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Report to Congress on Abnormal Occurrences

Fiscal Year 2009

Office of Nuclear Regulatory Research

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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 three events that NRC identified as AOs during Fiscal Year (FY) 2009 based on the criteria defined in Appendix A to this report. All three events occurred at NRC-licensed or regulated medical institutions and are medical events, as defined in Title 10, Part 35, of the *Code of Federal Regulations* (10 CFR Part 35).

In addition, this report describes six events that Agreement States identified as AOs during FY 2009, 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 37 Agreement States. The first and second Agreement State events 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 2008 Report to Congress on Abnormal Occurrences regarding the medical events at the Department of Veterans Affairs. During FY 2009, one item was identified as meeting the guidelines for inclusion in Appendix C, "Other Events of Interest" on leaks in underground pipes at some nuclear power plants. Appendix D, "Glossary," contains a glossary of terms used throughout this report. Appendix E, "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) 2009, 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 2008 Report to Congress on Abnormal Occurrences regarding the medical events at the Department of Veterans Affairs. During FY 2009, one item was identified as meeting the guidelines for inclusion in Appendix C, "Other Events of Interest" on leaks in underground pipes at some nuclear power plants. Appendix D, "Glossary," contains a glossary of terms used throughout this report. Appendix E, "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 Commission policy statement 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 AEA, 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 2009, there were 37 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 2008 Report to Congress on Abnormal Occurrences regarding the medical events at the Department of Veterans Affairs.

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. During FY 2009, one item was identified as meeting the guidelines for inclusion in Appendix C, "Other Events of Interest" on leaks in underground pipes at some nuclear power plants.

ABBREVIATIONS

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act
AO	abnormal occurrence
CFR	*Code of Federal Regulations*
cGy	centigray
Ci	curie
cm	centimeter
DVA	Department of Veterans Affairs
FR	*Federal Register*
FY	Fiscal Year
GB	gigabecquerel
Gy	gray
HDR	high dose-rate afterloader
MBq	megabecquerel
mCi	millicurie
mm	millimeter
mSv	millisievert
No.	number
NRC	U.S. Nuclear Regulatory Commission
RSO	radiation safety officer
Sv	sievert
TBq	terabecquerel
U.S.	United States
VA	Veterans Affairs

ABNORMAL OCCURRENCES IN FISCAL YEAR 2009

The following is a brief explanation of the outline numbering system used in this section of the report. Appendix A provides the specific criteria for determining when an event is an abnormal occurrence (AO) and provides the guidelines for reporting other events of interest which may not meet the AO criteria but which the Commission has determined should be in this report. Appendix A contains four major categories: I. For All Licensees, II. For Commercial Nuclear Power Plant Licensees, III. Events at Facilities Other Than Nuclear Power Plants and all Transportation Events, and IV. Other Events of Interest. Category IV events are discussed in Appendix C of the report and Categories I, II, and III are discussed in this section. Categories I and II contain significant subelements labeled A, B, C, and D and Category III goes to subelement C. This section of the report only discusses the specific subelement in Categories I, II, and III for which an AO was reported. The identification number for all Agreement State AO reports start with "AS." Similarly, the identification number for all Nuclear Regulatory Commission (NRC) AO reports start with "NRC." Medical terms have been defined in Appendix D, "Glossary."

I. FOR ALL LICENSEES

A. Human Exposure to Radiation from Licensed Material

During this reporting period, two events at Agreement State-licensed facilities were significant enough to be reported as abnormal occurrences, based on the criteria in Appendix A to this report. Although both of these events occurred at medical facilities, they both involved unintended exposures to individuals who were not the patient. Therefore, these events belong under the criteria I.A, "For All Licensees" category as opposed to the criteria III.C, "For Medical Licensees" category.

AS09-01 Human Exposure to Radiation at Chester County Hospital in West Chester, Pennsylvania

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provide, in part, 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 – March 30, 2009, West Chester, Pennsylvania

Nature and Probable Consequences – Chester County Hospital (the licensee) reported that a therapeutic dose of 2,001.7 MBq (54.1 mCi) of iodine-131 resulted in a dose to an embryo/fetus of 119 mSv (11.9 rem). On March 30, 2009, the patient was given a pregnancy test and it yielded a negative result. Based on the negative pregnancy test, the licensee administered the iodine-131 to the patient.

On May 13, 2009, the patient informed the authorized user that she was pregnant. The administration of iodine-131 was given to the patient approximately 5 days post-conception, a time period at which the thyroid had not developed. The hospital discovered the pregnancy at

9.5 weeks gestation, at which time the thyroid had developed. Due to residual iodine-131 in the patient's system, both a whole body and an organ dose exposure occurred. The hospital calculated a total whole body dose to the embryo/fetus of 119 mSv (11.9 rem) and a fetal thyroid dose of 9.7 mSv (0.97 rem). The hospital recommended that the patient consult with a genetic counselor for any potential health effects to the embryo/fetus.

Cause(s) – The cause of this event was the close proximity of conception, which resulted in a negative pregnancy test, to the administration of iodine-131.

Actions Taken to Prevent Recurrence

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

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

This event is closed for the purpose of this report.

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AS09-02 Human Exposure to Radiation at Loyola University Medical Center in Maywood, Illinois

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provide, in part, 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 – September 21, 2009, Maywood, Illinois

Nature and Probable Consequences – Loyola University Medical Center (the licensee) reported that the administration of 925 MBq (25 mCi) of iodine-131 resulted in a dose to an embryo/fetus of 67 mSv (6.7 rem). Prior to the administration of iodine-131, a urinary pregnancy test was conducted by the licensee on September 21, 2009, and it yielded a negative result. On September 29, 2009, the patient notified the licensee that she took a home pregnancy test and it was positive. The patient's pregnancy was confirmed by an independent clinic that administered a second pregnancy test.

The administration of iodine-131 was given to the patient at 2 to 3 weeks gestation (as determined by a consulting physician), a time period at which the thyroid had not developed. Shortly thereafter, the pregnancy ended. The licensee calculated a total whole body dose of 67 mSv (6.7 rem) to the embryo/fetus. There was no dose to the fetal thyroid since the pregnancy ended before the thyroid had developed.

Cause(s) – The cause of this event was the close proximity of conception, which resulted in a negative pregnancy test, to the administration of iodine-131.

Actions Taken To Prevent Recurrence

Licensee – The licensee reviewed its established patient selection criteria, screening methods, and testing protocols for any procedural changes. A more sensitive pregnancy test for women capable of bearing children will now be conducted no more than a few days prior to the dose administration.

State – After consulting an expert, the State determined that the administration occurred before the development of the thyroid. The State also performed independent calculations that verified the estimate of the fetal dose by the licensee. The State reviewed and accepted the licensee's formal report on October 14, 2009.

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, three 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.

AS09-03 Medical Event at St. Vincent's Medical Center Inc., in Jacksonville, Florida

Criterion 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 – September 10-17, 2008, Jacksonville, Florida

Nature and Probable Consequences – St. Vincent's Medical Center Inc., (the licensee) reported that a medical event occurred associated with a high dose-rate (HDR) mammosite treatment for breast cancer containing 199.8 GBq (5.4 Ci) of iridium-192. A patient was prescribed to receive 34 Gy (3,400 rad) to the right breast but received 34 Gy (3,400 rad) to the skin of the left breast.

On October 16, 2008, the patient notified her physician of erytherma on her left breast. During a records review, the medical physicist determined that an error in programming the catheter length in the HDR device caused the source to stop 10 cm short of the intended tumor site in the right breast. Due to this programming error, the dose intended for the right breast was delivered to the skin of the left breast. The authorized user concluded that no chronic health effect to the patient is expected.

Cause(s) – The medical event was caused by human error in failing to verify that the correct catheter length was entered into the treatment planning system.

Actions Taken To Prevent Recurrence

Licensee – The licensee committed to taking several corrective actions as a result of the medical event that include (1) utilizing a catheter length worksheet to determine and verify the mammosite catheter length, (2) documenting the mammosite catheter length by two individuals – one physicist and either a dosimetrist, physicist, or radiation therapist – during simulation treatment set-up, (3) providing procedures for the medical physicist and authorized user on documenting the catheter length on the catheter worksheet during the review of the treatment control unit and treatment plan, and (4) conducting a second measurement of the catheter length to verify that the length agrees with the data in the treatment control unit.

State – The Florida Bureau of Radiation Control 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.

NRC09-01 Medical Event at Saint Mary's Medical Center in Huntington, West Virginia

Criterion 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 the lens of the eye, or the gonads) and represents either 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 – October 15, 2008, Huntington, West Virginia

Nature and Probable Consequences – Saint Mary's Medical Center (the licensee) reported that a medical event occurred associated with the administration of a 5.55 GBq (150 mCi) iodine-131 capsule for thyroid cancer. A patient was prescribed to receive 10.12 Gy (1,012 rad) to the esophagus but received 18 Gy (1,800 rad) to the esophagus. The patient and the referring physician were informed of this event.

During the administration, the patient attempted to swallow the capsule, but it became lodged in an obstruction in the upper portion of the esophagus. Licensee staff provided the patient with soda and applesauce to help dissolve the capsule, and after 2.5 hours the capsule passed the obstruction. Since the capsule was lodged in the patient's upper portion of the esophagus for longer than expected, an estimated dose of 18 Gy (1,800 rad) was received to a small area of esophageal tissue. If the capsule had not become lodged in the upper portion of the patient's esophagus, the esophagus would have received the intended dose of 10.12 Gy (1,012 rad) instead of 18 Gy (1,800 rad). The dose to the esophagus exceeded the intended dose by 78 percent.

On October 22, 2008, the event was discussed with the patient during a follow-up visit with the prescribing physician. The prescribing physician indicated that potential health effects from this administration could include esophagitis and radiation fibrosis.

Cause(s) – The cause of the medical event was human error in failing to recognize that the esophageal obstruction might interfere with the patient's ability to swallow the iodine-131 capsule.

Actions Taken To Prevent Recurrence

Licensee – The licensee modified its procedure to include a pre-therapy esophageal dilation for patients known to have difficulty swallowing. In addition, patients known to have this difficulty may be administered liquid iodine-131 for treatment.

NRC – NRC contracted a medical consultant to review this event, its effect on the patient, and the licensee's corrective actions taken to prevent recurrence of similar events. The medical consultant concluded that no significant adverse health effect to the patient is expected. The NRC concluded an inspection on February 6, 2009, and one non-cited violation was issued to the licensee on February 10, 2009.

This event is closed for the purpose of this report.

AS09-04 Medical Event at Presbytarian Hospital of Dallas in Dallas, Texas

Criterion III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, 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 – December 2, 2008, Dallas, Texas

Nature and Probable Consequences – Presbytarian Hospital of Dallas (the licensee) reported that a medical event occurred associated with its gamma stereotactic radiosurgery unit (gamma knife) containing 125.8 TBq (3,400 Ci) of cobalt-60. A patient being treated for trigeminal neuralgia was prescribed to receive 80 Gy (8,000 rad) to the fifth intracranial nerve but received 14.95 Gy (1,495 rad) to the seventh intracranial nerve. The patient and the referring physician were informed of this event.

An error in entry of information into the treatment planning system caused the wrong nerve to receive treatment. The error was identified by the neurosurgeon 9 minutes into the 45-minute treatment. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s) – The medical event was caused by the misidentification of the anatomical target site listed on the written directive.

Actions Taken to Prevent Recurrence

Licensee – The licensee modified its written procedure to include verification of the target site, by the neuroradiologist, for each treatment. In addition, an updated written directive will document the new procedure to ensure that the correct treatment site is targeted and treated in each procedure.

State – The State will conduct a review of at least 20 percent of the past treatment cases to ensure that this error had not previously occurred.

This event is closed for the purpose of this report.

AS09-05 Medical Event at Cancer Care Northwest PET Center in Spokane, Washington

Criterion III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, 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 – April 14, 2009, Spokane, Washington

Nature and Probable Consequences – Cancer Care Northwest PET Center (the licensee) reported that a medical event occurred associated with a HDR brachytherapy treatment for prostate cancer containing 185 GBq (5 Ci) of iridium-192. During patient treatment, the aluminum connector to needle 13 became detached from the plastic guide tube and a dose of 12.5 Gy (1,250 rad) was delivered to a small area of the patient's inner thigh (wrong treatment site). The patient and the referring physician were informed of this event.

The source wire for needle 13 hung about 6 inches past the disconnected guide tube, which resulted in the skin dose. The licensee conducted several follow-up examinations of the patient's inner thigh and noted that no skin reddening or injury has occurred and the patient is not experiencing any pain in this area. Therefore, the licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s) – The cause of the medical event was the source wire, for needle 13, snagged on the seam between the aluminum connector and the plastic guide tube during retraction.

Actions Taken to Prevent Recurrence

Licensee – The licensee committed to taking several actions as a result of the medical event that include (1) requiring the staff to sign the patient quality assurance list when they check the applicators, transfer guide tubes, and aluminum connectors; (2) inspecting the guide tube catheters daily and examining the aluminum connectors prior to patient use; and (3) revising the refresher training to include new procedures for staff prior to patient treatment.

State – The State conducted follow-up inspection activities from April-May 2009, and reviewed the licensee's corrective actions. The State found the licensee's corrective actions adequate and did not take any enforcement action regarding this event.

This event is closed for the purpose of this report.

AS09-06 Medical Event at The Urology Center in Cincinnati, Ohio

Criterion 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 11, 2009, Cincinnati, Ohio

Nature and Probable Consequences – The Urology Center (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed to receive a total dose of 144 Gy (14,400 rad) to the prostate using 64 iodine-125 seeds as permanent implants. Instead, the patient received an approximate dose of 76 Gy (7,600 rad) to the urethra and bulb of the penis (unintended sites). The patient and the referring physician were informed of this event.

According to the licensee, an interpretation of the ultrasound image of the patient's prostate resulted in 30 of the 64 seeds delivered to the prostate while the other 34 seeds were delivered outside the prostate. Due to the patient's prostate being smaller than normal, the prostate received 68 Gy (6,800 rad) of the prescribed dose and the urethra and bulb of the penis (unintended sites) received approximately 76 Gy (7,600 rad). Prior to the seeds being implanted, the urologist and radiation oncologist should have consulted on the ultrasound image of the patient's prostate to determine the correct seed placement. The licensee concluded that no significant adverse health effect on the patient is expected. On May 19, 2009, the patient returned for a second treatment to compensate for the original underdosing to the prostate.

Cause(s) – The cause of the medical event was the misinterpretation of the correct size of the patient's small prostate gland by ultrasound.

Actions Taken To Prevent Recurrence

Licensee – Corrective actions taken by the licensee included instituting a new policy requiring agreement by both the urologist and radiation oncologist on seed placement for all prostate glands measuring 20 cubic centimeters or less. On May 26, 2009, the licensee submitted a written report of this event to the Ohio Department of Health, Bureau of Radiation Protection (ODH BRP).

State – On June 12, 2009, ODH BRP conducted an inspection of this event and determined that the licensee had followed the correct procedures for administrations requiring a written directive. ODH BRP reviewed the licensee's corrective actions for this event and found the corrective actions to be adequate.

This event is closed for the purpose of this report.

NRC09-02 Medical Event at Gamma Knife Center of the Pacific in Honolulu, Hawaii

Criterion III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, 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 – July 2, 2009, Honolulu, Hawaii

Nature and Probable Consequences – Gamma Knife Center of the Pacific (the licensee) reported that a medical event occurred associated with its gamma stereotactic radiosurgery unit (gamma knife) containing 104.86 TBq (2,834 Ci) of cobalt-60. A patient being treated for multiple brain metastatic sites was prescribed to receive 24 Gy (2,400 rad) to seven discrete brain sites using an 8 mm collimator. However, an 18 mm collimator was used to treat two of the discrete brain sites, resulting in a dose of 24 Gy (2,400 rad) to additional brain tissue. The patient and the referring physician were informed of this event.

The patient received treatment to the first and second discrete brain sites and after receiving treatment to the second discrete site, it was discovered that an 18 mm collimator was used to deliver treatment instead of the prescribed 8 mm collimator. The larger collimator caused the volume of each of the two discrete sites to increase by 2.45 cubic meters, resulting in a dose of 24 Gy (2,400 rad) to additional brain tissue. After the 18 mm collimator was discovered, it was replaced with the 8 mm collimator and the patient received treatment to the five remaining discrete sites as prescribed. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s) – The cause of the medical event was human error in failing to check the collimator size prior to patient treatment.

Actions Taken To Prevent Recurrence

Licensee – Corrective actions taken by the licensee included (1) sending a notice to all authorized users, neurosurgeons, and medical physicists reiterating that they should each independently check the collimator size prior to patient treatment and (2) revising procedures to have a second independent verification of all treatment parameters, including the collimator size, by a treatment team member.

NRC – NRC conducted an onsite inspection and hired a medical consultant to review the event. The conclusions from the onsite inspection and medical consultant's review are ongoing.

This event is open for the purpose of this report.

NRC09-03 Medical Event at the Veterans Affairs San Diego Health Care System in San Diego, California

Criterion III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, 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 – September 21, 2009, San Diego, California

Nature and Probable Consequences – The Department of Veterans Affairs (the licensee), National Health Physics Program (NHPP) reported that a medical event occurred at the Veterans Affairs (VA) San Diego Health Care System associated with a therapeutic dosage of iodine-131 for the treatment of metastatic thyroid cancer. A patient was prescribed to receive 6.9 GBq (187 mCi) of iodine-131 to the metastatic sites around the body but received 6.1 GBq (166 mCi) to the stomach (wrong treatment site). The patient and the referring physician were informed of this event.

On September 21, 2009, a dosage of 6.9 GBq (187 mCi) of iodine-131 was administered to the patient through an existing feeding tube. Daily radiation measurements indicated small decreases in radiation readings that were consistent with the physical decay of iodine-131, but not consistent with the biological elimination of iodine-131. On September 25, 2009, the feeding tube was replaced and a subsequent investigation revealed that the majority of the dosage, 6.1 GBq (166 mCi), was administered to the wrong orifice of the feeding tube. As a result, the dosage remained in the balloon of the feeding tube and irradiated the patient's stomach, resulting in an approximate dose of 16 Gy to 19 Gy (1,600 rad to 1,900 rad) to the stomach.

Cause(s) – Three root causes were identified for this medical event: (1) inadequate training of staff, (2) inadequate procedures, and (3) an inadequate procedure on the verification that administrations involving feeding tubes were being administered in accordance with a written directive.

Actions Taken To Prevent Recurrence

Licensee – Corrective actions taken by the licensee included (1) immediate suspension of any further gastric tube administrations until the direct cause of the medical event was identified, (2) suspension of one individual's participation in administrations requiring a written directive, (3) informal training of the nuclear medicine technologists by the Radiation Safety Officer, and (4) development of draft written policies and procedures on the administration of iodine-131 through a gastric tube.

NRC – The NRC Region III Office conducted a reactive inspection on November 3, 2009, and also contracted a medical consultant to review this event. Based on the results of the inspection, five apparent violations of NRC's regulations were identified. Enforcement action is pending and the medical consultant's review is on-going.

This event is open 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 Title 10 of the *Code of Federal Regulations* (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[1,2]

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[3] case of actual theft or diversion of licensed, risk-significant radioactive sources or a formula quantity[4] of special nuclear material; or act that results in radiological sabotage[5].

3. Any substantiated[3] loss of a formula quantity[4] of special nuclear material or a substantiated[3] inventory discrepancy of a formula quantity[4] of special nuclear material that is judged to be caused by theft or diversion or by a substantial breakdown[6] of the accountability system.

4. Any substantial breakdown[6] of physical security or material control (i.e.,

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1 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.

2 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.

3 "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.

4 A formula quantity of special nuclear material is defined in 10 CFR 70.4.

5 Radiological sabotage is defined in 10 CFR 73.2.

6 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.

access control containment or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.

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.[7]

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 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.[8]

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7 This subelement addresses 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."

8 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 (ΔCDP) of greater than 1×10^{-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).[9]

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 an 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

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9 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.

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) 2008" regarding the medical events at the Department of Veterans Affairs.

Medical Events at the Department of Veterans Affairs (previously reported as NRC08-02 in NUREG-0090, Volume 31)

Date and Place – February 2002 to May 2008, Department of Veterans Affairs, Philadelphia, Pennsylvania

Background – The VA Medical Center – Philadelphia reported that 97 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 67 of the 97 patients received less than 80 percent of the prescribed dose to the prostate. The licensee reported that 35 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 reviewed each medical event for possible health effects on the patients. The circumstances specific to each patient were evaluated to determine if follow-up medical care was necessary. The full details of the event are discussed in the FY 2008 abnormal occurrence report as NRC08-02. At the time the report was issued, the event was listed as closed. However, due to follow-up actions taken by the NRC and the Department of Veterans Affairs, there is significant updated information to report on this event.

Update on Actions Taken To Prevent Recurrence

On June 11, 2008, the licensee suspended its prostate brachytherapy program and committed to taking several corrective actions regarding these medical events. The licensee's corrective actions included: (1) revising its procedures for prostate brachytherapy treatments to include an evaluation and verification that the administered dose is in accordance with the written directive, (2) developing procedures that include directions that require the radiation oncology staff to stop a procedure if there was any uncertainty associated with the treatment, (3) amending the Philadelphia VA Medical Center Sealed Source Radiotherapy Policy to include i) a comparison and evaluation of both treatment plans and associated calculations with the written directive; ii) developing procedures that include directions that allow prostate brachytherapy treatments to proceed only when the treatment planning computer is able to produce pre- and post-treatment plans; and iii) immediate reporting of all deviations that exceed 10 percent of the prescribed dose or dose fraction to the Radiation Safety Officer (RSO) and quality management staff, (4) instituting a medical center peer-review system for radiation oncology services and post-treatment evaluations, (5) providing radiation safety training to radiation oncology staff, nuclear medicine staff, new employees, trainees, and contractors regarding NRC regulations for written

directives and reporting of medical events, (6) revising the contract for radiation oncology services to realign these services under the RSO, and (7) instituting an internal quality assurance program to ensure communications between radiation oncology team members regarding safety and treatment concerns. In addition, the licensee committed to suspending prostate brachytherapy treatments until all corrective actions have been completed and have been approved to re-start by the NHPP. The licensee will also conduct an external review of the former prostate implant program, by physicians and medical physics consultants who are experts in performing prostate brachytherapy treatments, and incorporate the recommendations from this review into the hospital's policies and procedures.

On October 19, 2009, the VA Medical Center – Philadelphia submitted its final dose assessments for the 114 patients that received permanent prostate implants at the medical center between February 25, 2002 to June 5, 2008. After careful review of the summary of patient dose data, the staff identified 17 cases that met the current NRC abnormal occurrence criteria. In all cases, the prescribed dose to the prostate was 160 Gy (16,000 rad) and the dose actually delivered to the prostate was in the range of 39 Gy to 111 Gy (3,900 rad to 11,100 rad). The dose to the periprostatic tissues ranged between 248 Gy and 588 Gy (24,800 rad and 58,800 rad).

Each of the 17 cases was considered to be a medical event because (1) the region of the patient's periprostatic tissue or rectum where the seeds were placed received a dose that was greater than 0.5 Gy (50 rad) and was 50 percent greater than the expected dose the area would have received if the treatment had been administered in accordance with the written directive and treatment plan, and (2) the prostate received 20 percent less than the prescribed dose of 160 Gy (16,000 rad).

Of the 97 medical events reported by the licensee, an NRC medical consultant reviewed 39 of these medical events, including the written directives and treatment plans, with NRC inspectors and the licensee's consulting medical physicist. The medical consultant reviewed the permittee's spreadsheet summarizing the treatments and provided a statistical analysis of the data. The medical consultant was in general agreement with the licensee's dose estimates to the patients; however, the medical consultant indicated that variable seed placement caused a number of patients to have elevated doses to the rectum, bladder, or periprostatic tissue. The medical consultant identified specific patients with rectal bleeding where the increased dose to the patient's colon, which resulted from variable seed placement, may have been a contributing factor to the bleeding.

During the October 2009 NRC inspection, the licensee committed to taking several additional corrective actions regarding these events including (1) performing verification computed tomography scans on all patients who received prostate implants between February 25, 2002, and May 12, 2008, and re-evaluating the dose delivered to the prostate and periprostatic tissue and/or rectum, (2) referring eight patients to the VA Puget Sound Health Care System – Seattle for re-implantation procedures, and (3) removing one individual from performing brachytherapy treatments at VA facilities.

The NRC Region III Office issued its inspection reports on March 30, 2009, and November 17, 2009. Based on the results of the inspections, eight apparent violations of NRC regulations were identified. A pre-decisional enforcement conference was held on December 17, 2009. On March 17, 2010, the NRC issued a Notice of Violation and a proposed imposition of a civil penalty in the amount of $227,500. Payment of the civil penalty was made by the Department of Veterans Affairs and was received by the NRC on April 8, 2010.

APPENDIX C
OTHER EVENTS OF INTEREST

This appendix discusses "Other Events of Interest" that do not meet the 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.

NUCLEAR POWER PLANTS – LEAKS IN UNDERGROUND PIPES

Ground water contamination caused by undetected leakage of radioactive water was discussed in the "Report to Congress on Abnormal Occurrences: Fiscal Year 2006" and is being discussed in this report due to recent stakeholder interest on this topic.

The NRC is aware of significant Congressional interest and media coverage of leaks in underground pipes at some nuclear power plants as well as information indicating that there may be perceptions that these underground pipe leaks have had high health and safety significance. Tritium is a mildly radioactive isotope of hydrogen that occurs both naturally and during the operation of nuclear power plants. Nuclear plants normally release water containing tritium and other radioactive substances under controlled, monitored conditions that the NRC mandates to protect public health and safety. Although none of these releases meet the abnormal occurrence criteria, they are being included in this report because of the significant public, Congressional, and media interest.

Over the past year, instances of buried piping leaks have occurred in safety-related and nonsafety-related piping at nuclear power plants. Some of these leaks have caused inadvertent releases of low-level radioactive material. This has resulted in groundwater contamination at several plants. The pipe degradation leading to these leaks has not affected the operability of safety systems, and the type and amount of radioactive material released to the environment have been a small fraction of the regulatory limits. To date, the leaks have not presented a public health and safety risk.

The NRC reviews affected plants' groundwater monitoring programs to confirm the leaks do not affect public health and safety and the environment. The NRC's oversight of the overarching buried pipe issue focuses on ensuring nuclear power plant operators properly monitor and when necessary repair the pipes, maintaining their ability to safely run the plants.

APPENDIX D
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

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

[1]**Balloon Catheter** – a catheter that has two lumens and an inflatable tip which can be expanded by the passage of gas, water, or a radiopaque medium through one of the lumens and that is used especially to measure blood pressure in a blood vessel or to expand a partly closed or obstructed bodily passage or tube (as a coronary artery)

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

[1]**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

[1]**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

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

[1] 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).

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 ($H_E = \Sigma\, w_T H_T$)

[1]**Esophagitis** – inflammation of the esophagus

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

[1]**Fibrosis** – a condition marked by increase of interstitial fibrous tissue

[2]**Gamma Knife** – a type of radiosurgery (radiation therapy) machine that acts by focusing low-dosage gamma radiation from many sources on a precise target. Areas adjacent to the target receive only slight doses of radiation, while the target gets the full intensity. The gamma knife may be used to treat brain tumors; meningiomas (tumors on the protective layers of the brain); and trigeminal neuralgia causing severe facial pain

[2]**Glans (Bulb of Penis)** – the rounded head of the penis

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)

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

[2]**Hybridoma** – a cell hybrid resulting from the fusion of a cancer cell and a normal lymphocyte (a type of white blood cell)

[1]**Interstitial** – situated within but not restricted to or characteristic of a particular organ or tissue, used especially of fibrous tissue

[1]**Lumen** – the bore of a tube (as of a hollow needle or catheter)

[3]**Mammosite Treatment** – a minimally invasive radiation therapy technique used to treat breast cancer. This technique uses brachytherapy to deliver radiation directly to the site of the tumor bed from inside the body. A soft balloon, attached to a thin catheter, is inserted into the cavity where the tumor was removed. The balloon is inflated and a computer-controlled machine delivers the radiation down the catheter into the balloon, where it irradiates the tumor bed

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[2] 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 MedicineNet's Online MedTerms Medical Dictionary. MedicineNet is an online service part of WebMD (www.medterms.com).

[3] This term is not defined in 10 CFR, a management directive, an inspection procedure, or in a NRC policy statement. Rather, these terms are defined based on the definitions in the online WebMD (www.webmd.com).

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

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

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

[1]**Metastasis** – the spread of a disease-producing agency (as cancer cells or bacteria) from the initial or primary site of disease to another part of the body

[1]**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

[1]**Neuralgia** – acute paroxysmal pain radiating along the course of one or more nerves usually without demonstrable changes in the nerve structure

[2]**Neuroradiologist** – a radiologist who specializes in the use of radioactive substances, x-rays and scanning devices for the diagnosis and treatment of diseases of the nervous system. A neuroradiologist may be concerned with the clinical imaging, therapy, and basic science of the central and peripheral nervous system, including but not limited to the brain, spine, head and neck

[2]**Neurosurgeon** – a physician trained in surgery of the nervous system and who specializes in surgery on the brain and other parts of the nervous system

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

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

[1]**Paroxysm** – a sudden attack or spasm (as of a disease), or a sudden recurrence of symptoms or an intensification of existing symptoms

[2]**Periprostatic** – cancerous tissue around the prostate gland

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

[2]**Radiation Oncologist** – a specialist in the use of radiation therapy as a treatment for cancer.

[2]**Radiation Therapy (Radiotherapy)** – in radiation therapy, high-energy rays are used to damage cancer cells and stop them from growing and dividing. A specialist in radiation therapy is called a radiation oncologist

[2]**Radiologist** – a physician specialized in radiology, the branch of medicine that uses ionizing and non-ionizing radiation for the diagnosis and treatment of disease

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)

Shallow-dose Equivalent (H_S) – 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^2)

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 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

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

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

[2]**Trigeminal Nerve** – the trigeminal nerve functions both as the chief nerve of sensation for the face and the motor nerve controlling the muscles of mastication (chewing). The trigeminal nerve is the fifth cranial nerve. The cranial nerves emerge from or enter the skull (the cranium), as opposed to the spinal nerves which emerge from the vertebral column. There are twelve cranial nerves

[1]**Trigeminal Neuralgia** – a very painful swelling (inflammation) of the nerve (trigeminal nerve) that delivers feeling to the face and "surface" of the eye

[2]**Urethra** – the transport tube leading from the bladder to discharge urine outside the body

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

APPENDIX E
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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Section 208 of the Energy Reorganization Act of 1974 identifies an abnormal occurrence (AO) as an unscheduled incident or event that the Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Report Elimination and Sunset Act of 1995 requires that the AOs be reported to Congress on an annual basis. This report includes those events that the NRC has determined to be AOs during fiscal year 2009.

This report describes three events at NRC-licensed facilities and six events at Agreement State Licensed facilities that meet the criteria to be classified as AOs. In addition, this report provides an update to one event reported in fiscal year 2008 and one other event of interest.

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