

**REPORT TO CONGRESS**  
**ON**  
**ABNORMAL OCCURRENCES**  
**FISCAL YEAR 2008**

Office of Nuclear Regulatory Research  
United States Nuclear Regulatory Commission  
Washington, DC 20555-0001

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## ABSTRACT

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) defines an “abnormal occurrence” (AO) as an unscheduled incident or event that the U.S. Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66) requires that the NRC report AOs to Congress annually.

This report describes six events that NRC identified as AOs during Fiscal Year (FY) 2008 based on the criteria defined in Appendix A to this report. All six events occurred at NRC-licensed or regulated medical institutions. The first event involved radiation exposure to an embryo/fetus. The other five events were medical events as defined in Title 10, Part 35, of the *Code of Federal Regulations* (10 CFR Part 35).

In addition, this report describes five events that Agreement States identified as AOs during FY 2008, based on the criteria in Appendix A to this report. Agreement States are those States that have entered into formal agreements with NRC, pursuant to Section 274 of the Atomic Energy Act (AEA), to regulate certain quantities of AEA material at facilities located within their borders. Currently, there are 35 Agreement States. The first Agreement State event involved radiation exposure to an embryo/fetus. The other four Agreement State events were medical events, as defined in 10 CFR Part 35.

Appendix A to this report presents NRC’s criteria for selecting AOs as well as the guidelines for selecting “Other Events of Interest.” Appendix B, “Updates of Previously Reported Abnormal Occurrences,” provides updated information for one event reported in the FY 2006 Report to Congress on Abnormal Occurrences regarding the spill of high-enriched uranium at a fuel fabrication facility. In addition, this appendix contains updated information for two events reported in the FY 2007 Report to Congress on Abnormal Occurrences regarding medical events at Agreement State-licensed medical institutions. Appendix C, “Other Events of Interest,” presents two events of interest identified during FY 2008 at materials facilities. Appendix D, “Updates of Previously Reported Other Events of Interest,” provides updated information for events at two U.S. commercial nuclear power plants that were reported in the FY 2007 Report to Congress on Abnormal Occurrences, regarding inattentive security officers and the installation of a new siren system. Appendix E, “Glossary,” contains a glossary of terms used throughout this report. Appendix F, “Conversion Table,” presents commonly used conversions when calculating doses.

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# EXECUTIVE SUMMARY

## INTRODUCTION

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) defines an “abnormal occurrence” (AO) as an unscheduled incident or event that the U.S. Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66) requires that NRC report AOs to Congress annually.

This report describes those events that NRC or an Agreement State identified as AOs during Fiscal Year (FY) 2008, based on the criteria defined in Appendix A to this report. Agreement States are those States that have entered into formal agreements with NRC pursuant to Section 274 of the Atomic Energy Act (AEA) to regulate certain quantities of AEA material at facilities located within their borders. NRC has determined that, of the incidents and events reviewed for this reporting period, only those that are described herein meet the criteria for being reported as AOs. For each AO, this report documents the date and place, nature and probable consequences, cause(s), and actions taken to prevent recurrence.

Appendix A to this report presents NRC’s criteria for selecting AOs as well as the guidelines for selecting “Other Events of Interest.” Appendix B, “Updates of Previously Reported Abnormal Occurrences,” provides updated information for one event reported in the FY 2006 Report to Congress on Abnormal Occurrences regarding the spill of high-enriched uranium at a fuel fabrication facility. In addition, this appendix contains updated information for two events reported in the FY 2007 Report to Congress on Abnormal Occurrences regarding medical events at Agreement State-licensed medical institutions. Appendix C, “Other Events of Interest,” presents two events of interest identified during FY 2008 at materials facilities. Appendix D, “Updates of Previously Reported Other Events of Interest,” provides updated information for events at two U.S. commercial nuclear power plants that were reported in the FY 2007 Report to Congress on Abnormal Occurrences regarding inattentive security officers and the installation of a new siren system. Appendix E, “Glossary,” contains a glossary of terms used throughout this report. Appendix F, “Conversion Table,” presents commonly used conversions when calculating doses.

## THE LICENSING AND REGULATORY SYSTEM

The system of licensing and regulation by which NRC carries out its responsibilities is implemented through the rules and regulations in Title 10 of the *Code of Federal Regulations* (10 CFR). Stakeholders are informed and involved, as appropriate, to ensure openness in the agency’s regulatory process, as stipulated in NRC’s Strategic Plan for FY 2008–2013 (NUREG-1614, Volume 4, February 2008). To accomplish its objectives, NRC regularly conducts licensing proceedings, inspection and enforcement activities, operating experience evaluations, and confirmatory research. NRC also maintains programs to establish standards and issue technical reviews and studies. In addition, NRC considers public participation as one essential element of the regulatory process.

NRC adheres to the philosophy that the health and safety of the public are best ensured by establishing multiple levels of protection. These levels are normally achieved and maintained

through regulations specifying requirements that ensure the safe use of radioactive materials. Those regulations contain design, operation, and quality assurance criteria appropriate for the various activities regulated by NRC. Licensing, inspection, and enforcement programs provide a regulatory framework to ensure compliance with the regulations. In addition, NRC is striving to make the regulatory system more risk-informed and performance-based, where appropriate.

## **REPORTABLE EVENTS**

NRC initially promulgated the AO criteria in a policy statement that the Commission published in the *Federal Register* on February 24, 1977 (42 FR 10950), followed by several revisions in subsequent years. The most recent revision to the AO criteria was published in the *Federal Register* on October 12, 2006 (71 FR 60198) and became effective on that date. That revision established the criteria that NRC used to define AOs for the purpose of this report, as set forth in Appendix A.

Review and response to operating experience are essential to ensure that licensed activities are conducted safely. Toward that end, the regulations require that licensees must report certain incidents or events to NRC. Such reporting helps to identify deficiencies and ensure that corrective actions are taken to prevent recurrence.

NRC and industry review and evaluate operating experience to identify safety concerns. NRC responds to risk significant issues through licensing activities and regulations. In addition, the agency maintains operational data in computer-based data files for more effective collection, storage, retrieval, and evaluation.

NRC also routinely disseminates (to the public, industry, and other interested groups) publicly available information and records regarding reportable events at licensed or regulated facilities. The agency achieves this dissemination through public announcements and special notifications to licensees and other affected or interested groups. To widely disseminate information to the public, NRC also issues a *Federal Register* notice describing AOs at facilities licensed or otherwise regulated by NRC or Agreement States that occurred in the previous fiscal year. In addition, NRC routinely informs Congress of significant events that occur at licensed or regulated facilities.

## **AGREEMENT STATES**

Section 274 of the Atomic Energy Act, as amended, authorizes the Commission to enter into agreements with States whereby the Commission relinquishes, and the States assume, regulatory authority over byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass. States that enter into such agreements with NRC are known as Agreement States. Agreement States must maintain programs that are adequate to protect public health and safety and are compatible with the Commission's program for such materials. At the end of FY 2008, there were 35 Agreement States.

Agreement States report event information to NRC in accordance with compatibility criteria established by the "Policy Statement on Adequacy and Compatibility of Agreement State Programs," which the agency published in the *Federal Register* on September 2, 1997 (62 FR 46517). NRC has also developed and implemented procedures for evaluating materials events

to identify those that should be reported as AOs. Toward that end, NRC uniformly applies the AO criteria (in Appendix A to this report) to events at facilities regulated by either NRC or Agreement States. In addition, in early 1977, the Commission determined that the annual report to Congress also should include events that meet the criteria for AOs at facilities licensed by Agreement States. In addition, those Agreement State AOs are included in the *Federal Register* notice that NRC issues to disseminate AO-related information to the public.

## **FOREIGN INFORMATION**

NRC exchanges information with various foreign governments that regulate nuclear facilities. This foreign information is reviewed and considered in the NRC's research and regulatory activities as well as its assessment of operating experience. Although such foreign information may occasionally be referred to in the AO reports to Congress, only domestic AOs are reported.

## **UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES**

NRC provides updates of previously reported AOs if significant new information becomes available. Appendix B, "Updates of Previously Reported Abnormal Occurrences," provides updated information for one event reported in the FY 2006 Report to Congress on Abnormal Occurrences regarding the spill of high-enriched uranium at a fuel fabrication facility. In addition, this appendix contains updated information for two events reported in the FY 2007 Report to Congress on Abnormal Occurrences regarding medical events at Agreement State-licensed medical institutions.

## **OTHER EVENTS OF INTEREST**

NRC provides information concerning events that are not reportable to Congress as AOs but are included in this report based on the Commission's guidelines, as listed in Appendix A. In this report, Appendix C, "Other Events of Interest," presents two events of interest identified during FY 2008 at materials licensee facilities.

## **UPDATES OF PREVIOUSLY REPORTED OTHER EVENTS OF INTEREST**

NRC provides updates of previously reported other events of interest if significant new information becomes available. Appendix D, "Updates of Previously Reported Other Events of Interest," provides updated information for other events of interest at two U.S. commercial nuclear power plants that were reported in the FY 2007 Report to Congress on Abnormal Occurrences regarding inattentive security officers and the installation of a new siren system.

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## ABBREVIATIONS

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act
AIT	augmented inspection team
AO	abnormal occurrence
CAL	confirmatory action letter
CFR	<i>Code of Federal Regulations</i>
cGy	centigray
Ci	curie
cm	centimeter
DOE	U.S. Department of Energy
DOH	Department of Health (New York State)
DVA	Department of Veterans Affairs
FEMA	Federal Emergency Management Agency
FR	<i>Federal Register</i>
FY	Fiscal Year
GB	gigabecquerel
Gy	gray
HEU	high-enriched uranium
HDR	high dose-rate afterloader
MBq	megabecquerel
$\mu$ Ci	microcurie
mCi	millicurie
mg	milligram
mm	millimeter
MRI	magnetic resonance imaging
mSv	millisievert
NIST	National Institute of Standards and Technology
NMT	Nuclear Medicine Technologist
No.	number
NOTAM	Notice to Airmen
NRC	U.S. Nuclear Regulatory Commission
OI	Office of Investigations
PBAPS	Peach Bottom Atomic Power Station
RAIs	Requests for Additional Information
RIC	Radioisotope Committee
RSO	radiation safety officer

SRM	Staff Requirements Memorandum
Sv	sievert
TBq	terabecquerel
USAF	United States Air Force
U.S.	United States
VA	Veterans Affairs

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## ABNORMAL OCCURRENCES IN FISCAL YEAR 2008

### I. FOR ALL LICENSEES

#### A. Human Exposure to Radiation from Licensed Material

During this reporting period, one event at an NRC-licensed facility and one event at an Agreement State-licensed facility were significant enough to be reported as abnormal occurrences (AOs), based on the criteria in Appendix A to this report.

#### **AS08-01 Human Exposure to Radiation at St. Luke's Hospital in Bethlehem, Pennsylvania**

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

Date and Place – April 11, 2008, Bethlehem, Pennsylvania

Nature and Probable Consequences – St. Luke's Hospital (the licensee) reported that a therapeutic dose of 4,958 MBq (134 mCi) of iodine-131, for thyroid cancer treatment, resulted in a dose to an embryo/fetus of 350 mSv (35 rem). Prior to administration of iodine-131, the patient was given a pregnancy test and it yielded a negative result. Following the treatment, the patient suspected she was pregnant and returned to the hospital on April 28, 2008. Subsequent testing indicated that the patient became pregnant approximately 4-6 days following her treatment. The patient and the referring physician were informed of this event.

The hospital calculated a total dose to the embryo/fetus of 350 mSv (35 rem). The hospital concluded that based on the total dose to the embryo/fetus of 350 mSv (35 rem), no immediate health effects would be experienced. On May 2, 2008, the patient met with a perinatologist and a recommendation was made to consult with a genetic counselor regarding the fetal exposure.

Cause(s) – The causes of this event were the negative pregnancy test and the patient not using a method of contraception, as advised, following the treatment.

#### Actions Taken to Prevent Recurrence

Licensee – The licensee is providing additional instructions to its staff to strongly emphasize to patients the risks associated with becoming pregnant following the administration of radioiodine treatments.

State – The State conducted a follow-up inspection on June 10, 2008, and did not take any enforcement action regarding this event.

This event is closed for the purpose of this report.

**Human Exposure to Radiation at Wilford Hall Medical Center on Lackland Air Force Base in San Antonio, Texas**

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

Date and Place – June 4, 2008, San Antonio, Texas

Nature and Probable Consequences – Wilford Hall Medical Center, a permit holder under the USAF Master Material license, reported that a therapeutic dose of 5.55 GB (150 mCi), for post-thyroidectomy therapy to a patient, resulted in a dose to an embryo/fetus of 315 mSv (31.5 rem). Two days prior to administration of the radioiodine-131, a pregnancy test was given to the patient and it yielded a negative result. Later, on June 26, 2008, the patient became aware that she was pregnant. The hospital's radiation safety staff did not become aware of the pregnancy until August 13, 2008, when the patient contacted the radiation safety staff asking about the consequences of the radioiodine ablation therapy on her embryo/fetus.

The hospital's radiation safety staff immediately conducted an investigation, in consultation with experts at the Department of Energy, and concluded that based on the total dose calculated of 315 mSv (31.5 rem) to the embryo/fetus, no immediate health effects would be experienced. The hospital estimated that the pregnancy was approximately seven days post-conception at the time of the administration and that the zygote (fertilized ovum) was in a pre-implantation state. This estimated condition is supported by the negative pregnancy test results prior to the administration. In addition, the hospital also estimated that the likelihood of childhood cancer had been increased by an estimated 1.9 percent. According to the licensee's report dated September 22, 2008, the pregnancy was progressing satisfactorily.

Cause(s) – Wilford Hall Medical Center believes that it followed its policies and standards of care. A pregnancy test does not typically have the capability to detect a pregnancy at such an early stage. The NRC special inspection is still being conducted and the review of this incident is ongoing.

Actions Taken to Prevent Recurrence

Wilford Hall Medical Center – Patients will be advised that serum pregnancy tests are not capable of detecting early stage pregnancy and therefore patients will be advised to abstain from intercourse for a period of 14 days prior to treatment or utilize an effective method of contraception for a period of 30 days prior to treatment. In addition, only quantitative serum tests will be used for detecting pregnancy for patients with the physiological capacity for becoming pregnant.

Department of the Air Force – The United States Air Force (USAF) Radioisotope Committee (RIC) is performing a root-cause analysis of this event. As part of its reviews, the USAF RIC is identifying other hospitals, under its Master Materials license, and asking them to review radioiodine procedures for the past two years to determine if patients had become pregnant either before or after receiving a radioiodine procedure. The USAF RIC will also review the policies and procedures of these hospitals. In addition, the USAF RIC is arranging to send an

inspector from the Air Force Inspection Agency to further assess procedures. The USAF Surgeon General issued a Notice to Airmen (NOTAM) on September 22, 2008, that outlined compliance objectives to reduce the likelihood of future occurrences. The USAF RIC is sending information to educate clinicians and support staff on the intent and implementation of the NOTAM.

NRC – NRC first learned of this incident on September 5, 2008, while conducting a routine unannounced inspection at Wilford Hall Medical Center. On September 9, 2008, NRC initiated a special inspection team to review this event and obtained the services of a medical consultant. NRC's medical consultant corroborated the hospital's total dose estimate to the fetus, with an estimated total dose of 325 mSv (32.5 rem). NRC's medical consultant also concurred with the hospital's assessment of the probable health effects to the fetus.

This event is closed for the purpose of this report.

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## **II. COMMERCIAL NUCLEAR POWER PLANT LICENSEES**

During this reporting period, no events at commercial nuclear power plants in the United States were significant enough to be reported as AOs based on the criteria in Appendix A to this report.

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### III. EVENTS AT FACILITIES OTHER THAN NUCLEAR POWER PLANTS AND ALL TRANSPORTATION EVENTS

#### C. Medical Licensees

During this reporting period, five events at NRC-licensed or regulated facilities and four events at Agreement State-licensed facilities were significant enough to be reported as AOs, based on the criteria in Appendix A to this report.

#### **NRC08-02                      Medical Events at the Department of Veterans Affairs in Philadelphia, Pennsylvania**

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

Date and Place – February 2002 to May 2008, Philadelphia, Pennsylvania

Nature and Probable Consequences - The VA Medical Center - Philadelphia reported that 92 medical events involving prostate brachytherapy occurred between February 2002 and May 2008. Each patient was prescribed 160 Gy (16,000 rad) using permanent iodine-125 seeds. The licensee determined that 57 of the 92 patients received less than 80 percent of the prescribed dose to the prostate. Thirty-five patients received excessive doses to other organs. Of these 35 patients, 25 patients received a dose in excess of 100 Gy (10,000 rad) to the rectum due to misplaced iodine-125 seeds. Each patient and the referring physicians were notified of these events. The VA Medical Center – Philadelphia is reviewing possible health effects on the patients. The circumstances for each patient are being evaluated to determine if follow-up medical care is needed.

The NRC-contracted medical consultant reviewed a selected number of the cases and agreed with the licensee's dose analysis. However, in one overdose case, the patient experienced rectal bleeding of the colon and laboratory results indicated ulcerative colitis. The NRC-contracted medical consultant and the licensee agreed that the increased dose to the colon could be a contributing factor to the rectal bleeding.

Cause(s) – The VA Medical Center - Philadelphia identified three root causes as a result of these events in its *Report of Administrative Board of Investigation* dated September 5, 2008: (1) no corrective action was taken when post-implant dosimetry was performed and low doses were observed, (2) inadequate supervision by the physician/authorized users and (3) post-treatment plans were not performed on patients due to computer interface problems. In addition, two factors contributed to these events: (1) internal procedures were not followed and (2) the succession of minor technical errors that stemmed from a misperception that other team members performed safety checks.

## Actions Taken To Prevent Recurrence

Licensee – Corrective actions taken by the VA Medical Center - Philadelphia included: (1) the prostate brachytherapy program has been suspended until a standardized brachytherapy program is established and implemented; (2) a physician and medical physics consultant, who are experts in performing prostate implants, were hired to evaluate the prostate implant program; and (3) several key staff directly involved in the prostate brachytherapy procedures are no longer employed by the VA Medical Center - Philadelphia.

NRC – The NRC Region III Office conducted a reactive inspection on July 23-25, 2008. Based on the results of this inspection and the high number of medical events identified, NRC conducted a special inspection on September 9-12, 2008. On October 14, 2008, NRC issued a confirmatory action letter (CAL) to the Department of Veterans Affairs (DVA) National Health Physics Program due to the multiple medical events involving permanent prostate brachytherapy treatments. The CAL documents the commitments made by the DVA to identify and address the problems that have led to medical errors and to prevent their recurrence. NRC will verify, through inspections, that the items in the CAL have been successfully completed. Enforcement action is pending.

This event is closed for the purpose of this report.

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### **NRC08-03                      Medical Event at Karmanos Cancer Center in Detroit, Michigan**

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

Date and Place – October 24, 2007, Detroit, Michigan

Nature and Probable Consequences – Karmanos Cancer Center reported that a medical event occurred associated with its gamma stereotactic radiosurgery unit (gamma knife). A patient being treated for a metastatic brain tumor was scheduled to receive 18 Gy (1,800 rad) to the lesion in the right cerebella area of the brain but received 18 Gy (1,800 rad) to an unintended area adjacent to the tumor. An error in the setup of the magnetic resonance imaging (MRI) unit caused the MRI scan to be reversed (i.e., the image of the right side of the head was on the left side and vice versa). The patient and the referring physician were informed of this event.

Prior to the treatment, the medical physicist, authorized user physician, and neurosurgeon reviewed the MRI scan and treatment plan but failed to recognize the reversed MRI images. The reversed MRI images were scanned into the gamma knife treatment planning computer, and a treatment plan was generated based on the reversed MRI images. The authorized user physician and neurosurgeon reviewed and approved the treatment plan generated from the reversed MRI images, and again the reversed MRI images were not recognized.

The NRC staff conducted a reactive onsite inspection on October 29, 2007. The NRC-contracted medical consultant reviewed the case and agreed with the licensee's analysis, stating that no significant adverse health effect to the patient is expected.

Cause(s) – The medical event was caused by the MRI technologist who inadvertently performed the MRI scans in the “caudal” mode (from the jaw to the top of the head) rather than the “cranial” mode (from the top of the head to the jaw). This change in device mode caused the MRI images to be reversed.

#### Actions Taken to Prevent Recurrence

Licensee – The licensee initiated several corrective actions to reduce the likelihood of recurrence of a similar event. Specifically, those corrective actions included (1) weekly meetings with the physics staff to discuss technical issues, focusing on the importance of good communication and (2) new written procedures and policies for the MRI staff and gamma knife facility staff that require dual verification of the various steps in the process to ensure that the correct treatment plan is generated from the MRI images.

NRC – On January 10, 2008, NRC issued a Notice of Violation related to this event.

This event is closed for the purpose of this report.

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#### **AS08-02                      Medical Event at University of Mississippi Medical Center in Jackson, Mississippi**

Criteria III.C.1.b and III.C.2.b(iii), “For Medical Licensees,” of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

Date and Place – December 12 – 17, 2007, Jackson, Mississippi

Nature and Probable Consequences – University of Mississippi Medical Center (the licensee) reported that a medical event occurred during a high dose-rate (HDR) treatment for cervical cancer using an iridium-192 source with an activity of 185 GBq (5.0 Ci). The authorized user physician prescribed five fractionated doses of 600 cGy (600 rad) each to be administered using tandem and ovoid applicators. The licensee calculated that during the first, second, and third fractionated treatments, the patient received a total dose of 470 cGy (470 rad) to the treatment area and 1,300 cGy (1,300 rad) to the vaginal region inferior to the treatment area. The patient and the referring physician were informed of this event. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s) – The medical event was caused by human error due to the incorrect catheter length entered into the treatment planning system. The incorrect value of 128 cm was entered as the length instead of 120 cm, resulting in the 86 mm displacement. An HDR service technician identified the error in the treatment planning system on March 25, 2008.

## Actions Taken to Prevent Recurrence

Licensee – The licensee committed to taking several corrective actions as a result of the medical event, including (1) verification of the length of all disposal catheters and checking the integrity of the catheters prior to treatment, (2) placing an order for and use of a single set of reusable catheters for HDR cervical cancer treatments, (3) the treatment plan and catheter measurement will be independently checked prior to treatment, and (4) review and modification, if necessary, of the quality assurance plan to ensure accuracy.

State – The State cited the licensee with two violations for failing to verify the treatment plan.

This event is closed for the purpose of this report.

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### **AS08-03                      Medical Event at Southwest Volusia Healthcare Corporation in Orange City, Florida**

Criteria III.C.1.b and III.C.2.b(i), “For Medical Licensees,” of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or lens of the eye, or the gonads) and represents a prescribed dose or dosage that uses the wrong radiopharmaceutical shall be considered for reporting as an AO.

Date and Place – December 28, 2007, Orange City, Florida

Nature and Probable Consequences – Southwest Volusia Healthcare Corporation (the licensee, doing business as Florida Hospital Fish Memorial) reported that a patient received 81.4 MBq (2.2 mCi) of iodine-131 for a whole body scan, instead of the intended iodine-123 for a thyroid uptake scan. The administration of 81.4 MBq (2.2 mCi) of iodine-131 resulted in the patient receiving a dose of 17.6 Gy (1,760 rad) to the thyroid and a whole body effective dose equivalent of 1.034 cGy (1.034 rad). The authorized user physician ordered an iodine thyroid uptake scan procedure, but did not specify the isotope in the written directive. The licensee uses iodine-123 for thyroid uptake scan procedures and iodine-131 for whole body scan procedures. On December 17, 2007, the patient received an iodine-131 whole body scan. The patient and the referring physician were informed of this event. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s) – The licensee identified four causes of the medical event: (1) the incorrect examination was scheduled in their Radiology Information System, (2) the patient had a prescription from the ordering physician, but did not make it available for verification, (3) the isotope for the incorrect exam was ordered without verifying the prescription, and (4) the technologist involved in the administration did not recognize the error when the written directive was presented.

## Actions Taken to Prevent Recurrence

Licensee – The licensee implemented corrective actions by providing counseling and re-training to the hospital personnel involved in the medical event and notified hospital personnel that iodine-131 and iodine-123 studies must be verified prior to scheduling patients for these types of

procedures. In addition, the technologists have been instructed to visually verify the authorized user physician's order on the written directive before ordering the radioisotope and the technologist and radiologist will review the written directive prior to patient administration.

State – The State conducted an investigation and reviewed the licensee's corrective actions and found the corrective actions to be adequate.

This event is closed for the purpose of this report.

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**AS08-04                      Medical Event at Southern Baptist Hospital of Florida in Jacksonville, Florida**

Criteria III.C.1.b and III.C.2.b(i), "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or lens of the eye, or the gonads) and represents a prescribed dose or dosage that uses the wrong radiopharmaceutical shall be considered for reporting as an AO.

Date and Place – January 24, 2008, Jacksonville, Florida

Nature and Probable Consequences – Southern Baptist Hospital of Florida (the licensee, doing business as Baptist Medical Center) reported that a patient received 173.9 MBq (4.7 mCi) of iodine-131 for an uptake scan, instead of the intended iodine-123 for the same procedure. The administration of 173.9 MBq (4.7 mCi) of iodine-131 resulted in the patient receiving a dose of 61 Gy (6,100 rad) to the thyroid and a whole body effective dose equivalent of 180 cGy (180 rad). An authorized user physician gave a verbal order to a nurse, who wrote the order for an iodine-123 uptake scan. The nurse incorrectly scheduled an iodine-131 uptake scan and the authorized user physician did not review the order. On January 16, 2008, the authorized user physician reviewed the results of the iodine-131 uptake scan and identified that the wrong isotope had been used in the procedure. The patient and the referring physician were informed of this event. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s) – The cause of the medical event was the authorized user physician's failure to write a written directive and failure to review the order for the procedure.

Actions Taken to Prevent Recurrence

Licensee – The licensee implemented corrective actions by rewriting its procedures such that all written directives will be completed and reviewed by the authorized user physician prior to the administration to patients.

State – The State conducted an investigation and reviewed the licensee's corrective actions and found the corrective actions to be adequate.

This event is closed for the purpose of this report.

**NRC08-04**

**Medical Event at Geisinger Wyoming Valley Hospital in Wilkes-Barre, Pennsylvania**

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or lens of the eye, or the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed shall be considered for reporting as an AO.

Date and Place – February 7, 2008, Wilkes-Barre, Pennsylvania

Nature and Probable Consequences – Geisinger Wyoming Valley Hospital reported that a patient was administered 0.37 GBq (10 mCi) of iodine-131 for treatment of a hyperactive thyroid, instead of the prescribed 0.37 MBq (10 µCi). The incident was discovered on April 25, 2008, during a review of the hospital's written directives. Geisinger stated that the authorized user physician prepared a written directive that erroneously prescribed 0.37 MBq (10 µCi). The authorized user physician realized his error and telephoned the nuclear medicine technician to request a change in the activity to the correct dosage of 0.37 GBq (10 mCi). However, the authorized user physician did not revise or issue a new written directive for the administration. The referring physician was informed of this event. The patient was not informed of this event because the correct dosage of 0.37 GBq (10 mCi) was administered for treatment.

Causes – The cause of the medical event was human error in failing to prepare and issue a corrected written directive for the iodine-131 administration.

Actions Taken to Prevent Recurrence

Licensee – The licensee's corrective actions taken to prevent recurrence included counseling the nuclear medicine technician on following procedures, revising the written directive form to exclude a choice of activity units, and enforcing that telephone requests from authorized user physicians, on changing the activity of an administration, will not be accepted until a new or revised written directive is issued for the administration.

NRC – This event was reported to NRC in April 2008 after the license transfer to Pennsylvania, which became a new Agreement State on March 31, 2008. The NRC Region I Office contacted the State about follow-up inspection actions.

State – The State did not conduct a follow-up inspection because the patient received the correct administration for treatment. However, the State noted that had the dosage prescribed in the written directive, 0.37 MBq (10 µCi), been administered to the patient, the patient would have received 288 Gy (28,000 rad) to the thyroid.

This event is closed for the purpose of this report.

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

Date and Place – February 27, 2008, Richmond, Indiana

Nature and Probable Consequences – Reid Hospital and Health Care Services reported that a medical event occurred during a brachytherapy seed implant procedure to treat prostate cancer. The written directive prescribed a total dose of 110 Gy (11,000 rad) to the patient's prostate using 62 iodine-125 seeds as permanent implants. The licensee calculated that the patient received less than 15 Gy (1,500 rad) to the prostate and the region of the patient's perineum, where the seeds were placed, received a dose of 55 Gy (5,500 rad). The patient and the referring physician were informed of this event.

According to the licensee, the base of the prostate was misidentified through ultrasound, causing 37 of the prescribed 62 seeds to be placed approximately 1 cm to 2 cm below the prostate in the perineum. When it was recognized that the seeds were not in the prostate, the procedure was halted. The licensee physicians stated that the patient may develop possible complications, including fibrosis and necrosis of the tissue in the perineum, where the seeds were implanted.

The NRC-contracted medical consultant agreed with the licensee's dose estimate and stated it was unlikely that the patient would experience radiation-induced rectal wall necrosis or soft-tissue necrosis below the prostate in the perineum area, but that it was possible to have delayed fibrosis of some areas of the genital tract. The NRC-contracted medical consultant further stated that because no tissue necrosis had occurred one month after the medical event, tissue necrosis was very unlikely to occur.

Cause(s) – The licensee determined the root cause of the medical event was the misidentification of the base of the prostate. Specifically, the prostate/bladder interface was not identified properly using the ultrasound due to poor image quality. As a result, the needle used to implant the seeds was not located in the prostate during the implantation.

#### Actions Taken to Prevent Recurrence

Licensee – The licensee's corrective actions to prevent recurrence included revising its procedure for prostate seed implants to require that the needle location in the prostate be verified by x-ray imaging at the beginning of the procedure, prior to any seeds being implanted, and halting the procedure if the location of the needle in the prostate cannot be verified with certainty.

NRC – On July 11, 2008, NRC issued a Notice of Violation related to this event.

This event is closed for the purpose of this report.

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

Date and Place – May 1, 2008, Richmond, Virginia

Nature and Probable Consequences – Bon Secours Virginia Health Source reported that a medical event occurred during a high dose-rate (HDR) treatment for breast cancer using an iridium-192 source with an activity of 165.4 GBq (4.47 Ci). The authorized user physician prescribed 10 fractions of 340 cGy (340 rad) each to be administered using a balloon catheter technique. The licensee calculated that a portion of the target volume received a dose in the range of 86 cGy (86 rad). In addition, a small volume of skin, at the catheter entrance into the patient, received a dose in the range of 1,142 cGy (1,142 rad). The patient and the referring physician were informed of this event.

During the check source run for the first fraction, an HDR alarm interrupted the run. Rather than investigate the cause of the alarm, the physicist concluded that a 2 mm error had been made in the measurement of the catheter length and the alarm occurred because the check source hit the end of the catheter. The physicist adjusted the catheter length value at the treatment console from 1300 mm to 1280 mm, believing this to be a change of 2 mm, and the treatment was administered. Immediately following the first treatment, it was determined that the original catheter length measurement of 1300 mm was correct and the length change made at the treatment console was 20 mm rather than 2 mm. As a result, the source dwell positions were 20 mm from the intended locations and were closer than intended to the skin entry point of the HDR catheter.

Subsequent HDR treatment fractions were administered as intended, with adjustments to the final two treatment fractions to assure that all areas of the target volume received an adequate dose over the course of the treatment. An NRC medical consultant concluded that no significant adverse health effect to the patient is expected.

Cause(s) – The cause of the medical event was human error in (1) failing to investigate the cause of the HDR alarm and (2) adjusting the catheter length value at the console by 20 mm instead of the intended 2 mm.

#### Actions Taken to Prevent Recurrence

Licensee – The licensee's corrective actions taken to prevent recurrence included updating procedures to define steps that will be taken to resolve HDR device alarms.

NRC – NRC performed a reactive inspection at the facility and issued a Notice of Violation for three violations of regulatory requirements on October 10, 2008.

This event is closed for the purpose of this report.

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## **AS08-05                      Medical Event at Lehigh Valley Hospital in Allentown, Pennsylvania**

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or lens of the eye, or the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed shall be considered for reporting as an AO.

Date and Place – July 17, 2008, Allentown, Pennsylvania

Nature and Probable Consequences – Lehigh Valley Hospital (the licensee) reported that a patient was prescribed a dose of 740 MBq (20 mCi) of iodine-131, for treatment of a thyroid condition, but instead was administered 2,775 MBq (75 mCi). The licensee discovered the event within an hour of the administration and gave the patient 130 mg of potassium iodide, a blocking agent, to prevent the uptake of iodine-131 in the thyroid. As a result of the administration, next day measurements indicated that the patient had a 74 MBq (2 mCi) uptake to the thyroid and 370 MBq (10 mCi) whole body retention, resulting in an approximate thyroid dose of 26 Gy (2,600 rad) and whole body effective dose equivalent of 8.7 cGy (8.7 rad). The patient and the referring physician were informed of this event. The licensee determined that as a result of giving the patient 130 mg of potassium iodide, no significant adverse health effect to the patient is expected.

Cause(s) – The cause of the medical event was human error because the technologist accidentally switched the doses between two patients.

### Actions Taken to Prevent Recurrence

Licensee – The licensee implemented corrective measures by modifying current procedures involving the administration of radiopharmaceuticals.

State – The State conducted a follow-up inspection on August 21, 2008, to ensure that the licensee's actions taken to prevent recurrence had been implemented and issued a Notice of Violation.

This event is closed for the purpose of this report.

## APPENDIX A

### ABNORMAL OCCURRENCE CRITERIA AND GUIDELINES FOR OTHER EVENTS OF INTEREST

An accident or event will be considered an AO if it involves a major reduction in the degree of protection of public health or safety. This type of incident or event would have a moderate or more severe impact on public health or safety and could include, but need not be limited to, the following:

- (1) Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission;
- (2) Major degradation of essential safety-related equipment; or
- (3) Major deficiencies in design, construction, use of, or management controls for facilities or radioactive material licensed by or otherwise regulated by the Commission

The following criteria for determining an AO and the guidelines for "Other Events of Interest" were stated in an NRC policy statement published in the *Federal Register* on October 12, 2006 (71 FR 60198).

#### Abnormal Occurrence Criteria

Criteria by types of events used to determine which events will be considered for reporting as AOs are as follows:

#### I. For All Licensees

##### A. Human Exposure to Radiation from Licensed Material

1. Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 mSv (25 rem) or more; or an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ other than the lens of the eye, the bone marrow, and the gonads of 2,500 mSv (250 rem) or more; or an annual dose equivalent to the lens of the eye of 1 Sv (100 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow of 1 Sv (100 rem) or more; or a committed dose equivalent to the gonads of 2,500 mSv (250 rem) or more; or an annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more.
2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.
3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

- B. Discharge or dispersal of radioactive material from its intended place of confinement which results in the release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceeds 5,000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20, unless the licensee has demonstrated compliance with §20.1301 using §20.1302(b)(1) or §20.1302(b)(2)(ii). This criterion does not apply to transportation events.
- C. Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach<sup>1,2</sup>
1. Any unrecovered lost, stolen, or abandoned sources that exceed the values listed in Appendix P to Part 110, "High Risk Radioactive Material, Category 2." Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur while the source was missing; and unrecoverable sources (sources that have been lost and for which a reasonable attempt at recovery has been made without success) lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 are not known to have occurred and the agency has determined that the risk of theft or diversion is acceptably low.
  2. A substantiated<sup>3</sup> case of actual theft or diversion of licensed, risk-significant radioactive sources or a formula quantity<sup>4</sup> of special nuclear material; or act that results in radiological sabotage<sup>5</sup>.
  3. Any substantiated<sup>3</sup> loss of a formula quantity<sup>4</sup> of special nuclear material or a substantiated<sup>3</sup> inventory discrepancy of a formula quantity<sup>4</sup> of special nuclear material that is judged to be caused by theft or diversion or by a substantial breakdown<sup>6</sup> of the accountability system.
  4. Any substantial breakdown<sup>6</sup> of physical security or material control (i.e., access control containment or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.

<sup>1</sup> Information pertaining to certain incidents may be either classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Section 208 of the ERA of 1974, as amended. Any classified details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

<sup>2</sup> Due to increased terrorist activities worldwide, the AO report would not disclose specific classified information and sensitive information, the details of which are considered useful to a potential terrorist. Classified information is defined as information that would harm national security if disclosed in an unauthorized manner.

<sup>3</sup> "Substantiated" means a situation where an indication of loss, theft, or unlawful diversion such as: an allegation of diversion, report of lost or stolen material, statistical processing difference, or other indication of loss of material control or accountability cannot be refuted following an investigation; and requires further action on the part of the Agency or other proper authorities.

<sup>4</sup> A formula quantity of special nuclear material is defined in 10 CFR 70.4.

<sup>5</sup> Radiological sabotage is defined in 10 CFR 73.2.

<sup>6</sup> A substantial breakdown is defined as a red finding in the security inspection program, or any plant or facility determined to have overall unacceptable performance, or in a shutdown condition (inimical to the effective functioning of the Nation's critical infrastructure) as a result of significant performance problems and/or operational events.

5. Any significant unauthorized disclosures (loss, theft, and/or deliberate) of classified information that harms national security or safeguards information that harms the public health and safety.

D. Initiation of High-Level NRC Team Inspections.<sup>7</sup>

II. For Commercial Nuclear Power Plant Licensees

A. Malfunction of Facility, Structures, or Equipment

1. Exceeding a safety limit of license technical specification (TS) [10 CFR 50.36(c)].
2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.
3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy

1. Discovery of a major condition not specifically considered in the safety analysis report (SAR) or TS that requires immediate remedial action.
2. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions so that a release of radioactive materials which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, GDC 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod drive mechanism).

C. Any reactor events or conditions that are determined to be of high safety significance.<sup>8</sup>

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<sup>7</sup> Initiation of any Incident Investigation Teams, as described in NRC Management Directive (MD) 8.3, "NRC Incident Investigation Program," or initiation of any Accident Review Groups, as described in MD 8.9, "Accident Investigation."

<sup>8</sup> The NRC ROP uses four colors to describe the safety significance of licensee performance. As defined in NRC Management Directive 8.13, "Reactor Oversight Process," green is used for very low safety significance, white is used for low to moderate safety significance, yellow is used for substantial safety significance, and red is used for high safety significance. Reactor conditions or performance indicators evaluated to be red are considered Abnormal Occurrences. Additionally, Criterion II.C also includes any events or conditions evaluated by the NRC ASP program to have a conditional core damage probability (CCDP) or change in core damage probability ( $\Delta$ CDP) of greater than  $1 \times 10^{-3}$ .

- D. Any operating reactor plants that are determined to have overall unacceptable performance or that are in a shutdown condition as a result of significant performance problems and/or operational event(s).<sup>9</sup>

### III. Events at Facilities Other than Nuclear Power Plants and all Transportation Events

#### A. Events Involving Design, Analysis, Construction, Testing, Operation, Transport, Use, or Disposal of Licensed Facilities or Regulated Materials

1. An accidental criticality [10 CFR 70.52(a)].
2. A major deficiency in design, construction, control, or operation having significant safety implications that require immediate remedial action.
3. A serious safety-significant deficiency in management or procedural controls.
4. A series of events (in which the individual events are not of major importance), recurring incidents, or incidents with implications for similar facilities (generic incidents) that raise a major safety concern.

#### B. For Fuel Cycle Facilities

1. Absence or failure of all safety-related or security-related controls (engineered and human) for a NRC-regulated lethal hazard (radiological or chemical) while the lethal hazard is present.
2. An NRC-ordered safety-related or security-related immediate remedial action.

#### C. For Medical Licensees

A medical event that:

1. Results in a dose that is
  - a. Equal to or greater than 1 Gy (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal or greater than 2.5 Gy (250 rad) to the gonads; or
  - b. Equal to or greater than 10 Gy (1,000 rad) to any other organ or tissue; and
2. Represents either
  - a. A dose or dosage that is at least 50 percent greater than that prescribed, or

<sup>9</sup>

Any plants assessed by the ROP to be in the unacceptable performance column, as described in NRC Inspection Manual Chapter 0305, "Operating Reactor Assessment Program." This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

- b. A prescribed dose or dosage that
  - (i) Uses the wrong radiopharmaceutical or unsealed byproduct material; or
  - (ii) Is delivered by the wrong route of administration; or
  - (iii) Is delivered to the wrong treatment site; or
  - (iv) Is delivered by the wrong treatment mode; or
  - (v) Is from a leaking source or sources; or
  - (vi) Is delivered to the wrong individual or human research subject.

IV. Other Events of Interest

The Commission may determine that events other than AOs may be of interest to Congress and the public and should be included in an appendix to the AO report as "Other Events of Interest." Such events may include, but are not necessarily limited to, events that do not meet the AO criteria but that have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.

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## **APPENDIX B**

### **UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES**

During this reporting period, updated information became available for an AO event NRC previously reported in the "Report to Congress on Abnormal Occurrences: Fiscal Year (FY) 2006" regarding the spill of high-enriched uranium at a fuel fabrication facility. In addition, updated information became available for two AO events the NRC previously reported in the "Report to Congress on Abnormal Occurrences: Fiscal Year (FY) 2007" regarding medical events at Agreement State-licensed medical institutions.

**Spill of High-Enriched Uranium Solution at Fuel Fabrication Facility** (previously reported as 06-01 in NUREG-0090, Volume 29)

Date and Place – March 6, 2006, Nuclear Fuel Services, Erwin, Tennessee

Background – A fuel fabrication facility reported that a transfer of high-enriched uranium (HEU) solution through a transfer line resulted in a portion of the HEU solution, approximately 35 liters, leaking into a glovebox where criticality was possible and subsequently to the floor where criticality also was possible because of the presence of an elevator pit. The full details of the event are discussed in the FY 2006 abnormal occurrence report as 06-01. At the time the report was issued, the event was listed as closed. However, NRC and the licensee have taken certain actions concerning this event.

Between March and October 2006, NRC conducted five team inspections to verify the licensee's immediate corrective actions. On October 18, 2006, NRC authorized the full restart of Nuclear Fuel Services' operations. This document is publicly available through NRC's Agencywide Documents Access and Management System (ADAMS), under Accession No. ML062920143.

In September and November 2006, NRC conducted Alternative Dispute Resolution negotiations with the licensee concerning the licensee's long-term actions. As a result, NRC issued an Order on February 21, 2007 (72 FR 41528), to require that the licensee (1) submit a license amendment upgrading the licensee's configuration management program and (2) conduct safety culture assessments using an independent third party.

On August 31, 2007, NRC revised its policy for withholding information from the public, regarding Category I fuel facilities including Nuclear Fuel Services, to address concerns that too much information was being withheld. The Staff Requirements Memorandum (SRM-SECY-07-0129) revising the policy also directed the staff to redact and release many of the documents that had been withheld. The SRM is publicly available through ADAMS, under Accession No. ML072430701.

Update on Actions Taken To Prevent Recurrence

One of the root causes of the HEU spill was the licensee's failure to manage the configuration of its processing system. As a result of the amendment request required by the 2007 Order,

Amendment 82 was issued to Material License SNM-124 on May 22, 2008, to approve the new configuration management program. This document is publicly available through ADAMS, under Accession No. ML080980310.

Another apparent cause of the HEU spill was safety culture deficiencies at the licensee's facility. In response to the 2007 Order, the licensee submitted, on May 15, 2008, the results of the independent third-party safety culture assessment and the licensee's plan for implementing the recommendations in the assessment. The document is publicly available through ADAMS, under Accession No. ML081410164. NRC will conduct special inspections and reviews as program improvements are implemented. Another independent safety culture assessment will be completed in 2010.

In response to the Commission's SRM of August 31, 2007, the staff completed, on May 21, 2008, a review of documents withheld from the public from 2004 to 2007. A total of 727 documents were redacted and made available to the public.

This event is closed for the purpose of this report.

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#### **Medical Event in New York** (previously reported as AS07-03 in NUREG-0090, Volume 30)

Date and Place – March 7, 2007, New York

Background – The licensee reported a brachytherapy medical event to the New York State Department of Health (DOH). The event involved a patient with a history of vaginal cancer. The treatment involved the use of both cesium-137 and iridium-192 seeds. Each ribbon contained eight seeds with an activity of 1.855 milligram radium equivalent (118 MBq or 3.19 mCi). The patient was to be administered a total dose of 25 Gy (2,500 rad) via interstitial brachytherapy. The patient received an estimated dose of 45.9 Gy (4,590 rad) to the treatment site, rather than the intended 25 Gy (2,500 rad). The full details of the event are discussed in the FY 2007 abnormal occurrence report as AS07-03. At the time the report was issued, the event was listed as open.

#### Update on Actions Taken To Prevent Recurrence

The New York State DOH staff performed a reactive inspection on March 21, 2007. The DOH staff interviewed radiation oncologists/authorized users, authorized medical physicist, risk management and administrative staff. In addition, the DOH staff reviewed the licensee's radiation therapy quality assurance policies, procedures and records, and the patient's medical record. Two items of noncompliance with regulations associated with the event were cited: (1) failure to perform acceptance testing on the treatment planning system for iridium-192 and (2) failure to report the event to the New York State DOH and the referring physician within the timeframe required by the regulation. The licensee was fined \$2,000 for each of these violations.

The New York State DOH sent the patient's medical record for review by a radiation oncologist and medical physicist. The reviewer's report identified several issues for which DOH will follow-up with the licensee during its next inspection in 2009.

This event is closed for the purpose of this report.

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**Medical Event at Memorial Mission Hospital of Asheville, North Carolina** (previously reported as AS07-04 in NUREG-0090, Volume 30)

Date and Place – April 24, 2007, Memorial Mission Hospital, Asheville, North Carolina

Background – Memorial Mission Hospital reported that a patient was prescribed a dose of 1.24 MBq (33.4  $\mu$ Ci) of iodine-131 for a diagnostic scan to assess the health of her thyroid, but received a dose of approximately 287.3 Gy (28,728 rad). The full details of the event are discussed in the FY 2007 abnormal occurrence report as AS07-04. At the time the report was issued, the event was listed as open.

Update on Actions Taken To Prevent Recurrence

The Nuclear Medicine Technologist (NMT) initially thought the high counts were due to an equipment malfunction and notified the Radiation Safety Officer (RSO). The RSO performed diagnostic checks on the equipment and found everything in working order. The licensee had the patient return for a second uptake scan on April 26, 2007. The RSO and the NMT observed unusually high count rates and an inconsistent gamma spectrum.

The patient received an ablative quantity of radioactive iodine and initially showed classic signs of thyroiditis, including inflammation, swelling, pain, and difficulty in swallowing. The patient was expected to experience permanent decreased thyroid function and is taking a synthetic thyroid hormone.

The State radiation control agency conducted an investigation into this incident assisted by the State board of pharmacy. Several items of noncompliance were issued to the licensee. The licensee's actions to prevent recurrence will be inspected at its next regularly scheduled inspection in 2009.

This event is closed for the purpose of this report.

## **APPENDIX C OTHER EVENTS OF INTEREST**

This appendix discusses “Other Events of Interest” that do not meet the abnormal occurrence (AO) criteria in Appendix A, but have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused NRC to increase its attention to or oversight of a program area, including a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.

### **FACILITIES OTHER THAN NUCLEAR POWER PLANTS**

#### **EOI-01      Plutonium Contamination Event at the National Institute of Standards and Technology – Boulder, Colorado Laboratory**

On June 9, 2008, a plutonium contamination event occurred at the National Institute of Standards and Technology (NIST) laboratory in Boulder, Colorado. A junior researcher had broken a glass vial containing one-fourth of a gram of plutonium powder. The junior researcher and other individuals, working both inside and outside the specific laboratory, were contaminated. In addition, the junior researcher washed his hands in the laboratory sink to remove the plutonium contamination, thus introducing a small amount of plutonium into the sewer system of the City of Boulder. Moreover, the junior researcher and several others ingested or inhaled some of the plutonium.

NRC was notified of the event late in the afternoon on June 10, 2008. A health physics inspector was dispatched the following day and commenced on-site inspection activities on June 12, 2008. The inspector verified that the laboratory had been acceptably isolated and that no immediate threat existed to additional workers or to public health and safety. A second health physics inspector was dispatched the following week on June 19, 2008. Based on the inspectors’ observations, NRC management determined that an enhanced agency response was needed to ensure that the licensee conducted licensed activities safely in the short-term and that further inspection follow-up was needed to more fully understand the circumstances, causes, and licensee actions.

A five-member special inspection team was dispatched from NRC’s Region IV Office and commenced team inspection activities on June 30, 2008. The special inspection team conducted extensive interviews of personnel to verify that all personnel potentially exposed to plutonium from the contamination event have been identified. Preliminarily, no personnel – whether occupational workers or members of the public as defined by Title 10 of the *Code of Federal Regulations*, Part 20 (10 CFR Part 20) – exceed any radiation dose limits. The special inspection team performed independent radiation surveys to ensure that any releases to the environment have been properly bounded. Although the team has not completed its work, they have identified a number of issues regarding the licensee’s possession and use of special nuclear material of less than a critical mass. The special inspection team’s preliminary findings include (1) insufficient training of occupational workers and laboratory frequenters, (2) operating procedures that were never developed or fully implemented, (3) safety modifications that were

not made to the laboratory where the plutonium sources were stored and used, (4) required audits of the radiation safety program that were not conducted and (5) inadequate emergency procedures.

On July 2, 2008, NRC issued a confirmatory action letter (CAL) to NIST confirming the agreed-upon actions to ensure safety and to adequately evaluate the event. Pursuant to the CAL, NIST agreed to take several actions, including (1) suspending the use of plutonium sources, (2) determining the radiation doses to all individuals potentially exposed, (3) ensuring that all personnel using licensed material were properly trained, and (4) providing NRC with a written plan for remediation of the site.

NRC has approved NIST's written plan for source recovery actions, including laboratory stabilization, remediation, and release. The NRC special inspection team has observed the retrieval and transfer of the radioactive sources and contaminated objects to the U.S. Department of Energy (DOE) for recovery of plutonium. The agency's special inspection is continuing with onsite monitoring of significant decontamination actions and free-release of equipment to ensure remediation operations are appropriate. The NRC staff will consider potential enforcement action upon the completion of NIST's and its investigation.

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#### **EOI-02 Human Exposure to Radiation at a Hospital in São Paulo, Brazil**

On July 21, 2008, the State of Maryland reported that an event occurred at Instituto de Cancer Arnaldo Viera de Carvalho involving human exposure to radiation. An occupational worker received an approximate whole body dose of 135 mSv (13.5 rem) and 730 mSv (73 rem) to the extremity (left hand) while conducting a source exchange transfer on a cancer teletherapy unit. The teletherapy unit contained 55,130 GBq (1490 Ci) of cobalt-60. This event was reported by Brazil in the International Nuclear Event Scale Report (Rating 3) because the event occurred within its border. In addition, this event involved a U.S. citizen working under an active Maryland Agreement State license in Brazil.

During the process of removing the removal tool from the transfer cask, it was determined by audible alarms that the cobalt-60 source was still connected to the end of the removal tool. The occupational worker reinserted the removal tool into the cask and steps were repeated to ensure that the cobalt-60 source was disengaged from the removal tool. The worker's hand was in close proximity to the source end of the removal tool for a short period of time.

An estimated dose of approximately 5,000 mSv–10,000 mSv (500 rem–1,000 rem) to the extremity was calculated through event re-enactment and dose reconstruction. The occupational worker later experienced radiation burn symptoms (reddening and blistering of the skin) on his left index finger. Based on these physical symptoms, an experienced physician estimated a shallow dose to the extremity between 20,000 mSv–30,000 mSv (2,000 rem–3,000 rem). The latest report from the licensee indicated that the burn had healed and scar tissue was evident. The licensee continues to monitor the worker's medical condition.

One cause of the event was due to an inadequate licensee procedure. Deficiencies in the procedure were related to the specific technique and tooling used to conduct the activity, as well

as the conduct of adequate radiological surveys. The licensee did not follow existing procedures with respect to radiation surveys and monitoring, did not have adequate training of personnel, failed to use appropriate dosimetry during radiological surveys, and failed to have adequate management oversight of activities conducted at temporary job sites. Another cause of the event appears to be inadequate engineering of the teletherapy source/holder. The teletherapy source/holder did not properly disengage from the source exchange tool prior to the removal of the tool from the source cask.

The licensee revised procedures, modified the source transfer tool, and conducted training prior to resuming radiological activities. These actions adequately addressed and corrected the root causes of the event.

The Maryland State Department of the Environment staff completed its inspection and issued a Notice of Violation in October 2008. A settlement with the licensee included a \$20,000 penalty.

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## APPENDIX D

### UPDATES OF PREVIOUSLY REPORTED OTHER EVENTS OF INTEREST

This appendix discusses “Updates of Previously Reported Other Events of Interest” that the NRC previously reported in the “Report to Congress on Abnormal Occurrences: Fiscal Year (FY) 2007” at two U.S. commercial nuclear power plants. During this reporting period, updated information became available regarding inattentive security officers and the installation of a new siren system.

#### NUCLEAR POWER PLANTS

**Peach Bottom Atomic Power Station: Security Officers Inattentive to Duty** (previously reported as EOI-01 in NUREG-0090, Volume 30)

Background – The issue of security officer inattentiveness at the Peach Bottom Atomic Power Station (PBAPS) came to NRC’s attention on March 27, 2007, when it received an allegation that some security officers at PBAPS were sleeping on duty while in security watch towers and other areas. After receiving the allegation, NRC convened an Allegation Review Board, which determined that Exelon needed to investigate the allegation and provide the results of its investigation to NRC for review. NRC did not contact the person who made the allegation for additional information because the individual clearly stated in the allegation letter that he did not want to be contacted by NRC. Although not directly related to the allegation, the NRC Region I Office conducted a scheduled baseline security inspection at PBAPS from April 30, 2007, to May 4, 2007. During that inspection, four regional inspectors made unannounced tours of the security posts, including several watch towers, and did not find any security officers to be inattentive.

In June 2007, Exelon reported that its investigation did not uncover instances of inattentive security personnel. Based on Exelon’s report, NRC could not substantiate the allegation regarding sleeping security officers in security watch towers and other areas.

In September 2007, NRC was made aware of the existence of, and later provided with, video evidence of inattentive security officers at PBAPS. NRC staff immediately contacted Exelon to confirm that short-term compensatory actions were taken. Shortly afterwards, NRC dispatched an augmented inspection team (AIT) and a follow-up team to investigate. An AIT is an infrequent reactive inspection conducted for the purpose of event assessment and follow-up actions. The events that led to this inspection began when a Peach Bottom security officer videotaped multiple instances of several security officers inattentive to duty at the station’s former power block “ready rooms.” The ready rooms are locations within the protected area where officers are staged for response functions while not conducting security patrols.

The AIT conducted a public exit meeting on October 9, 2007, and concluded that Exelon’s prompt compensatory measures and immediate actions were appropriate to ensure PBAPS’ continued ability to properly implement the Security Plan. NRC determined that the inattentive security officers and deficiencies in Exelon’s behavioral observation program, which could have identified and corrected the problem, represent a White finding. In accordance with

NRC's reactor oversight program, a White finding is an NRC-identified or self-revealing issue of concern that is associated with a licensee performance deficiency of low-to-moderate safety significance.

#### Update on Actions Taken To Prevent Recurrence

NRC received 100 percent of licensee responses to NRC Bulletin 2007-01, "Security Officer Attentiveness." The NRC staff performed an initial review of the industry responses and concluded that all licensees provided answers to all questions as requested by the Bulletin. After reviewing all licensee responses to the security Bulletin, the NRC staff identified the need for additional information. To gather that information, NRC issued Requests for Additional Information (RAIs) to all licensees in July 2008. NRC has received 100 percent of licensee responses to the RAIs and has assessed, in total, all of the licensee responses to the security Bulletin and subsequent RAIs. The NRC staff is evaluating the licensee's responses to the security Bulletin and associated RAIs. If this evaluation indicates that additional regulatory action is warranted, the NRC staff will make that recommendation to the Commission.

On July 25, 2008, the NRC Office of Investigations (OI) issued its report regarding the inattentive security officers. NRC has taken extensive actions to confirm that the PBAPS security force remains attentive to its duties, including augmented team inspections, enhanced inspection oversight, and issuance of a confirmatory action letter (CAL) to Exelon to confirm NRC expectations regarding the licensee's root cause determinations and effective implementation of corrective actions. Upon completion of commitments by Exelon, NRC closed the CAL on August 28, 2008.

On January 6, 2009, NRC took enforcement action against Exelon, issuing a Severity Level III violation with a \$65,000 civil penalty for multiple instances of willful security officer inattentiveness.

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**Indian Point Nuclear Station: New Sirens** (previously reported as EOI-02 in NUREG-0090, Volume 29)

Background – On January 31, 2006, NRC issued a Confirmatory Order modifying the Indian Point license based on congressional action directed by the Energy Policy Act of 2005. This order required that the sirens used to alert the public in the 10-mile emergency planning zone around sites with a specified high population density (for which the Indian Point nuclear station, located 24 miles north of New York City on the Hudson River, was the only affected site) be provided with backup power. Entergy (the Indian Point licensee) decided to install a new siren system rather than retrofit the existing sirens.

The backup power supply was to be operable by January 30, 2007. However, Entergy requested, and NRC granted, a relaxation of the Order until April 15, 2007. On April 13, 2007, NRC received an additional extension request from Entergy; however, NRC denied the additional extension request because Entergy did not demonstrate good cause.

NRC issued a violation of the siren Order on April 23, 2007, and imposed a significant civil penalty of \$130,000 for failing to have the new siren system fully operable in the timeframes directed by the Order and the granted extension. On May 23, 2007, Entergy acknowledged the

violation, paid the civil penalty, and committed to having the siren system fully operable by August 24, 2007. NRC issued a second Order on July 30, 2007, requiring Entergy to meet the August 24, 2007 commitment.

Entergy also failed to fully meet the terms of the second Order since the Federal Emergency Management Agency (FEMA) had not performed its acceptance review by August 24, 2007. NRC issued a violation of the second Order to Entergy on August 30, 2007. On September 12, 2007, FEMA concluded that the new siren system was not adequate in that it did not meet several performance criteria set forth in FEMA guidance. On January 24, 2008, the NRC issued another notice of violation with a proposed civil penalty of \$650,000. On February 22, 2008, Entergy responded to the notice of violation and paid the civil penalty. Entergy's response is publicly available through ADAMS, under Accession No. ML080560260.

FEMA communicated to NRC that "the old siren system still in place had been performing above the required thresholds for reliability during routine siren tests, and was acknowledged to be more than adequate in terms of audibility and coverage of the 10-mile emergency planning zone." This provided reasonable assurance that the existing system was adequate to protect the health and safety of the public while issues with the new system were being resolved. The licensee's failure to have the new siren system in operation and approved by FEMA within the timeframe directed by the Order was resolved by NRC, but the delay did not endanger the public's health and safety.

#### Update on Actions Taken To Prevent Recurrence

FEMA approved the new siren system for service on August 22, 2008, and Entergy placed the new siren system in service on August 27, 2008. The NRC Order required the system to pass three consecutive monthly actuation tests with an actuation rate of at least 97 percent. Those tests were performed in September, October, and November 2008 and were successful, with siren actuation rates of 99.4 percent, 98.3 percent, and 99.4 percent, respectively. System reliability testing required by the NRC Order demonstrated that the new siren system was reliable. NRC notified stakeholders that the new siren system was operational on August 27, 2008. NRC's press release is publicly available through ADAMS, under Accession No. ML082350676.

On December 5, 2008, FEMA issued its final technical review of the preliminary siren design report. The final design report will be submitted to FEMA after approximately one year of reliability testing has been completed. The NRC Order also requires that Entergy receive FEMA approval prior to dismantling the old siren system. FEMA indicated its plans to grant permission to dismantle the old siren system after completion of the review of the final design report. Throughout installation of the new siren system, the existing siren system remained available and operated in a reliable manner. Final NRC closeout, including additional enforcement action (if any), regarding this issue are pending.

## APPENDIX E GLOSSARY

**Absorbed Dose** – as defined in 10 CFR 20.1003, means the energy imparted by ionizing radiation per unit mass of irradiated material; the units of absorbed dose are the rad and the gray (Gy)

**Act** – as defined in 10 CFR 40.4, means the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto

**Augmented Inspection Team (AIT)** – as defined in Management Directive 8.3, “NRC Incident Investigation Program,” is a group consisting of technical experts from the region in which an incident took place, augmented by personnel from headquarters, other regions, or contractors. The team performs an inspection of a significant operating event and reports directly to the appropriate regional administrator. The objectives of an AIT are to conduct a timely, thorough, and systematic inspection related to significant operational events at facilities licensed by the NRC; assess the health and safety significance of the event and communicate to regional and headquarters management the facts and safety concerns related to the event so that appropriate follow-up actions can be taken (e.g., study a generic concern, issue an information notice or bulletin); collect, analyze, and document factual information and evidence sufficient to determine the cause(s), conditions, and circumstances pertaining to the event

**Authorized Medical Physicist** – as defined in 10 CFR 35.2, is an individual who (1) meets the requirements in §§35.51(a) and 35.59; or (2) is identified as an authorized medical physicist or teletherapy physicist on (i) a specific medical use license issued by the Commission or Agreement State; (ii) a medical use permit issued by a Commission master material licensee; (iii) a permit issued by a Commission or Agreement State broad scope medical use licensee; or (iv) a permit issued by a Commission master material license broad scope medical use permittee

**Authorized User (AU)** – as defined in 10 CFR 35.2, is a physician who (1) meets the requirements in §§35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or (2) is identified as an authorized user on (i) a Commission or Agreement State license that authorizes the medical use of byproduct material; (ii) a permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material; (iii) a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or (iv) a permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material

<sup>1</sup>**Balloon Catheter** – a catheter with an inflatable balloon tip which is used during a procedure to enlarge a narrow opening or passage within the body. The deflated balloon catheter is positioned, then inflated to perform the necessary procedure, and then deflated again to be removed

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<sup>1</sup> These terms are not defined in 10 CFR, a management directive, an inspection procedure, or in a NRC policy statement. Rather, these terms are defined based upon definitions in the online *Wikipedia: The Free Encyclopedia* (<http://wikipedia.org>).

**Brachytherapy** – as defined in 10 CFR 35.2, is a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application

**Brachytherapy Source** – as defined in 10 CFR 35.2, means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters

**Confirmatory Action Letters** – as defined in NRC's Enforcement Policy, means letters confirming a licensee's or a contractor's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment

<sup>2</sup>**Catheter** – a tubular medical device for insertion into canals, vessels, passageways, or body cavities, for diagnostic or therapeutic purposes, as to permit injection or withdrawal of fluids or to keep a passage open

**Civil Penalty** – as defined in NRC's Enforcement Manual, is a monetary fine that is used to emphasize compliance in a manner that deters future violations and to focus licensee's attention on significant violations

<sup>2</sup>**Computed Tomography (CT)** – radiography in which a three-dimensional image of a body structure is constructed by computer from a series of cross-sectional images made along an axis

**Critical Mass of Special Nuclear Material** – as defined in 10 CFR 70.4, as used in subpart H, means special nuclear material in a quantity exceeding 700 grams of contained uranium-235; 520 grams of uranium-233; 450 grams of plutonium; 1500 grams of contained uranium-235, if no uranium enriched to more than 4 percent by weight of uranium-235 is present; 450 grams of any combination thereof; or one-half such quantities if massive moderators or reflectors made of graphite, heavy water, or beryllium may be present

**Dose Equivalent ( $H_T$ )** – as defined in 10 CFR 20.1003, means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest; the units of dose equivalent are the rem and sievert

**Effective Dose Equivalent ( $H_E$ )** – as defined in 10 CFR 20.1003, is the sum of the products of the dose equivalent to the organ or tissue ( $H_T$ ) and the weighting factors ( $w_T$ ) applicable to each of the body organs or tissues that are irradiated ( $H_E = \sum w_T H_T$ )

**Exposure** – as defined in 10 CFR 20.1003, means being exposed to ionizing radiation or to radioactive material

**External Dose** – as defined in 10 CFR 20.1003, means that portion of the dose equivalent received from radiation sources outside the body

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<sup>2</sup> These terms are not defined in 10 CFR, a management directive, an inspection procedure, or in a NRC policy statement. Rather, these terms are defined based upon definitions in Merriam-Webster's MedlinePlus Online Medical Dictionary. MedlinePlus is a service of the U.S. National Library of Medicine and the National Institutes of Health (<http://www.nlm.nih.gov/medlineplus/mplusdictionary.html>).

**Extremity** – as defined in 10 CFR 20.1003, means hand, elbow, arm below the elbow, foot, knee, or leg below the knee

<sup>1</sup>**Fibrosis** – the formation or development of excessive connective tissue in an organ or tissue as a reparative or reactive process

<sup>2</sup>**Gamma Knife** – a medical device that emits a highly focused beam of gamma radiation used in non-invasive surgery

**Gray (Gy)** – as defined in 10 CFR 20.1004, is the international system of unit of absorbed dose; one gray is equal to an absorbed dose of 1 Joule/kilogram (100 rads)

**Guide Tube (Projection Sheath)** – as defined in 10 CFR 34.3, means a flexible or rigid tube (i.e., “J” tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head

**High Dose-Rate (HDR) Remote Afterloader** – as defined in 10 CFR 35.2, is a brachytherapy device that remotely delivers a dose rate in excess of 12 Gy (1,200 rad) per hour at the point of surface where the dose is prescribed

**Industrial Radiography (Radiography)** – as defined in 10 CFR 34.3, means an examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images

<sup>1</sup>**Magnetic Resonance Image (MRI)** – primarily a medical imaging technique most commonly used in radiology to visualize the structure and function of the body. It provides detailed images of the body in any plane

**Manual Brachytherapy** – as defined in 10 CFR 35.2, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume

<sup>1</sup>**Maternal-Fetal Medicine** – is the branch of obstetrics that focuses on the medical and surgical management of high-risk pregnancies

**Medical Event** – as defined in 10 CFR 35.2, is an event that meets the criteria in §35.3045(a) or (b). 10 CFR 35.3045(a) states that a licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in (1) a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin and (i) the total dose delivered differs from the prescribed dose by 20 percent or more, (ii) the total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range, or (iii) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more; (2) a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following (i) an administration of a wrong radioactive drug containing byproduct material, (ii) an administration of a radioactive drug

containing byproduct material by the wrong route of administration, (iii) an administration of a dose or dosage to the wrong individual or human research subject, (iv) an administration of a dose or dosage delivered by the wrong mode of treatment, or (v) a leaking sealed source; (3) a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 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). 10 CFR 35.3045(b) states that a licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician

**<sup>1</sup>Medical Imaging** – refers to the techniques and processes used to create images of the human body (or parts thereof) for clinical purposes (medical procedures seeking to reveal, diagnose or examine disease) or medical science (including the study of normal anatomy and physiology)

**<sup>1</sup>Medical Sonography (Ultrasonography)** – is an ultrasound-based diagnostic medical imaging technique used to visualize muscles, tendons, and many internal organs, their size, structure and any pathological lesions with real time tomographic images

**Member of the Public** – as defined in 10 CFR 20.1003, means any individual except when that individual is receiving an occupational dose

**<sup>1</sup>Metastatic Disease** – is the spread of a disease from one organ or part to another non-adjacent organ or part. Only malignant tumor cells and infections can metastasize

**<sup>2</sup>Necrosis** – death of a portion of tissue differentially affected by local injury, such as loss of blood supply, corrosion, burning, or the local lesion of a disease

**Non-stochastic Effect (Deterministic Effect)** – as defined in 10 CFR 20.1003, means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a non-stochastic effect

**Notice of Violation** – as defined in NRC's Enforcement Policy, is a written notice setting forth one or more violations of a legally binding requirement. The Notice of Violation normally requires the recipient to provide a written statement describing (1) the reasons for the violation or, if contested, the basis for disputing the violation; (2) corrective steps that have been taken and the results achieved; (3) corrective steps that will be taken to prevent recurrence; and (4) the date when full compliance will be achieved. The NRC may waive all or portions of a written response to the extent that relevant information has already been provided to the NRC in writing or documented in an NRC inspection report or inspection record

**<sup>1</sup>Obstetrics** – is the surgical specialty dealing with the care of a woman and her offspring during pregnancy, childbirth, and the period shortly after birth

**Occupational Dose** – as defined in 10 CFR 20.1003, means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses

received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under §35.75, from voluntary participation in medical research programs, or as a member of the public

**Orders** – as defined in NRC's Enforcement Manual, can be used to modify, suspend, or revoke licenses or require specific actions by licensees or other persons. Orders can also be used to impose civil penalties

<sup>2</sup>**Ovum** – is a female reproductive cell, especially a mature egg that is ready for fertilization

<sup>1</sup>**Perinatologist** – is an obstetrician who practices maternal-fetal medicine

<sup>3</sup>**Potassium Iodide (brand name SSKI)** – is used along with antithyroid medicines to prepare the thyroid gland for surgical removal, to treat certain overactive thyroid conditions (hyperthyroidism), and to protect the thyroid in a radiation exposure situation; it works by shrinking the size of the thyroid gland and decreasing the amount of thyroid hormones produced; in a radiation exposure situation, it blocks only the thyroid from absorbing radioiodine

**Prescribed Dosage** – as defined in 10 CFR 35.2, means the specified activity or range of activity of unsealed byproduct material as documented (1) in a written directive; or (2) in accordance with the directions of the authorized user for procedures performed pursuant to §§35.100 and 35.200

**Prescribed Dose** – as defined in 10 CFR 35.2, means (1) for gamma stereotactic radiosurgery, the total dose as documented in the written directive; (2) for teletherapy, the total dose and dose per fraction as documented in the written directive; (3) for manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or (4) for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive

**Quality Factor (Q)** – as defined in 10 CFR 20.1003, means the modifying factor (listed in tables 1004(b).1 and 1004(b).2 of §20.1004) that is used to derive dose equivalent from absorbed dose

**Rad** – as defined in 10 CFR 20.1004, is the special unit of absorbed dose; one rad is equal to an absorbed dose of 100 ergs/gram or 0.01 Joule/kilogram (0.01 gray)

**Radiation (ionizing radiation)** – as defined in 10 CFR 20.1003, means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions; radiation, as used in 10 CFR Part 20, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light

**Radiation Safety Officer (RSO)** – as defined in 10 CFR 35.2, means an individual who (1) meets the requirements in §§35.50(a) or (c)(1) and 35.59; or (2) is identified as a Radiation Safety Officer on (i) a specific medical use license issued by the Commission or Agreement State; or (ii) a medical use permit issued by a Commission master material licensee

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<sup>3</sup> This term is not defined in 10 CFR, a management directive, an inspection procedure, or in a NRC policy statement. Rather, this term is defined based on the definitions in the online WebMD (<http://www.webmd.com/drugs>).

**<sup>1</sup>Radiation Therapy (Radiotherapy)** – the medical use of ionizing radiation as part of cancer treatment to control malignant cells

**Radiographer** – as defined in 10 CFR 34.3, means any individual who performs or who, in attendance at the site where the sealed source or sources are being used, personally supervises industrial radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of the Commission's regulations and the conditions of the license

**Radiographic Exposure Device (also called a camera, or a projector)** – as defined in 10 CFR 34.3, means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure

**<sup>1</sup>Radiology** – the medical specialty directing medical imaging technologies to diagnose and treat diseases

**Reactive Inspection** – as defined in NRC Inspection Procedure 43003, "Reactive Inspections of Nuclear Vendors," means an inspection performed for the purpose of obtaining additional information and/or verifying adequate corrective actions on reported problems or deficiencies

**Rem** – as defined in 10 CFR 20.1004, is the special unit of any of the quantities expressed as dose equivalent; the dose equivalent in rems is equal to the the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert)

**Severity Level III Violation** – as defined in NRC's Enforcement Manual, reflects the level of regulatory concern associated with the violation and usually involves actions with actual or high potential to have serious consequences on public health and safety or the common defense and security. This type of violation is significant enough to warrant consideration of a civil penalty

**Shallow-dose Equivalent (H<sub>s</sub>)** – as defined in 10 CFR 20.1003, which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm<sup>2</sup>)

**Shielded Position** – as defined in 10 CFR 34.3, means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement

**Sievert (Sv)** – as defined in 10 CFR 20.1004, is the internal system of unit of any of the quantities expressed as dose equivalent; the dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems)

**Source Material** – as defined in 10 CFR 70.4, means source material as defined in section 11z. of the Act and in the regulations contained in Part 40 of this chapter; as defined in 10 CFR 40.4, means: (1) uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05 percent) or more of: (i) uranium, (ii) thorium or (iii) any combination thereof. Source material does not include special nuclear material

**Special Inspection Team (SIT)** – as defined in Management Directive 8.3, “NRC Incident Investigation Program,” and Inspection Procedure 93812, “Special Inspection,” is similar to an AIT inspection except that the group is generally smaller (the number of members is based on management’s judgment) and is generally not augmented by personnel from headquarters or other regions or by contractors. The special inspection team reports directly to the appropriate regional administrator. The objective of an SIT is to assess an event and its causes

**Special Nuclear Material** – as defined in 10 CFR 70.4, means (1) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing but does not include source material

**Stereotactic Radiosurgery** – as defined in 10 CFR 35.2, means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume

**Stochastic Effects** – as defined in 10 CFR 20.1003, means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold; hereditary effects and cancer incidence are examples of stochastic effects

<sup>4</sup>**Tandem and Ovoid Brachytherapy** – is a method of intracavitary radiation therapy in which sources are used to deliver a radiation dose by using an applicator called a tandem and two ovoids for the treatment of early stage cervical cancer; the tandem is a hollow metal tube inserted into the uterus and the two ovoids are positioned on either side of the cervix

**Teletherapy** – as defined in 10 CFR 35.2, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject

**Therapeutic Dose** – as defined in 10 CFR 35.2, means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment

<sup>1</sup>**Thyroidectomy** – the surgical removal of all or part of the thyroid gland; surgeons often perform a thyroidectomy when a patient has thyroid cancer or some other condition of the thyroid gland (such as hyperthyroidism); other indications for surgery include cosmetic (very enlarged thyroid), or symptomatic obstruction (causing difficulties in breathing or swallowing)

**Treatment Site** – as defined in 10 CFR 35.2, is the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive

<sup>1</sup>**Ulcerative Colitis** – is a disease of the intestine, specifically the large intestine or colon, that includes open sores in the colon

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<sup>4</sup> This term is not defined in 10 CFR, a management directive, an inspection procedure, or in a NRC policy statement. Rather, this term is defined based on the definitions on the CET Cancer Center web page (<http://www.cetmc.com/gynecologic.html>).

**Weighting Factor ( $w_T$ )** – as defined in 10 CFR 20.1003, for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly; weighting factors are listed in the table “Organ Dose Weighting Factors”

**Whole Body** – as defined in 10 CFR 20.1003, means for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee

**Written Directive** – as defined in 10 CFR 35.2, means an authorized user’s written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in §35.40

**<sup>1</sup>Zygote** – is a cell that is the result of fertilization, usually formed from an ovum from a female and a sperm cell from a male

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## APPENDIX F CONVERSION TABLE

### Radioactivity and Ionizing Radiation

QUANTITY	FROM METRIC UNITS	TO NON-SI UNITS	DIVIDE BY
(Radionuclide) Activity	MBq	Curie (Ci)	37,000
	TBq	Ci	0.037
	GBq	Ci	37
Absorbed dose	Gy (gray)	Rad	0.01
	cGy	rad	1.0
Dose equivalent	Sv (sievert)	rem	0.01
	cSv	rem	1.0
	mSv	rem	10
	mSv	mrem	0.01
	μSv	mrem	10

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