issued for a Severity Level III violation involving the failure to control and maintain constant surveillance of licensed material in three laboratories that were in unrestricted areas, and where the material was not in storage.

#### **Department of Veteran Affairs, AR (EA-03-162)**

A Notice of Violation was issued for a Severity Level III violation involving the failure to secure from unauthorized removal, or limit access to, licensed materials located in the nuclear medicine department's hot laboratory nor did the licensee control and maintains constant surveillance of this licensed material. Specifically, the hot laboratory was left unattended, and contained 74 gigabecquerels (GBq) (2 curies) of molybdenum-99 in a molybdenum-99/technetium-99m generator; 740 megabecquerels (20 millicuries (mCi)) of iodine-125 in 52 brachytherapy seeds; and 2.2 GBq (60 mCi) of cesium-137 in two sources.

### **Department of Veterans Affairs (EA-04-019)**

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.

### **Department of the Navy - National Naval Medical Center (EA-04-075)**

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.

### **Caribe Medical Plaza (EA-03-134)**

A Notice of Violation was issued for a willful Severity Level III problem involving the failure [through its Radiation Safety Officer (RSO)] to ensure that radiation safety activities were being performed in accordance with the radiation safety Program; the failure to provide radiation safety training; the failure to issue film or Thermoluminescent Dosimeter finger monitors to appropriate individuals; and the failure of a Caribe representative to provide information to the Commission that was complete and accurate in all material respects. Specifically, the licensee initiated brachytherapy procedures without assuring, through the RSO, that individuals who would be involved in this activity received appropriate training or proper dosimetry.

### **Department of Veteran Affairs, AR (EA-03-162)**

A Notice of Violation was issued for a Severity Level III violation involving the failure to secure from unauthorized removal, or limit access to, licensed materials located in the nuclear medicine department's hot laboratory, which is a controlled area, nor did the licensee control and maintain constant surveillance of this licensed material. Specifically, the hot laboratory was left unattended, with a door open, and contained 74 gigabecquerels (GBq) (2 curies) of molybdenum99 in a molybdenum-99/technetium-99m generator; 740 megabecquerels (20 millicuries (mCi)) of iodine-125 in 52 brachytherapy seeds; and 2.2 GBq (60 mCi) of cesium-137 in two sources.

### **State of Alaska Department of Transportation & Public Facilities (EA-03-126) - DISCRIMINATION**

A Notice of Violation was issued for a Severity Level II violation based on the licensee discriminating against one of its employees for raising safety concerns regarding radiation exposures to other employees. NRC also issued an immediately effective Confirmatory Order to confirm certain commitments, as set forth in the Order, involving the licensee's internal policies and procedures pertaining to assuring compliance with NRC employee protection requirements.

### **UNDERSTANDING 10 CFR 35.3045(a)(3) REGULATION**

#### **NRC INTERPRETATION WITH EXAMPLE**

A few medical use licensees have incorrectly interpreted the criteria in 10 CFR 35.3045(a)(3) for determining when a medical event involving the "wrong site" must be reported to the U.S. Nuclear Regulatory Commission (NRC). 10 CFR 35.3045(a)(3) requires a licensee to report any events, except for an event that results from patient intervention, if there is a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 sievert (Sv) (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site)."

Some licensees erroneously believed that if the “wrong site” received 0.5 Sv (50 rem) then it needed to receive at least 50 percent of the dose intended for the correct treatment site before the event met the criteria in 10 CFR 35.3045(a)(3). The correct interpretation is that once the “wrong site” receives 0.5 Sv (50 rem), the event is reportable if this site also receives a dose that is 50 percent more than anticipated at the “wrong site” if the administration had been delivered correctly (i.e., the right dose was delivered in accordance with the written directive to the correct treatment site).

When the written directive specifies the dose to the treatment site, it is understood that, even when the administration is delivered correctly, doses may be delivered to areas beyond the treatment site. For radiopharmaceuticals, tables may be used to identify the expected doses to other organs or tissues. When using sealed sources or the radiation from sealed sources, treatment planning systems are used to estimate and map expected dose curves at or near the correctly placed sources or correctly delivered radiation beam. When the dose or dosage is not given in accordance with the written directive, the licensee needs to determine the total dose delivered to the “wrong site” and compare it to the dose that would have been delivered to this “wrong site” if the administration had been given correctly.

If the “wrong site” were not expected to receive any dose during the correct administration, and it received .05 Sv (50 rem), the medical event needs to be reported. If the “wrong site” was suppose to receive .01 Sv (10 rem) during the correct administration but received .06 Sv (60 rem), the medical event would be reportable. In this case, the dose received by the “wrong site” exceeded by .05 Sv (50 rem) the dose it should have received, as well as more than 50 percent of what it should have received. If the “wrong site” was suppose to receive .01 Sv (10 rem) and it received .04 Sv (40 rem), the medical event would not be reportable because the dose to the “wrong site” was under .05 Sv (50 rem) even though the “wrong site” received more than 50 percent of what it should have.

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