REPORT TO CONGRESS

ON

ABNORMAL OCCURRENCES

FISCAL YEAR 2007

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 the five events that the NRC identified as AOs during Fiscal Year (FY) 2007, based on the criteria defined in Appendix A to this report. All five of those events occurred at NRC-licensed medical institutions. The first event involved radiation exposure to an embryo/fetus. The other four NRC-licensee 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 six events that Agreement States identified as AOs during FY 2007, based on the criteria in Appendix A to this report. Agreement States are those States that have entered into formal agreements with the 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 34 Agreement States. All six of the events that were reported by Agreement States occurred at medical institutions and were medical events, as defined in 10 CFR Part 35.

Appendix A to this report presents the 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 an update regarding an event that was reported in the FY 2006 Report to Congress on Abnormal Occurrences, which involved a spill of high-enriched uranium at a fuel fabrication facility. Appendix C, "Other Events of Interest," presents two events of interest identified during FY 2007 at two U.S. commercial 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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CONTENTS

ABSTRACT iii

EXECUTIVE SUMMARY
INTRODUCTION vii
THE LICENSING AND REGULATORY SYSTEM vii
REPORTABLE EVENTS viii
AGREEMENT STATES viii
FOREIGN INFORMATION ix
UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES ix
OTHER EVENTS OF INTEREST ix

ABBREVIATIONS xi

ABNORMAL OCCURRENCES IN FISCAL YEAR 2007
FOR ALL LICENSEES 1
NRC07-01 Human Exposure to Radiation at Washington University Medical Center in St. Louis, Missouri 1
COMMERCIAL NUCLEAR POWER PLANT LICENSEES 2
EVENTS AT FACILITIES OTHER THAN NUCLEAR POWER PLANTS AND ALL TRANSPORTATION EVENTS 2
MEDICAL LICENSEES 2
NRC07-02 Medical Event at St. Luke's Hospital of Kansas City, Missouri 2
NRC07-03 Medical Event at Hackley Hospital in Muskegon, Michigan 3
NRC07-04 Medical Event at Kennedy Memorial Hospitals in Turnersville, New Jersey 4
NRC07-05 Medical Event at the University of Virginia at Charlottesville, Virginia 5
AS07-01 Medical Event at St. James Hospital and Health Center in Olympia Fields, Illinois 6
AS07-02 Medical Event at Aroostook Medical Center of Presque Isle, Maine 7
AS07-03 Medical Event in New York 8
AS07-04 Medical Event at Memorial Mission Hospital of Asheville, North Carolina 9
AS07-05 Medical Event at University of Washington Harborview Gamma Knife in Seattle, Washington 10
AS07-06 Medical Event at Physician Reliance of Forth Worth, Texas 11

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Appendices

A. ABNORMAL OCCURRENCE CRITERIA AND GUIDELINES FOR OTHER EVENTS OF INTEREST……...13

B. UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES…….18

C. OTHER EVENTS OF INTEREST……..20
EOI-01 Peach Bottom Atomic Power Station……20
EOI-02 Indian Point Nuclear Station……21

D. GLOSSARY……..23

E. CONVERSION TABLE……...28

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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 the NRC report AOs to Congress annually.

This report describes those events that the NRC or an Agreement State identified as AOs during Fiscal Year (FY) 2007, based on the criteria defined in Appendix A to this report. Agreement States are those States that have entered into formal agreements with the NRC pursuant to Section 274 of the Atomic Energy Act (AEA) to regulate certain quantities of AEA material at facilities located within their borders. The 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 the 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 an update regarding an event that was reported in the FY 2006 Report to Congress on Abnormal Occurrences, which involved the spill of high-enriched uranium at a fuel fabrication facility. Appendix C, "Other Events of Interest," presents two events of interest identified during FY 2007 at two U.S. commercial 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 the 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 the NRC's Strategic Plan for FY 2004–2009 (NUREG-1614, Volume 3, August 2004). To accomplish its objectives, the NRC regularly conducts licensing proceedings, inspection and enforcement activities, operating experience evaluations, and confirmatory research. The NRC also maintains programs to establish standards and issue technical reviews and studies. In addition, the NRC considers public participation as one essential element of the regulatory process.

The 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 and quality assurance criteria appropriate for the various activities regulated by the NRC. Licensing, inspection, and enforcement programs provide a regulatory framework to ensure compliance with the regulations. In addition, the NRC is striving to make the regulatory system more risk-informed and performance-based, where appropriate.

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REPORTABLE EVENTS

The 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 the 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 the NRC. Such reporting helps to identify deficiencies and ensure that corrective actions are taken to prevent recurrence.

The NRC and industry review and evaluate operating experience to identify safety concerns and the NRC disseminates the information from those reviews and evaluations to licensees 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.

As defined in Title 10 of the *Code of Federal Regulations*, the 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, the NRC also issues *Federal Register* notices describing AOs at facilities licensed or otherwise regulated by the NRC or Agreement States. In addition, the 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 capable of sustaining a chain reaction. States that enter into such agreements with the 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 2007, there were 34 Agreement States.

Agreement States report event information to the 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). The NRC has also developed and implemented procedures for evaluating materials events to identify those that should be reported as AOs. Toward that end, the NRC uniformly applies the AO criteria (in Appendix A to this report) to events at facilities regulated by either the NRC or Agreement States. In addition, in early 1977, the Commission determined that the annual report to Congress should also 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 the NRC issues to disseminate AO-related information to the public.

FOREIGN INFORMATION

The 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

The NRC provides updates of previously reported AOs if significant new information becomes available. Appendix B, "Updates of Previously Reported Abnormal Occurrences," provides an update regarding an event that was reported in the FY 2006 Report to Congress on Abnormal Occurrences, which involved the spill of high-enriched uranium at a fuel fabrication facility.

OTHER EVENTS OF INTEREST

The 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 2007 at two U.S. commercial nuclear power plants.

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ABBREVIATIONS

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act
AIT	augmented inspection team
AO	abnormal occurrence
Bq	becquerel
CFR	*Code of Federal Regulations*
cGy	centigray
Ci	curie
cm	centimeter
cSv	centisievert
DRF	dose rate factor
FEMA	Federal Emergency Management Agency
FR	*Federal Register*
FY	Fiscal Year
GBq	gigabecquerel
Gy	gray
HEU	high-enriched uranium
HDR	high dose-rate afterloader
in	inch
MBq	megabecquerel
μCi	microcurie
mCi	millicurie
mSv	millisievert
No.	number
NRC	U.S. Nuclear Regulatory Commission
PBAPS	Peach Bottom Atomic Power Station
QA	quality assurance
RCP	Radiation Control Program
RSO	radiation safety officer
Sv	sievert
TAC	Texas Administrative Code
TBq	terabecquerel

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ABNORMAL OCCURRENCES IN FISCAL YEAR 2007

I. FOR ALL LICENSEES

A. Human Exposure to Radiation from Licensed Material

During this reporting period, one event at an NRC-licensed and regulated facility was significant enough to be reported as an abnormal occurrence (AO), based on the criteria in Appendix A to this report.

NRC07-01 Human Exposure to Radiation at Washington University Medical Center in St. Louis, Missouri

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report states 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 – May 29, 2007, St. Louis, Missouri

Nature and Probable Consequences – Washington University Medical Center (the licensee) reported that cancer treatment to a 22 year old patient using iodine-131 resulted in a dose to an embryo/fetus. On May 29, 2007, the treatment was conducted at Barnes Jewish Hospital, the affiliated teaching hospital of Washington University School of Medicine, using 4.64 GBq (126 mCi) of iodine-131. Prior to that treatment, the patient saw her prescribing physician on May 22, 2007, for a related consultation. In addition, because hospital procedures require a pregnancy test within 1 week before the therapy is administered, the licensee conducted a pregnancy test on the patient the same day. That test yielded a negative result and the patient was advised not to get pregnant prior to the treatment. Moreover, before treatment on May 29, 2007, the patient signed a statement that, to the best of her knowledge, she was not pregnant. However, on May 30, 2007, the patient performed a home pregnancy test, which yielded a positive result. Consequently, the licensee performed another pregnancy test the same day, and the results indicated that the patient had been pregnant for 4–5 weeks at the time of the iodine-131 administration. The patient and the referring physician were informed of this event. As an approximation for the dose equivalent received by the embryo/fetus, the licensee's staff calculated an annual total effective dose equivalent to the patient's uterus, which was estimated to be 250–340 mSv (25–34 rem).

The NRC-contracted medical consultant confirmed the licensee's dose estimate and determined that the most likely result would be delivery of a normal infant (with regard to thyroid function) because the iodine-131 was administered at such an early stage in the pregnancy; however, the risk of childhood cancer may be slightly increased. The possible effects of the event have been discussed with the patient.

Cause(s) – The causes of this event were the false negative pregnancy test and the patient's lack of awareness that she might be pregnant.

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Actions Taken to Prevent Recurrence

Licensee – Because the causes of the event were beyond the licensee's control, the licensee determined that no corrective action was necessary to prevent recurrence.

NRC – There were no violations identified by the NRC.

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

NRC07-02 Medical Event at St. Luke's Hospital of Kansas City, Missouri

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report states 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 23–26, 2006, Kansas City, Missouri

Nature and Probable Consequences – On October 27, 2006, St. Luke's Hospital of Kansas City (the licensee) notified the NRC of a medical event that occurred during a high dose-rate (HDR) remote afterloader, using a 144 GBq (3.9 Ci) iridium-192 source, brachytherapy procedure to treat breast cancer.

The authorized user physician developed a written directive that prescribed 10 fractionated doses, to be administered to the patient's left breast using a balloon catheter technique, with each dose consisting of 3.4 Gy (340 rad), for a total dose of 34 Gy (3,400 rad). The first fractionated dose was administered to the patient on October 23, 2006. On October 26, 2006, after the seventh fraction and prior to administering the eighth fraction to the patient, the chief physicist noted a discrepancy. The investigation into the discrepancy revealed that the catheter length entered into the treatment planning computer was 93.0 cm (36.6 in), rather than 95.0 cm

(37.4 in). This error resulted in delivering an unplanned dose of 100 Gy (10,000 rad), 1.0 cm (0.4 in) from the treatment site and proximal from the balloon. The area proximal from the balloon would have received an intended dose of 24.5 Gy (2,450 rad), had the treatment been delivered as prescribed by the authorized user physician. Moreover, because the prescribed dosage was not delivered to the correct location, the patient also received an under dosage to the distal side of the balloon. Specifically, the area intended to be treated received a dose in the range of 7 Gy to 10 Gy (700 rad to 1,000 rad) rather than the prescribed dosage of 34 Gy (3,400 rad). The patient and the referring physician were informed of this event. The authorized user physician did not expect any acute adverse medical effects to the patient as a result of the medical event, but indicated that surgery may be required in the future. The authorized user physician discontinued further treatments and plans to follow-up on the patient clinically.

The NRC-contracted medical consultant expects some necrosis to fatty tissue in the overexposed region of the breast, within 2–4 months.

Cause(s) – The medical event was caused by the dosimetrist's failure to enter the correct catheter length in preparing the treatment plan parameters for the HDR brachytherapy treatment. In addition, the licensee's written procedures for implementing HDR treatment plans did not require verification of the treatment plan parameters to ensure that they were correct.

Actions Taken to Prevent Recurrence

Licensee – The licensee initiated several immediate and long-term corrective actions to prevent recurrence. Specifically, those corrective actions included (1) revising the procedures for HDR treatments to include verification of the catheter length and input to the treatment planning computer by both the medical physicist and the authorized user physician, (2) revising the treatment plan record to require that the authorized user physician and the medical physicist document the verification of the catheter length, and (3) conducting in-house training to ensure that staff are aware of the new procedural steps and to ensure that the prescribing authorized user physician and the medical physicist actively participate in the training.

NRC – On March 14, 2007, the NRC issued a Notice of Violation related to this event.

This event is closed for the purpose of this report.

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NRC07-03 Medical Event at Hackley Hospital in Muskegon, Michigan

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report states, 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 – January 8, 2007, Muskegon, Michigan

Nature and Probable Consequences – On January 8, 2007, Hackley Hospital (the licensee) notified the NRC of a medical event that occurred during a brachytherapy seed implant procedure to treat prostate cancer. The written directive prescribed a total dose of 120 Gy

(12,000 rad) to the patient's prostate using 41 iodine-125 seeds as permanent implants. According to the licensee, because the patient moved, only 7 of the prescribed 41 seeds were delivered to the prostate (the intended site), and the other 34 seeds were delivered to an unintended site located approximately 4 cm (1.6 in) inferior to the prostate. As a result, the prostate received a dose of approximately 13 Gy (1,300 rad) rather than the prescribed dose of 120 Gy (12,000 rad) (~90% less than the prescribed dose). In addition, the unintended site received a dose of approximately 110 Gy (11,000 rad) and the patient's skin around the unintended site received a dose of approximately 2.4 Gy (240 rad). The patient and the referring physician were informed of this event. The patient will require further treatment via external beam therapy in order to deliver the appropriate dose to the prostate.

The NRC-contracted medical consultant agreed with the licensee's dose estimate and concluded that the risk for impotence is somewhat increased by the additional radiation dose to the unintended site as a result of the medical event. There may also be some risk of perineal tissue fibrosis and skin irritation, although the risk may not be significant enough to cause clinical concerns.

Cause(s) – The licensee determined the root cause of the event was a failure to identify the patient's movement before continuing with the procedure. In addition, the NRC inspector determined that the licensee failed to develop adequate written procedures to provide high confidence that each brachytherapy administration was in accordance with the authorized user physician's written directive, as required by 10 CFR 35.41. Specifically, the licensee's procedures did not include appropriate steps or guidance to ensure that radioactive sources were positioned in the patient in accordance with the written directive and treatment plan.

Actions Taken to Prevent Recurrence

Licensee – The licensee's corrective actions to prevent recurrence included revising its written procedure to ensure that sources are positioned in the patient in accordance with the written directive, and ensuring that the staff implements those revisions.

NRC – On June 20, 2007, the NRC issued a Notice of Violation related to this event.

This event is closed for the purpose of this report.

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NRC07-04 Medical Event at Kennedy Memorial Hospitals in Turnersville, New Jersey

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report states, 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 25, 2006 (identified on December 8, 2006), Turnersville, New Jersey

Nature and Probable Consequences – Kennedy Memorial Hospitals (the licensee) reported that a patient was prescribed a brachytherapy treatment of 145 Gy (14,500 rad) to the prostate gland for prostate cancer using 104 iodine-125 seeds, but instead received a dose of 145 Gy (14,500 rad) to an unintended treatment site. The brachytherapy seeds were implanted under ultrasound guidance; however, a post-treatment computed tomography scan showed that the implanted seeds were displaced inferior to the intended position, resulting in a dose of approximately 8 Gy (800 rad) delivered to the intended treatment site. The patient and the referring physician were informed of this event, and additional external beam radiation treatment was recommended.

The NRC staff conducted a reactive onsite inspection on December 12, 2006. The NRC-contracted medical consultant reviewed the case and agreed with the licensee's analysis and conclusions, stating that no significant adverse health effect to the patient is expected.

Cause(s) – The medical event was caused by the licensee's failure to accurately identify the position of the prostate during the intraoperative ultrasound guidance procedure.

Actions Taken to Prevent Recurrence

Licensee – The licensee revised its procedures, including the use of a contrast medium in the Foley catheter balloon to more clearly identify the bladder/prostate interface, and use of fluoroscopic imaging to confirm anatomical positioning and verify seed placement.

NRC – There were no violations identified by the NRC.

This event is closed for the purpose of this report.

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NRC07-05 Medical Event at the University of Virginia at Charlottesville, Virginia

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report states, 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 2–4, 2007, Charlottesville, Virginia

Nature and Probable Consequences – University of Virginia at Charlottesville (the licensee) reported that a patient was prescribed a brachytherapy treatment of 30 Gy (3,000 rad) for treatment of cancer of the cervix using cesium-137 sources. Instead, the patient received 7.7 Gy (770 rad) to the cervix and small volumes of the rectum and vaginal mucosa received doses greater than intended, ranging from 14.14 Gy to 26.77 Gy (1,414 rad to 2,677 rad). Upon removal of the implant, the licensee discovered that the applicator had been loaded with a plastic radioactive source carrier insert that was approximately 4 cm (1.6 in) shorter than the intended 24 cm (9.5 in) insert, which caused the sources to be displaced from the intended

position. The patient and the referring physician were informed of this event, and additional external beam radiation treatment was recommended.

The NRC staff conducted a reactive onsite inspection on February 12, 2007. The NRC-contracted medical consultant reviewed the case and agreed with the licensee's analysis and conclusions, stating that no significant adverse health effect to the patient is expected.

Cause(s) – The medical event was caused by the licensee's failure to ensure that the insert was of the correct length before preloading the cesium-137 sources.

Actions Taken to Prevent Recurrence

Licensee – The licensee revised its procedures, including measuring the length of the insert before loading the source, and limiting the supply of inserts in the source loading room to inserts of the length used for standard applicator treatments. The licensee also implemented additional staff training.

NRC – On May 7, 2007, the NRC issued a Notice of Violation related to this event.

This event is closed for the purpose of this report.

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AS07-01 Medical Event at St. James Hospital and Health Center in Olympia Fields, Illinois

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report states, 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 will be considered for reporting as an AO.

Date and Place – November 29, 2006 – December 20, 2006, Olympia Fields, Illinois

Nature and Probable Consequences – St. James Hospital and Health Center (the licensee) reported that a 75-year-old female patient received a dose to an unintended area of approximately 4 cm^2 (0.6 in^2) of 20 Gy (2,000 rad), which was prescribed to supplement surgery and external radiation treatments for cancer of the uterus. The treatment used a high dose-rate (HDR) afterloader containing an iridium-192 source with an activity of 370 GBq (10 Ci). The source stopped 20 cm (7.9 in) short of the intended position; thus, the patient received none of the prescribed dose to the correct location. The patient and the referring physician were informed of this event. Over the next 4 weeks, the patient was treated for wet desquamation on both of her inner thighs, surrounded by a halo of erythema and the licensee continues to monitor the patient.

Cause(s) – This medical event was caused by human error. The licensee entered an incorrect initial value into the treatment system, and the treatment plan was not reviewed by an authorized medical physicist during the subsequent three weekly treatment sessions. The error was identified during a chart audit before the next similar HDR treatment was planned.

Actions Taken to Prevent Recurrence

Licensee – The licensee reviewed previous administrations to confirm that this event was an isolated incident. The licensee also developed new procedures requiring additional quality assurance steps, including the presence of a medical physicist during treatments. In addition, licensee personnel received additional training on the revised treatment procedures.

State – The State conducted an investigation on January 8, 2007, and issued a Notice of Violation. On March 8, 2007, the NRC-contracted medical consultant investigated the matter for the State and supported the licensee's conclusions. The State accepted the licensee's corrective actions on April 12, 2007.

This event is closed for the purpose of this report.

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AS07-02 Medical Event at Aroostook Medical Center of Presque Isle, Maine

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report states, 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 dose or dosage that is at least 50 percent greater than that prescribed, shall be considered for reporting as an AO.

Date and Place – January 16, 2007, Presque Isle, Maine

Nature and Probable Consequences – Aroostook Medical Center (the licensee) reported that a patient received 148 MBq (4 mCi) of iodine-131 for a whole body scan, instead of the prescribed 5.6 MBq (0.151 mCi) for a thyroid uptake scan. On March 6, 2007 during a follow-up visit with an endocrinologist, it was recognized that the wrong scan was performed. The patient and referring physician were informed of this event. Using the methodology in NUREG-CR-6345, "Radiation Dose Estimates for Radiopharmaceuticals", the licensee estimated that the administration of 148 MBq (4 mCi) resulted in a thyroid dose of 51.22 Gy (5,122 rad) and a whole body effective dose equivalent of 1.537 Sv (153.7 rem). The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s) – The medical event was caused by human error. The licensee failed to verify the prescribed dosage for a specific patient directly with the referring physician. In addition, a written directive was not completed for this procedure.

Actions Taken to Prevent Recurrence

Licensee – Corrective actions taken by the licensee included revising procedures to improve communication with referring physicians, to allow the certified nuclear medicine technologist to speak directly with the referring physician or authorized user to confirm the type of test to be conducted. Also, written directives will be required for all administrations of iodine-131 in quantities greater than 1.11 MBq (30 µCi).

State – The State Radiation Control Program (RCP) performed an onsite investigation on May 24, 2007, and requested that the licensee take corrective actions to prevent recurrence. The RCP initially reviewed and accepted the licensee's proposed corrective actions during this onsite investigation. The RCP issued a Notice of Violation on November 1, 2007, and awaits the licensee's response.

This event is closed for the purpose of this report.

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AS07-03 Medical Event in New York

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report states, 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 tissue or organ (other than the lens of the eye, the gonads, or a major portion of the bone marrow), 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 – March 7, 2007; (Licensee) New York

Nature and Probable Consequences – The licensee reported a brachytherapy medical event to the New York State Department of Health. The event involved a 31-year-old female patient with a history of vaginal cancer. The treatment involved the use of both cesium-137 and iridium-192 seeds. Each ribbon contained 8 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, to be delivered to the 0.5 Gy (50 rad) isodose line for a total treatment time of 50 hours.

On March 6, 2007, the iridium-192 seeds and the cesium-137 seeds were placed into the patient. Late in the morning of March 7, 2007, the medical physicist performed a manual check of the treatment plan calculations, and discovered that the hand calculations indicated a significantly higher dose rate than was generated using the treatment planning software. The ensuing investigation revealed that the original treatment plan was in error. On March 7, 2007, after 27 hours of treatment, the seeds were removed from the patient.

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 rectal dose was 73 Gy (7,300 rad). The radiation oncologist disclosed that the patient is at risk for radiation cystitis, rectal proctitis, and more importantly, fistula formation between the rectum and the vagina. The patient and the referring physician were informed of this event. The patient will be monitored closely over the next year by both her gynecologic oncologist and the radiation oncologist. The patient is being treated with broad spectrum antibiotics, along with daily treatments in a hyperbaric oxygen chamber.

Cause(s) – The primary cause was the use of an inappropriate Dose Rate Factor (DRF) in the treatment planning system. The value used corresponded to the DRF for air kerma, however, the seed strength entered was in milligram radium equivalent. Other causes and contributing factors included failure to check the treatment pre-plan before the seeds arrived although there was time to do so; failure to double-check the calculations either prior to the implant or shortly thereafter; use of a treatment planning system that underwent acceptance testing for cesium-137 and iodine-125, but not iridium-192; and lack of recent experience preparing a

treatment plan using iridium-192. Neither the physicist nor the radiation oncologist had prepared a treatment plan using iridium-192 in 6 years.

Actions Taken to Prevent Recurrence

Licensee – The licensee changed its policy and procedures to require a check of calculations for any single-fraction brachytherapy treatment.

State – The State plans to follow-up on the licensee's implementation of their new procedures during the next scheduled inspection.

This event is open for the purpose of this report.

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AS07-04 Medical Event at Memorial Mission Hospital of Asheville, North Carolina

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report states, 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 dose or dosage that is at least 50 percent greater than that prescribed, shall be considered for reporting as an AO.

Date and Place – April 24, 2007, Asheville, North Carolina

Nature and Probable Consequences – Memorial Mission Hospital (the licensee) reported that a 19-year-old female patient was prescribed a dose of 1.24 MBq (33.4 µCi) of iodine-131 for a diagnostic scan to assess the health of her thyroid, however, she was administered a dose of 1235.8 MBq (33,400 µCi) on April 24, 2007. The licensee discovered the event when the patient returned the next day for her uptake scan. The licensee had the patient return for a second uptake scan on April 26, 2007. The patient was placed on a gamma camera and given a whole body scan. The spectrum was identified as iodine-131 and the uptake was concentrated in the patient's neck area, consistent with a thyroid uptake. As a result, the patient received a dose to the thyroid of approximately 287.3 Gy (28,728 rad). The patient and the referring physician were informed of this event.

The patient received an ablative quantity of radioactive iodine and initially showed classic signs of thyroidoitis, including inflammation, swelling, pain, and difficulty swallowing. The patient has recently started taking a synthetic thyroid hormone.

Cause(s) – The radiopharmacy provided the hospital an incorrect and mislabeled dose. The hospital failed to conduct a proper and accurate receipt survey on the package when it arrived in the hospital's nuclear medicine department. The nuclear medicine technologist, who performed the package receipt survey, failed to investigate the higher-than-expected dose rate off the transport container to determine if anything unusual was present. The nuclear medicine technologist assigned to the patient failed to correctly and accurately assay the dose in the dose calibrator. A second nuclear medicine technologist who is supposed to perform a quality assurance (QA) check of the dose calibrator reading, taken by the nuclear medicine technologist assigned to the patient, failed to correctly and accurately read the dose calibrator. The nuclear

medicine technologist assigned to the patient failed to recognize that the number of counts obtained from the neck phantom used for the uptake scan baseline was unusually high for the quantity of radioactive material prescribed for the patient.

Actions Taken to Prevent Recurrence

Licensee **–** The licensee ceased purchasing radiopharmaceuticals from the radiopharmacy that provided the incorrect and mislabeled dose. The licensee set aside a designated area for receiving shipments of radiopharmaceuticals and posted a list of expected dose rates per shipment (based upon contents of the shipment). The licensee redesigned the patient administration log to serve as a check list for QA, instituted procedural changes to include a one-meter survey of each diagnostic capsule while it is being counted in the neck phantom prior to administration, and implemented updated training to acquaint all nuclear medicine technologists with these new policies.

State **–** The State radiation control agency conducted an investigation into this incident assisted by the State board of pharmacy. The licensee's actions to prevent recurrence will be inspected at their next regularly scheduled inspection.

This event is open for the purpose of this report.

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AS07-05 Medical Event at University of Washington Harborview Gamma Knife of Seattle, Washington

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report states, 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 dose or dosage that is at least 50 percent greater than that prescribed, shall be considered for reporting as an AO.

Date and Place – November 16, 2006, Seattle, Washington

Nature and Probable Consequences – University of Washington Harborview Gamma Knife (the licensee) reported that a patient who was prescribed to receive 18 Gy (1,800 rad) during a gamma knife treatment actually received 28 Gy (2,800 rad). The gamma knife contained 267.7 TBq (7,236 Ci) of cobalt-60. 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 incident was determined to be human error. The prescribing physician prescribed 18 Gy (1,800 rad) and erroneously entered 28 Gy (2,800 rad). The physician entered the prescribed value into the computer treatment planning system, rather than having the medical physicist enter the value as is the usual procedure, resulting in a failure to follow an established procedure.

Actions Taken to Prevent Recurrence

Licensee – Corrective actions taken by the licensee included a verification process to ensure that the prescribed treatment value is transferred from the treatment planning computer to the gamma knife computer prior to patient therapy. Also, a treatment plan signed by the treating oncologist, physicist, and neurosurgeon is now required. In addition, the treating oncologist and physicist will verify and initial the prescribed dose and isodose treatment parameters prior to patient therapy.

State – The State reviewed the licensee's corrective actions and determined that the procedures were adequate to ensure that this type of event should not happen in the future.

This event is closed for the purpose of this report.

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AS07-06 Medical Event at Physician Reliance of Fort Worth, Texas

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report states, 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 dose or dosage that is at least 50 percent greater than that prescribed, shall be considered for reporting as an AO.

Date and Place – August 22, 2007, Fort Worth, Texas

Nature and Probable Consequences – Physician Reliance (the licensee, dba Texas Oncology at Klabzuba) reported that a patient who was being treated for lung cancer, with a high dose-rate (HDR) afterloader and an iridium-192 source, received 2,500 cGy (2,500 rad) during the first fraction, instead of the prescribed dose of 500 cGy (500 rad). The patient was prescribed to receive five fractions with 500 cGy (500 rad) per fraction over five weeks. The incident was discovered following an independent physicist's review of the treatment plan. The patient and the referring physician were informed of this event. The patient's pulmonologist concluded that no significant adverse health effect to the patient is expected.

Cause(s) – The incident occurred as a result of the incorrect isodose line being chosen and entered into the treatment planning system. The oncologist signed and approved the treatment plan and the radiation safety officer performed a second calculation to check the treatment plan. The treatment planning system then normalized the calculations to the incorrect isodose line and delivered the resulting treatment. The calculation error was identified by an independent physicist prior to administration of the second fraction.

Actions Taken to Prevent Recurrence

Licensee – The licensee's corrective action was to change their procedure to include a second check by a licensed medical physicist of all treatment plans.

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State – The State issued two violations related to this event: (1) a violation of 25 Texas Administrative Code (TAC) §289.256(p)(4)(A) and (B) was cited because the procedure as implemented was insufficient to ensure that a second check of the printed output of the treatment plan was performed to verify the accuracy of the planned treatment factors prior to treatment; and (2) a violation of 25 TAC §289.256(o)(1) and §289.256(p)(1) was cited because the instructions of obtaining the authorized physician's signed and dated written directive for each therapeutic administration were not followed. In addition, the State reviewed the licensee's corrective action of changing their procedures to include a second check by a licensed medical physicist of all treatment plans.

This event is closed for the purpose of this report.

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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).

<u>Abnormal Occurrence Criteria</u>
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.

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

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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.

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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 (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.[8]

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7 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 $1x10^{-3}$.

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 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

[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.

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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 the 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.

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 – In a facility authorized to process high-enriched uranium (HEU), a transfer of 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 was also 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, this event has received public, media, and Congressional interest, and the NRC and the licensee have taken certain actions concerning this event.

Update on Actions Taken To Prevent Recurrence

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

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

The licensee submitted the license amendment request on April 20, 2007. The NRC staff requested additional information concerning the new configuration management programs on October 17, 2007. The additional information was submitted on December 14, 2007 and the NRC staff review is ongoing.

The licensee submitted a safety culture assessment plan on May 22, 2007, and then revised it on September 24, 2007, in response to NRC comments. The independent third party provided its assessment results to the licensee on February 15, 2008. The licensee is required to brief the NRC on the assessment results and its plan for implementing recommendations by May 15, 2008. On May 30, 2007, the licensee management briefed the Commission in a closed portion

of an Agency Action Review Meeting on its actions to improve performance. The transcript of the closed meeting has been released to the public. The document is publicly available through ADAMS, under Accession No. ML071930389.

The NRC also took additional actions regarding its policy for withholding sensitive information from the public, including: (1) during June through July 2007, the NRC staff briefed the House and Senate staffers concerning this event and the NRC's policy for withholding information from the public; (2) on August 31, 2007, the NRC issued a Staff Requirements Memorandum (SRM-SECY-07-0129) revising the policy for withholding information and directing the staff to review and release many of the documents that had been withheld. This document is publicly available through ADAMS, under Accession No. ML072430701. The review and release of documents is still ongoing; and (3) on September 17, 2007, the NRC conducted public meetings in Erwin, Tennessee, to provide information and answer questions concerning this event and related issues. This document is publicly available through ADAMS, under Accession No. ML072700060.

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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 the 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

EOI-01 Peach Bottom Atomic Power Station: Security Officers Inattentive to Duty

The NRC initiated an Augmented Inspection Team (AIT) in the security area at the Peach Bottom Atomic Power Station (PBAPS) in late September 2007. 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 PBAPS 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 NRC was made aware of the existence of these videos by WCBS-TV (New York City), on September 10, 2007. While the validity and nature of inattentiveness were not yet known, the NRC began enhanced inspection and oversight of security at PBAPS and verbally communicated the information to Exelon management for investigation the same day. On September 19, 2007, the NRC had the opportunity to first view the subject videos, which depicted multiple security officers inattentive to duty on four separate occasions in the station's ready room between March and August 2007.

In response to the viewing of these allegations and NRC knowledge of Exelon's investigation details, the NRC determined that an AIT was warranted. A charter was developed for the AIT on September 20, 2007, and the NRC commenced the inspection on September 21, 2007. The team was comprised of several security inspectors and specialists and had oversight from a senior NRC manager, and concluded their inspection on September 28, 2007.

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 the station's continued ability to properly implement the Security Plan. The 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 low-to-moderate significance finding in accordance with the NRC's reactor oversight program.

The NRC issued Confirmatory Action Letter 1-07-005, dated October 19, 2007, to ensure that Exelon's compensatory measures remain in place until the NRC has completed its review of Exelon's causal evaluation and corrective action plan. The AIT inspection report and Exelon's submittals to the NRC in this matter are available to the public. The AIT inspection report is publicly available through ADAMS, under Accession No. ML073550590. A follow-up inspection was completed in November 2007 and the results published in mid-December 2007; enforcement considerations continue.

On September 27, 2007, NRC Security Advisory, SA-07-a, “Security Officer Inattentive to Duty,” was issued to all U.S. commercial power reactors and many material licensees. The purpose of this advisory was to reinforce with facility managers, and other security personnel, their responsibility for protecting nuclear facilities and to address the importance of remaining attentive while on duty.

In addition to this security advisory, on December 12, 2007, the NRC issued bulletin 2007-01, “Security Officer Attentiveness,” and announced this bulletin in press release number 07-167, “NRC Seeks Information on Nuclear Plant Security Policies and Practices, Including Security Officer Inattentiveness.” The purpose of this bulletin was to: (1) notify addressees about the NRC staff’s need for information associated with licensee security program administrative and management controls as a result of security personnel inattentiveness, especially involving complicity, and related concerns with the behavior observation program; (2) determine if further regulatory action was warranted, if the necessary inspection program needs to be enhanced, or if additional assessment of security program implementation is needed; and (3) obtain information on licensee administrative and managerial controls to deter and address inattentiveness and complicity among licensee security personnel including contractors and subcontractors. This bulletin also required that addressees provide a written response to the NRC in accordance with 10 CFR Section 50.54(f) or 10 CFR Section 70.22(d). This bulletin is publicly available through ADAMS, under Accession No. ML073400150.

The NRC has 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 has concluded that all licensees have provided answers to all questions as required by the bulletin. The NRC staff will likely request additional information from some of the licensees to obtain more details on certain responses.

EOI-02 Indian Point Nuclear Station: New Sirens

The 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 the NRC granted, a relaxation of the order until April 15, 2007. On April 13, 2007, the NRC received an additional extension request from Entergy; however, the NRC denied the request because Entergy did not demonstrate good cause.

The 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 time frames directed by the order and the allowed 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. The 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. The 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 has communicated to the NRC that "the old siren system still in place has been performing above the required thresholds for reliability during routine siren tests, and is acknowledged to be more than adequate in terms of audibility and coverage of the 10-mile emergency planning zone." This provides reasonable assurance that the existing system is adequate to protect the health and safety of the public while issues with the new system are being resolved.

FEMA has not yet approved the new siren system (with the backup power capability) for use and has issues with the coverage, loudness, and reliability of the new system. These technical issues are being addressed by Entergy (through testing and the addition of more new sirens) and will be fully reviewed by FEMA and resolved before the new system is placed in service. The licensee's failure to have the siren system in operation and approved by FEMA within the time frame directed by the order is still under further review by the NRC, but the delay has not endangered the public's health and safety.

Once the new siren system technical issues are resolved and the system is reviewed and approved for use by FEMA, the NRC will inform the appropriate Congressional representatives, State and local authorities, and the general public that the new Indian Point siren system is operational and in service. Entergy plans to have the service in place in August 2008. The NRC is monitoring their progress closely, and will take additional actions if needed to ensure that the new siren system is made operational.

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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)

[1]**Air Kerma** – the sum of the initial kinetic energies of all charged particles liberated by uncharged ionizing radiation (i.e., indirectly ionizing radiation such as photons and neutrons) in a sample of matter (such as air or water), divided by the mass (weight) of the sample

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 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 before October 24, 2005, meets the requirements in §§35.910(a), 35.920(a), 35.930(a), 35.940(a), or 35.960(a) and 35.59; 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 with an inflatable balloon at its 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

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

[1] These terms are not defined in defined in 10 CFR, a management directive, or an inspection procedure. Rather this term is defined in the online *Wikipedia: The Free Encyclopedia* (http://en.wikipedia.org)

DRAFT

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

[2]**Catheter** – a tubular medical device for insertion into canals, vessels, passageways, or body cavities as to permit injection or withdrawal of fluids or to keep a passage open

[2]**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

[2]**Cystitis** – inflammation of the urinary bladder

[2]**Desquamation** – to peel off in the form of scales

[2]**Distal** – located away from the center of the body

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

[3]**Dose Rate Factor (DRF)** – a factor by which the effect caused by a specific dose of radiation changes at low dose rates (as compared to high dose rates)

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]**Endocrinologist** – a doctor that deals with disorders of the endocrine system and its specific secretions of hormones; the main glands that comprise the endocrine system include the pituitary gland, the pancreas, the gonads, the thyroid gland, and the adrenal glands

[2]**Erythema** – abnormal redness of the skin as a result of inflammation

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

[1]**External Beam Radiation Treatment (Radiotherapy)** – the most frequently used form of radiotherapy in which a patient sits or lies on a couch and an external source of radiation is pointed at a particular part of the body

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[2] These terms are not defined in 10 CFR, a management directive, or an inspection manual. Rather, these terms are defined 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)

[3] This term is not defined in 10 CFR, a management directive, or an inspection procedure. Rather, this term is defined in *Health Effects of Exposure to Low Levels of Ionizing Radiation (BEIR V)*, published in 1990 by the National Academies, National Research Council, BEIR V Committee.

DRAFT

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

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

[1]**Fibrosis** – the formation or development of excess connective tissue in an organ or tissue as a reparative or reactive process

[2]**Fistula** – an abnormal passage that leads from an abscess or hollow organ to the body surface

[2]**Foley Catheter** – a catheter with an inflatable balloon tip for retention in the bladder; in 1937, Frederic Foley introduced an operation that entailed the insertion of a rubber catheter now known as the Foley catheter

[2]**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)

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]**Isodose** – equal doses of radiation

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 35.3045(a), is any event that a licensee must report, 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

DRAFT

[2]**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

Patient Intervention – as defined in 10 CFR 35.2, means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration

[2]**Perineal** – of or relating to the area between the anus and the posterior part of the external female genitalia

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

[2]**Proctitis** – inflammation of the anus and rectum

[2]**Proximal** – located toward the center of the body

[1]**Pulmonologist** – a doctor that deals with diseases of the lungs and respiratory tract

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, before October 24, 2005, §§35.900(a) 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

[1]**Radiation Therapy (Radiotherapy)** – the medical use of ionizing radiation as part of cancer treatment to control malignant cells

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)

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

Therapeutic Dose – as defined in 10 CFR 35.2, means a radiation dose delivered from a source containing byproduct material to a patient 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

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, is an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient

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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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