Report to Congress on Abnormal Occurrences

Fiscal Year 2025

U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ABSTRACT

Section 208 of the Energy Reorganization Act of 1974, as amended (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) changed the AO reporting frequency from quarterly to annual.

This report on AOs for fiscal year (FY) 2025 describes seven events involving Agreement State licensees and two events involving NRC licensees. These events were identified based on the criteria in the NRC policy statement, "Abnormal Occurrence Reporting," published in the *Federal Register* (FR) on August 12, 2025 (90 FR 38828). Four AOs were medical events, as defined in Title 10 of the *Code of Federal Regulations* Part 35, "Medical Use of Byproduct Material." The remaining five AOs consisted of one loss of an industrial radiography source, two events involving overexposure of declared pregnant radiation workers, one significant breakdown in radiological controls, and one unintended fetal/embryo exposure. No events at commercial nuclear power plants met the criteria for an AO.

Appendix A, "Abnormal Occurrence Criteria," to this report presents the NRC's criteria for identifying AOs. The NRC identified no events during FY 2025 that met the guidelines for inclusion in Appendix B, "Other Events of Interest." One event met the guidelines for inclusion in Appendix C, "Updates on Previously Reported Abnormal Occurrences." Appendix D, "Glossary," defines terms used throughout this report. Appendix E, "Conversion Table," presents conversions commonly used when calculating doses.

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EXECUTIVE SUMMARY

INTRODUCTION

Section 208 of the Energy Reorganization Act of 1974, as amended (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) changed the AO reporting frequency from quarterly to annual.

This report describes nine events identified as AOs in fiscal year (FY) 2025, based on the criteria in the NRC policy statement, "Abnormal Occurrence Reporting," published in the *Federal Register* (FR) on August 12, 2025 (90 FR 38828). For each AO, this report documents the date and place, nature and probable consequences, cause or causes, and actions taken to prevent recurrence.

Appendix A, "Abnormal Occurrence Criteria," to this report presents the NRC's criteria for identifying AOs. The NRC identified no events during FY 2025 that met the guidelines for inclusion in Appendix B, "Other Events of Interest." During this reporting period, one event met the guidelines for inclusion in Appendix C, "Updates on Previously Reported Abnormal Occurrences." Appendix D, "Glossary," defines terms used throughout this report. Appendix E, "Conversion Table," presents conversions commonly used when calculating doses.

THE LICENSING AND REGULATORY SYSTEM

The NRC implements its system of licensing and regulation through the regulations in Title 10 of the *Code of Federal Regulations* (10 CFR). The NRC regularly conducts licensing reviews, inspections, enforcement, investigations, operating experience evaluations, incident response, and confirmatory research. The agency informs and involves stakeholders and the public to ensure openness and transparency in its regulatory process.

The NRC adheres to the philosophy that multiple levels of protection best ensure public health and safety. The agency achieves and maintains these levels of protection through regulations specifying requirements that ensure the safe use of radioactive materials. Those regulations contain design, operation, and quality assurance criteria for the various activities regulated by the NRC. Licensing, inspection, investigation, and enforcement programs offer a regulatory framework to ensure compliance with the regulations.

REPORTABLE EVENTS

The NRC initially issued the AO criteria in a Commission policy statement published in the FR on February 24, 1977 (42 FR 10950). The Commission policy statement has since undergone several revisions. The agency published the most recent revision to the AO criteria in the FR on August 12, 2025 (90 FR 38828), and the revised criteria became effective on that date. The NRC staff used these criteria to identify AOs for this FY 2025 report.

Reviews of and responses to operating experience are essential to ensure that licensees conduct their activities safely. To that end, the NRC regulations require licensees to report certain incidents or events to the NRC. Such reporting helps identify deficiencies and ensures that corrective actions are taken to prevent recurrence.

The NRC and its licensees review and evaluate operating experience to identify safety concerns. The NRC responds to risk-significant issues through licensing reviews, inspections, enforcement, and enhancements to regulations. In addition, the agency maintains operational data in electronic files for more effective collection, storage, retrieval, and evaluation of event information.

The NRC routinely makes information and records on reportable events at licensed facilities available to the public. The agency also disseminates information through public announcements and special notifications to licensees and other stakeholders. The NRC issues an FR notice describing AOs that occurred in the previous FY at facilities licensed or otherwise regulated by the NRC or an Agreement State. In addition, the NRC promptly informs Congress of any significant events, including AOs.

AGREEMENT STATES

Agreement States are those States that have entered into formal agreements with the NRC, in accordance with section 274 of the Atomic Energy Act of 1954, as amended (AEA), to regulate certain quantities of AEA material at facilities within their borders. Agreement States must maintain programs that are adequate to protect public health and safety and are compatible with the NRC's program for such materials. Currently, there are 40 Agreement States. All Agreement States report event information in accordance with the compatibility criteria in the NRC's Agreement State Program Policy Statement (82 FR 46840; October 6, 2017). The NRC also has procedures for evaluating materials events and identifying those that meet the AO criteria. The NRC uniformly applies the AO criteria (see Appendix A) to events at licensee facilities and to activities involving the use of radioactive material, whether regulated by the NRC or an Agreement State.

INTERNATIONAL INFORMATION

The NRC exchanges information with various international counterparts that regulate nuclear facilities and materials. The agency reviews and considers this international information in its research and regulatory activities and in its assessment of operating experience. Although the NRC may occasionally refer to such information in its AO reports to Congress, the agency reports only domestic AOs.

OTHER EVENTS OF INTEREST

In Appendix B to this report, the NRC offers information about events that do not meet the criteria for AOs but are of interest based on the criteria. The NRC identified no events of interest that occurred during FY 2025.

UPDATES ON PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

Appendix C includes updates on previously reported AOs that remained open, or for which significant new information became available, during the FY addressed in this report. During this reporting period, one event met the guidelines for inclusion in Appendix C.

ABBREVIATIONS

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
AO	abnormal occurrence
CCDP	conditional core damage probability
ΔCDP	change in core damage probability
CFR	*Code of Federal Regulations*
Ci	curie(s)
CT	computed tomography
FR	*Federal Register*
FY	fiscal year
GBq	gigabecquerel(s)
GI	gastrointestinal
Gy	gray(s)
hr	hour
I	iodine
Lu	lutetium
MAA	macroaggregated albumin
MBq	megabecquerel(s)
mCi	millicurie(s)
mGy	milligray(s)
MD	management directive
NMED	Nuclear Material Events Database
mrem	millirem(s)
MRI	magnetic resonance imaging
mSv	millisievert(s)
NKCH	North Kansas City Hospital
NRC	U.S. Nuclear Regulatory Commission
PET	positron emission tomography
R	roentgen
Ra	radium
ROP	Reactor Oversight Process
SDE	shallow dose equivalent
Sv	sievert(s)
TBq	terabecquerel(s)
Tc	technetium
TEDE	total effective dose equivalent

TS	technical specification(s)
Y	yttrium

ABNORMAL OCCURRENCES IN FISCAL YEAR 2025

Appendix A, “Abnormal Occurrence Criteria,” supplies the specific criteria for determining whether an event is an abnormal occurrence (AO). Appendix A contains criteria for three major categories:

I. All Licensees
II. Commercial Nuclear Power Plant Licensees
III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events

This section of the report includes only the specific events in Categories I, II, and III that met the AO criteria. The identification numbers for the events reported by Agreement States start with “AS.” Similarly, the identification numbers for the U.S. Nuclear Regulatory Commission (NRC) licensee reports start with “NRC.”

I. ALL LICENSEES

During this reporting period, four events were identified as an AO based on the criteria under Category I, “All Licensees,” in Appendix A.

AS25-01 Missing Industrial Radiography Camera from IQS Inspection, Kernersville, North Carolina

Criterion I.C.1 of Appendix A to this report provides that any stolen, diverted, abandoned, or unrecovered lost radioactive material that meets or exceeds the thresholds listed in Appendix A, “Category 1 and Category 2 Radioactive Materials,” to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,” shall be considered for reporting as an AO, subject to certain exceptions not applicable to this event.

Date and Place—February 27, 2025, Kernersville, North Carolina

Nature and Probable Consequences—On February 27, 2025, IQS Inspection (the licensee) reported a missing radiography exposure device that contained a 2.74 terabecquerels (TBq) (74.1 curies (Ci)) of iridium-192 source. The radiographer stayed the night in a hotel and, upon returning to their vehicle the following morning, noticed the device was missing. North Carolina state authorities and local law enforcement were notified; a search of the area failed to locate the device. Local authorities have continued with their investigation but have been unsuccessful in locating the device.

Cause(s)—The investigation identified that the incident resulted from human error and the radiographer's failure to adhere to established procedures for securing the radiography source.

Actions Taken to Prevent Recurrence

Licensee—To prevent recurrence, the licensee conducted additional training for radiography staff on the approved procedures for securing radiographic sources.

State—The investigation remains ongoing. The State has not taken any actions.

This event is open for the purpose of this report.

NRC25-01 Human Exposure Event at North Kansas City Hospital, Kansas City, Missouri

Criterion I.A.2 of Appendix A to this report provides, in part, that any unintended radiation exposure 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 10, 2023 (identified on July 25, 2025), Kansas City, Missouri

Nature and Probable Consequences—On July 21, 2023, North Kansas City Hospital (NKCH) (the licensee) reported the possibility that an embryo/fetus had received an unplanned radiation dose. On May 10, 2023, the patient was administered 4.65 gigabecquerels (GBq) (125.68 mCi) of iodine (I)-131 for a thyroid cancer ablation treatment. On July 21, 2023, NKCH was notified that the patient was pregnant at the time of administration, with an estimated conception date of May 6, 2023. An NRC-contracted consultant performed an analysis and calculated that the embryo/fetus had received a dose of 333 mSv (33 rem). On February 2, 2024, NKCH reported that the patient had given birth with no complications or noted issues. This event was not identified as a potential AO in the Nuclear Material Events Database (NMED) until July 25, 2025, due to staff oversight, which has been the subject of corrective action to prevent recurrence.

Cause(s)—This event was caused by procedures not accounting for the detection window of the pregnancy test used before treatment. The hospital procedures required a negative pregnancy test be obtained before the administration of I-131, and a negative test was obtained on May 8, 2023. However, due to the recency of conception, most pregnancy tests would be ineffective and provide a false negative.

Actions Taken to Prevent Recurrence

Licensee—Following this incident, the licensee reviewed its I-131 program and implemented additional preventive measures. NKCH also reviewed and updated patient education material, including pre- and post-procedure material. Additionally, the licensee reviewed applicable policies and procedures, implementing changes as needed. Finally, NKCH validated re-education and competency of all staff involved in I-131 therapies.

NRC—The NRC conducted a reactive inspection, beginning on August 17, 2023, and ending on March 6, 2024. During the inspection, the NRC reviewed the circumstances of the event and the licensed activities associated with the use of I-131 at the facility. The NRC concluded that the licensee had taken sufficient action to prevent recurrence and did not identify any violations. Additionally, with regard to the delayed identification of this event as a potential AO in NMED, the NRC staff has taken action to prevent the recurrence of such delays by arranging for frequent periodic reviews of the database for potential AOs.

This event is closed for the purpose of this report.

AS25-02 Human Exposure Event at Shields Imaging of Massachusetts, Quincy, Massachusetts

Criterion I.A.2 of Appendix A to this report provides, in part, that any unintended radiation exposure 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—August 5 to September 5, 2023 (identified on January 28, 2026), Quincy, Massachusetts

Nature and Probable Consequences—On November 30, 2023, Shields Imaging of Massachusetts (the licensee) reported a radiation overexposure to an embryo/fetus of a declared pregnant worker. The licensee received the exposure report from Landauer on October 16, 2023, which indicated a reading of 57.7 mSv (5.77 rem) to the embryo/fetus during the time period of August 5, 2023, to September 5, 2023. Following this discovery, the worker was removed from clinical duties until after their maternity leave period ended. The worker stated that she properly wore her dosimetry badges, that they were never lost nor misplaced, and that no spill or contamination occurred. The licensee reviewed the dosimetry reports for other staff that worked with the employee but did not note any increase in their radiation exposures. The licensee indicated that declared pregnant worker had given birth with no complications or noted issues to the employee or the embryo/fetus. This event was not identified as a potential AO until January 28, 2026, due to process gaps which have been the subject of corrective action to prevent recurrence.

Cause(s)—During a special inspection of the licensee conducted from November 11, 2023, to January 12, 2024, the Massachusetts Radiation Control Program noted several deficiencies including failure to calibrate instruments at required intervals. Upon interviewing the licensee's physicists and technicians, the cause of this event was determined to be lack of supervision and lack of proper training for technicians.

Actions Taken to Prevent Recurrence

Licensee—Shields Imaging of Massachusetts committed to perform a special management audit with a focus on worker compliance with the radiation safety program and to use Mirion Instadose Badges which would allow the licensee to more promptly access their workers exposures.

State—The Massachusetts Radiation Control Program cited the licensee for two violations: for failing to ensure that the dose equivalent to an embryo/fetus remains within limits, and for failing to ensure adequate precautions were taken to prevent a deceptive exposure.

NRC—With regard to the delayed identification of this event as a potential AO, the NRC staff has taken action to prevent the recurrence of such delays by arranging for frequent periodic reviews of NMED for potential AOs and by augmenting the processes used by the staff for early identification of potential AOs.

This event is closed for the purpose of this report.

AS25-03 Human Exposure Event at Johns Hopkins Medical Imaging, Bethesda, Maryland

Criteria I.A.1(a) and I.A.2 of Appendix A to this report provide, in part, that any unintended radiation exposure to an adult resulting in an annual total effective dose equivalent (TEDE) of 250 mSv (25 rem) and that any unintended radiation exposure to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more shall be considered for reporting as AOs.

Date and Place—March 15 to June 27, 2025, Bethesda, Maryland

Nature and Probable Consequences—On June 27, 2025, Johns Hopkins Medical Imaging (the licensee) identified and reported a radiation overexposure event involving a declared pregnant worker. The positron emission tomography (PET) technician received a whole-body exposure, according to dosimetry results, of 299.7 mSv (29.97 rem) from mid-March to June 2025. The worker also received an extremity exposure of 63.3 mSv (6.33 rem) over that time. The fetal radiation exposure was determined to be 148 mSv (14.8 rem). Elevated exposure results were identified in the April and May dosimetry records. The worker's June dosimetry report was then expedited and confirmed to be overexposure. Dosimetry results were further confirmed by a reanalysis by the Maryland Department of the Environment. As of January 21, 2026, the state's investigation is still ongoing. Probable consequences are currently being evaluated as part of the ongoing investigation.

Cause(s)—The licensee initiated a root-cause investigation, which yielded no indication of a spill or spread of contamination at their facility. No cause has been identified at this time.

Actions Taken to Prevent Recurrence

Licensee—Following the June 2025 dosimetry results, the worker was promptly notified and removed from work involving radioactive material. The investigation is currently ongoing and, once completed, appropriate actions will be evaluated to prevent recurrence.

State—The Maryland Department of the Environment confirmed dosimetry results in an additional reanalysis. The investigation is currently ongoing and, once completed, appropriate actions will be evaluated to prevent recurrence.

This event is open for the purpose of this report.

II. COMMERCIAL NUCLEAR POWER PLANT LICENSEES

During this reporting period, no event at any commercial nuclear power plant in the United States met the criteria for an AO under Category II, "Commercial Nuclear Power Plant Licensees," in Appendix A.

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

During this reporting period, five events were identified as AOs based on the criteria in Appendix A under Category III, "Events at Facilities Other Than Nuclear Power Plants and All Transportation Events."

AS25-04 Medical Event at an Unspecified Medical Licensee, Unspecified City, New York[1]

Criteria III.C.1(b) and III.C.2(b)(iii) of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in an unintended dose from the administration that exceeds, by 10 gray (Gy) (1,000 rad), the intended dose to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) that would have resulted from delivery of the prescribed dose, dosage, or activity, and the event involves a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place—September 15, 2023, Unspecified City, New York

Nature and Probable Consequences—On September 20, 2023, the unspecified medical licensee discovered and reported to New York State an event associated with an yttrium (Y)-90 microsphere administration. On September 15, 2023, during palliative treatment of a liver tumor, the patient received, in accordance with the written directive, an administered activity to the right liver lobe of 3.2 GBq (86.5 mCi) for a prescribed dose of 123 Gy (12,300 rad). However, post-therapy imaging revealed uptake to both the right and left lobes of the liver. It was calculated that the left liver lobe had received a dose of 78 Gy (7,800 rad). The patient was informed and the authorized user concluded that there was no immediate or expected harm to the patient, noting that it was likely the patient would require treatment to the left lobe at a second stage. New York State reported this event to the NRC as an AO on June 6, 2025, once the dose information was updated to confirm the event met the AO criteria.

Cause(s)—The licensee indicated that diminished flow from the right hepatic artery is the likely cause. Pretreatment mapping did not indicate any delivery to the left lobe; therefore, nontarget treatment delivery was not expected during fluoroscopy.

Actions Taken to Prevent Recurrence

Licensee—The vendor of the Y-90 administration kit performed simulated hands-on training with the cold administration kit on October 9, 2023. In addition, refresher training on event reportability was held for Y-90 authorized users on November 15, 2023.

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[1] The State of New York Department of Health did not provide the facility name or location for the reported AO and informed the NRC that withholding this information is consistent with New York State Public Health Law, section 2805-l.

State—The State reviewed the event and deemed the corrective actions taken by the licensee to be sufficient to prevent recurrence. No further actions were taken.

This event is closed for the purpose of this report.

AS25-05 Medical Event at University of Texas Southwestern Medical Center, Dallas, Texas

Criteria III.C.1(b) and III.C.2(b)(iii) of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in an unintended dose from the administration that exceeds, by 10 Gy (1,000 rad), the intended dose to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) that would have resulted from delivery of the prescribed dose, dosage, or activity, and the event involves a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place—February 26, 2025, Dallas, Texas

Nature and Probable Consequences—On October 6, 2025, University of Texas Southwestern Medical Center (the licensee) reported an event involving an Elekta gamma knife treatment that had occurred on February 26, 2025. The written directive prescribed a total treatment dose of 20 Gy (2,000 rad) to a blood vessel malformation in the patient's brain. Due to the size of the malformation and the dose distribution of the treatment, 2 fractions of 12 Gy (1,200 rad) would have resulted in an average dose of 20 Gy (2,000 rad) to the treatment site. An error occurred during the first treatment, and the initial 12 Gy (1,200 rad) dose was delivered to an unintended site in the patient's brain. The second treatment was administered as prescribed by the written directive. This incident was discovered and reported on October 6, 2025, as part of an internal review triggered by a similar medical event that had occurred at the same facility on September 25, 2025 (AS25-07). The patient was informed and assessed at a routine follow-up appointment, and no complications, radiation injuries, or worsening of condition were present. The licensee intends to continue monitoring the patient's condition at three-month intervals.

Cause(s)—The licensee reported that a software anomaly caused the event by unlinking the co-registration between the planning magnetic resonance imaging (MRI) and ConeBeam computed tomography (CT) scan. This resulted in incorrect targeting of the treatment site during the gamma knife procedure. The licensee informed the manufacturer who is investigating the issue.

Actions Taken to Prevent Recurrence

Licensee—The licensee imposed a moratorium on all similar gamma knife treatments until further safeguards could be established, and it implemented changes to improve the gamma knife procedure.

State—The State conducted an onsite investigation and multiple online interviews with parties associated with the event. The State has also received, and is reviewing, relevant documentation related to this event. The investigation is ongoing.

This event is open for the purpose of this report.

NRC25-02 Deficiency in Control and Operation Event at Curium US LLC, Noblesville, Indiana

Criterion III.A.2 of Appendix A to this report provides that a major deficiency in design, construction, control, or operation having significant safety implications that require immediate remedial action shall be considered for reporting as an AO.

Date and Place—April 8, 2025, Noblesville, Indiana

Nature and Probable Consequences—On April 9, 2025, Curium US LLC (the licensee) reported that two workers had been overexposed while performing waste handling and remediation activities. The two had been working in a confined space below a bank of hot cells and, at one point, removed and replaced a bucket of liquid acid waste containing approximately 7.77 TBq (210 Ci) of various rubidium radionuclides from its shielded cask. The workers set the bucket on the floor nearby and continued with remediation activities. Upon exiting the confined space approximately 20 minutes later, the workers noted that their electronic dosimeters read 43.9 mSv (4.39 rem) and 29.2 mSv (2.92 rem). A third radiation worker entered the space and performed a survey. The worker found 2 roentgens (R) per hour (hr) at the entry point, 25 R/hr near the work location, and more than 999 R/hr (the upper limit of the instrument) on contact with the unshielded waste bucket. The actual contact rates were later estimated to have been as high as 5,500 R/hr.

Based on subsequent dose reconstruction, the licensee determined that one individual received occupational doses of 138 mSv (13.8 rem) TEDE and 2,400 mSv (240 rem) Shallow Dose Equivalent (SDE) to the skin of the lower extremities, and another individual received 9.9 rem TEDE between January 1 and April 8, 2025. The licensee acknowledged that the assigned SDE was overly conservative but did not pursue further refinement. No immediate health consequences were reported by either worker, nor are significant health consequences expected.

Cause(s)—This event was caused by multiple violations of Federal regulations and license conditions due to a breakdown in the licensee's radiation protection program. These violations included multiple failures to follow radiation safety procedures, multiple examples of inadequate radiological surveys and monitoring, inadequate radioactive waste labeling, and inadequate radiation protection program oversight.

Actions Taken to Prevent Recurrence

Licensee—The licensee performed an in-depth investigation and has taken extensive corrections to address each of the identified root causes and contributing factors, such as overhauling its radiological work permitting procedures, improving its training program, and enhancing overall safety culture.

NRC—Following reactive inspection activities to observe and confirm the licensee's restoration of normal operating conditions, Region III chartered a special inspection to develop a clear understanding of the circumstances, assess the adequacy of the licensee's initial response, and evaluate the licensee's dose assessment methods, material control and accountability measures, and radiation protection program. The inspection, completed on site the week of May 19, 2025, found six apparent violations of regulatory requirements. These violations were assessed collectively as a single Severity Level II Problem and a proposed civil penalty of $72,000 was issued.

The NRC also contracted with a scientific consultant to perform an independent dose assessment. The assessment generally agreed with the licensee's, except for SDE to the first worker. The special inspection team, informed by the consultant's assessment, concluded that SDE to the worker's lower extremities was more likely between 560 mSv (56 rem) and 1,350 mSv (135 rem), still above occupational limits but below the threshold for cutaneous radiation injury.

This event is closed for the purpose of this report.

AS25-06 Medical Event at Nebraska Medical Center, Omaha, Nebraska

Criteria III.C.1(a) and III.C.2(b)(i) in Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in an unintended dose that is equal to or greater than 1 Gy (100 rad) to a major portion of the bone marrow as a result of using the wrong radiopharmaceutical.

Date and Place—August 12, 2025, Omaha, Nebraska

Nature and Probable Consequences—On August 12, 2025, Nebraska Medical Center (the licensee) reported that an incorrect radioisotope had been administered during a treatment for prostate cancer. The written directive prescribed 7.4 GBq (200 mCi) of lutetium (Lu)-177 (Pluvicto); however, the patient was erroneously administered 5.77 megabecquerels (MBq) (0.16 mCi) of radium (Ra)-223 (Xofigo). This resulted in an estimated 0.133 Gy (13.3 rad) whole-body dose and a 6.65 Gy (665 rad) dose to the red bone marrow. The patient was notified and subsequently scheduled for follow-up assessments. Following verification of no adverse impacts (i.e., no bone marrow suppression), the patient subsequently received the intended treatments of Lu-177 (Pluvicto) later in the year.

Cause(s)—The event was caused by human error. The nuclear medicine technologist incorrectly assumed that the unit dose of the Ra-223 radiopharmaceutical, stored in the same area as the Lu-177 radiopharmaceutical unit dose, was the intended dose for the patient. Additionally, the licensee's staff failed to follow written procedure and did not confirm that the selected dose was correct during a mandatory timeout period before treatment.

Actions Taken to Prevent Recurrence

Licensee—The licensee has revised procedures to include additional checks to ensure the written directive is followed. During the timeout period before administration, the authorized user and nuclear medicine technologist must now verify that the selected radiopharmaceutical matches the written directive and that the activity matches the written directive, and both the authorized user and the nuclear medicine technologist will then sign a form confirming that the verification has been performed.

State—The State conducted a reactive inspection on August 22, 2025. The inspection confirmed that the root cause was failure to follow written directive procedures. In response, the State issued a citation to the licensee on September 16, 2025; no civil penalty was assessed.

This event is closed for the purpose of this report.

AS25-07 Medical Event at University of Texas Southwestern Medical Center, Dallas, Texas

Criteria III.C.1(b) and III.C.2(b)(iii) of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in an unintended dose from the administration that exceeds, by 10 Gy (1,000 rad), the intended dose to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) that would have resulted from delivery of the prescribed dose, dosage, or activity, and the event involves a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place—September 25, 2025, Dallas, Texas

Note: This event triggered an internal review which discovered that a similar event had occurred at the same facility on February 26, 2025. The earlier event is described previously in this report, in the entry identified as AS25-05 (Medical Event at University of Texas Southwestern Medical Center, Dallas, Texas).

Nature and Probable Consequences— On October 3, 2025, the University of Texas Southwestern Medical Center (the licensee) reported an Elekta gamma knife event involving three treatments performed on September 11, 17, and 25, 2025. The written directive prescribed a total treatment dose of 20 Gy (2,000 rad) to a blood vessel malformation in the patient's brain, to be delivered in six sequential stages of 12 Gy (1,200 rad) each. While preparing the fourth treatment, the treating physician discovered that the three previous treatments had each been delivered to an area of the brain other than the intended target, resulting in 12 Gy (1,200 rad) dose each to three unintended portions of the brain. The referring physician and patient were notified, and a meeting took place to discuss potential effects and mitigation strategies. The physician will continue to monitor for potential adverse impacts to the patient over the next several months.

Cause(s)— The licensee reported that a software anomaly caused the event by unlinking the co-registration between the planning magnetic resonance imaging (MRI) and ConeBeam computed tomography (CT) scan. This resulted in incorrect targeting of the treatment site during the gamma knife procedure. The licensee informed the manufacturer who is investigating the issue.

Actions Taken to Prevent Recurrence

Licensee— The licensee imposed a moratorium on all similar gamma knife treatments until further safeguards could be established, and it implemented changes to improve the gamma knife procedure

State—The State conducted an onsite investigation and multiple virtual interviews with parties associated with the event. The State has also received, and is reviewing, relevant documentation related to this event. The investigation is ongoing.

This event is open for the purpose of this report.

APPENDIX A
ABNORMAL OCCURRENCE CRITERIA

The U.S. Nuclear Regulatory Commission (NRC) applied the criteria below in identifying abnormal occurrences (AOs) in this report. These criteria are set forth in the NRC policy statement "Abnormal Occurrence Reporting," published in the *Federal Register* (FR) on August 12, 2025 (90 FR 38828).

Abnormal Occurrence Criteria; Abnormal Occurrence General Statement of Policy

The U.S. Nuclear Regulatory Commission (NRC) will apply the following policy in determining whether an incident or event at a facility or involving an activity that is licensed or otherwise regulated by the Commission or an Agreement State is an abnormal occurrence (AO):[1]

An incident or event is considered an AO if it involves a major reduction in the protection of public health or safety. The incident or event has a moderate or 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 or Agreement State;

(2) Major degradation of essential safety-related equipment;

(3) Major deficiencies in design, construction, use of, or management controls for, facilities or radioactive material licensed by or otherwise regulated by the Commission or Agreement State; or

(4) Substantiated case of actual loss, theft, or diversion of risk-significant radioactive material licensed by or otherwise regulated by the Commission or Agreement State.

Abnormal Occurrence Criteria

The following presents the criteria, by types of events, used to determine which events will be considered for reporting as AOs.

[1] Events reported to the NRC by Agreement States that reach the threshold for reporting as AOs will be reported as such by the Commission.

I. All Licensees[2]

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:

(a) An annual total effective dose equivalent (TEDE) of 250 millisieverts (mSv) (25 rem) or more;

(b) 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;

(c) An annual dose equivalent to the lens of the eye of 1 Sievert (Sv) (100 rem) or more;

(d) An annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow of 1 Sv (100 rem) or more;

(e) A committed dose equivalent to the gonads of 2,500 mSv (250 rem) or more; or

(f) 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 an independent physician[3] deemed qualified by the NRC or Agreement State.

B. Discharge or Dispersal of Radioactive Material from Its Intended Place of Confinement.

The release of radioactive material to an unrestricted area in concentrations that, if averaged over a period of 24 hours, exceed 5,000 times the values specified in Table 2 of Appendix B, “Annual Limits

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2 Medical patients and human research subjects are excluded from consideration under these criteria, and these criteria do not apply to medical events defined in § 35.3045 of Title 10 of the *Code of Federal Regulations* (10 CFR), “Report and notification of a medical event,” which are considered in AO Criteria III.C.

3 “Independent physician” is defined as a physician not on the licensee’s staff and who was not involved in the care of the patient involved.

on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," to 10 CFR part 20, "Standards for protection against radiation," unless the licensee has demonstrated compliance with § 20.1301, "Dose limits for individual members of the public," 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; Sabotage; or Security Breach[4,5,6]

1. Any stolen, diverted, abandoned, or unrecovered lost radioactive material that meets or exceeds the thresholds listed in Appendix A, "Category 1 and Category 2 Radioactive Materials," to 10 CFR part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Excluded from reporting under this criterion are those events involving sources that are lost or abandoned under the following conditions: sources that have been lost and for which a reasonable attempt at recovery has been made without success, or irretrievable well logging sources as defined in § 39.2, "Definitions." These sources are only excluded if there is reasonable assurance that the doses from these sources have not exceeded, and will not exceed, the reporting thresholds specified in AO Criteria I.A.1 and I.A.2 and the agency has determined that the risk of theft or diversion is acceptably low.

2. An act that results in radiological sabotage as defined in § 37.5 and § 73.2.

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[4] Information pertaining to certain incidents may either be classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Executive Order 13526, "Classified National Security Information," as amended (75 FR 707; January 5, 2010), or any predecessor or successor order to require protection against unauthorized disclosures. Any classified details about these incidents would be available to Congress upon request, under appropriate security arrangements.

[5] Information pertaining to certain incidents may be Safeguards Information as defined in § 73.2 because of safety and security implications. The AO report would withhold specific Safeguards Information in accordance with Section 147 of the Atomic Energy Act of 1954, as amended. Any safeguards details regarding these incidents would be available to Congress upon request, under appropriate security arrangements.

[6] Reporting lost or stolen material is based on the activity of the source at the time the radioactive material was known to be lost or stolen. If, by the time the AO report is due to Congress, the radioactive material has decayed below the thresholds listed in Appendix A to 10 CFR Part 37, the report will clarify that the radioactive material has decayed below the thresholds.

3. Any substantiated[7] case of actual theft, diversion, or loss of a formula quantity of special nuclear material,[8] or an inventory discrepancy of a formula quantity of special nuclear material that is judged to be caused by theft or diversion.

4. Any substantial breakdown[9] of physical security, cyber security, or material control and accountability programs that significantly weakens the protection against loss, theft, diversion, or sabotage.

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

D. Initiation of High-Level NRC Team Inspection.[10]

II. Commercial Nuclear Power Plant Licensees

A. Malfunction of Facility, Structures, or Equipment

1. Exceeding a safety limit of a license technical specification (TS) (§ 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 that could result in exceeding the dose limits of 10 CFR part 100, “Reactor site criteria,” or five times the dose limits of General Design Criteria (GDC) 19, “Control Room,” in Appendix A, “General Design Criteria for Nuclear Power Plants,” to 10 CFR part 50, “Domestic licensing of production and utilization facilities,” could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

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7 “Substantiated” means a situation in which there is an indication of loss, theft, or unlawful diversion, such as an allegation of diversion, report of lost or stolen material, or other indication of loss of material control or accountability that cannot be refuted following an investigation, and requires further action on the part of the agency or other proper authorities.

8 “Formula quantity of special nuclear material” is defined in § 70.4, “Definitions.”

9 A substantial breakdown is defined as a red finding under the Reactor Oversight Process (ROP) in the physical security inspection program or any plant or facility determined to have overall unacceptable performance.

10 This item addresses the initiation of any incident investigation teams, as described in NRC Management Directive (MD) 8.3, “NRC Incident Investigation Program” (ADAMS Accession No. ML13175A294), or initiation of any accident review groups, as described in MD 8.9, “Accident Investigation” (ADAMS Accession No. ML13319A133).

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 the loss of plant capability to perform essential safety functions such that a release of radioactive materials exceeding the dose limits of 10 CFR part 100 or five times the dose limits of GDC 19 in Appendix A to 10 CFR part 50, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod drive mechanism).

C. Any operating reactor events or conditions evaluated by the NRC ROP to be the result of or associated with licensee performance issues of high safety significance.[11]

D. Any operating reactor events or conditions evaluated by the NRC Accident Sequence Precursor (ASP) program to have a conditional core damage probability (CCDP) or change in core damage probability (ΔCDP) of greater than or equal to 1×10^{-3}.[12]

E. Any operating reactor plants that are determined to have overall unacceptable performance or are in a shutdown condition as a result of significant performance problems and/or operational event(s).[13]

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11 The NRC ROP uses four colors to describe the safety significance of licensee performance. As defined in NRC MD 8.13, "Reactor Oversight Process" (ADAMS Accession No. ML17347B670), 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 AOs.

12 Results from the NRC Accident Sequence Precursor program are used to monitor agency performance against the agency's strategic safety goal (e.g., ensure the safe use of radioactive materials) and objectives (e.g., prevent and mitigate accidents and ensure radiation safety). A precursor event with a CCDP or ΔCDP of greater than or equal to 1×10^{-3} is used as a performance indicator for the strategic safety goal by determining that there have been no significant precursors of a nuclear reactor accident and that there have been no more than one significant adverse trend in industry safety performance.

13 Any plants assessed by the ROP to be in the unacceptable performance column, as described in NRC Inspection Manual Chapter (IMC) 0305, "Operating Reactor Assessment Program" (ADAMS Accession No. ML19256A191), or under NRC IMC 0350, "Oversight of Reactor Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns" (ADAMS Accession No. ML17116A273). This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

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

1. An accidental criticality.

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. Fuel Cycle Facilities[14]

1. Absence or failure of all safety controls (engineered and human) such that conditions were present for the occurrence of a high-consequence event involving an NRC-regulated hazard (radiological or chemical).[15]

2. An NRC-ordered safety-related or security-related immediate remedial action.

C. Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects[16]

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14 Criterion III.A also applies to fuel cycle facilities.

15 High-consequence events for facilities licensed under 10 CFR part 70, "Domestic licensing of special nuclear material," are those that could seriously harm the worker or a member of the public in accordance with § 70.61, "Performance requirements." The integrated safety analysis conducted and maintained by the licensee or applicant of 10 CFR part 70 fuel cycle facilities identifies such hazards and the safety controls (§ 70.62(c)) applied to meet the performance requirements in accordance with § 70.61(b) through (d). Fuel cycle facilities licensed under 10 CFR part 40, "Domestic licensing of source material," or certified under 10 CFR part 76, "Certification of gaseous diffusion plants," have licensing basis documents that describe facility specific hazards, consequences, and those controls used to prevent or mitigate the consequences of such accidents. For these facilities, a high-consequence event would be a release that has the potential to cause acute radiological or chemical exposures to a worker or a member of the public similar to that defined in Appendix A to Chapter 3, Section A.2, of NUREG-1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications—Final Report," issued June 2015, under "Consequence Category 3 (High Consequences)" (ADAMS Accession No. ML15176A258).

16 Criteria III.A.2, III.A.3, and III.A.4 also apply to medical licensees.

1. A medical event, as defined in § 35.3045 or in conditions of a license,[17] which results in an unintended dose:

   (a) That is equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal to or greater than 2.5 Gy (250 rad) to the gonads; or

   (b) To any other organ or tissue from the administration that exceeds, by 10 Gy (1,000 rad), the intended dose or the dose that would have resulted from delivery of the prescribed dose, prescribed dosage, or prescribed activity; and

2. A medical event, as defined in § 35.3045 or in conditions of a license[17]

   (a) A dose or dosage that is at least 50 percent greater than that prescribed, or

   (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.

[17] "In conditions of a license" means either the specific 35.1000 medical criterion can be written out in a license condition, or a license condition can incorporate a commitment to use the applicable criteria.

APPENDIX B
OTHER EVENTS OF INTEREST

This appendix discusses other events of interest that do not meet the criteria for abnormal occurrences (AOs) in Appendix A, “Abnormal Occurrence Criteria,” to this report. The U.S. Nuclear Regulatory Commission (NRC) 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 have been perceived by Congress or the public to be of high health or safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of a program area. They may also include groups of similar events through which licensed materials have entered the public domain in an uncontrolled manner.

No other events of interest occurred during this reporting period.

APPENDIX C
UPDATES ON PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During the reporting period, updated information became available for one abnormal occurrence (AO) that the U.S. Nuclear Regulatory Commission (NRC) reported in NUREG-0090, Volume 47, "Report to Congress on Abnormal Occurrences: Fiscal Year 2024," issued May 2025 (ADAMS Accession No. ML25150A343). This AO involved a medical event at AdventHealth Altamonte in Altamonte Springs, Florida.

AS24-06 Medical Event at AdventHealth Altamonte, Altamonte Springs, Florida

Criteria III.C.1(b) and III.C.2(b)(iii) in Appendix A to this report [for Fiscal Year 2024] provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose that exceeds, by 10 gray (Gy) (1,000 rad), the expected dose to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) from the administration defined in the written directive, and involves a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place—September 6, 2024, Altamonte Springs, Florida

Nature and Probable Consequences—On September 6, 2024, AdventHealth Altamonte (the licensee) reported that a dose had been delivered to the wrong treatment site during a yttrium (Y)-90 microsphere administration. The written directive prescribed an activity of 1.31 gigabecquerels (35.3 millicuries) for an intended dose of 250 Gy (25,000 rad) to the patient's liver. However, it was later found that a portion of the Y-90 microspheres had migrated to the patient's gastrointestinal (GI) system. A dose assessment indicated that a majority of the dose had been delivered to the GI system. The patient was notified immediately and experienced severe health consequences.

Updated Cause(s)—The medical event was originally believed to be caused by human error, because the treatment team did not perform a pretreatment mapping study before administering the dose intended for the left lobe of the liver. After reviewing hospital procedure and manufacturer's recommendations, however, it was later determined that the licensee had followed their internal process as well as the manufacturer's recommendations for this procedure. As such it was determined that the event was caused by the complex vasculature of the liver and that an unappreciated vascular pathway caused the microsphere delivery to the GI tract.

Update on Actions Taken to Prevent Recurrence

State—The State investigated the circumstances of this event, including the licensee's procedural documentation and the manufacturer's dosing recommendations. The State determined that the licensee had followed the manufacturer's recommendations and that enforcement actions were not warranted.

This event is closed for the purpose of this report.

APPENDIX D
GLOSSARY

AEA—the Atomic Energy Act of 1954 (Public Law 83-703), including any amendments.

Authorized user—as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) 35.2, "Definitions," a physician, dentist, or podiatrist who (1) meets the requirements in 10 CFR 35.59, "Recentness of training," and 10 CFR 35.190(a), 10 CFR 35.290(a), 10 CFR 35.390(a), 10 CFR 35.392(a), 10 CFR 35.394(a), 10 CFR 35.490(a), 10 CFR 35.590(a), or 10 CFR 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.

Brachytherapy—as defined in 10 CFR 35.2, 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, 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.

ΔCDP—increase in core damage probability for a time period during which one or more components are deemed unavailable or degraded.

Conditional core damage probability—conditional probability that a core damage state is reached, given the occurrence of the observed initiating event (and any subsequent equipment failure or degradation).

Deep dose equivalent—as defined in 10 CFR 20.1003, "Definitions," the external whole-body exposure dose equivalent at a tissue depth of 1 centimeter (1,000 milligrams per square centimeter).

Dose equivalent (H_T)—as defined in 10 CFR 20.1003, 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 (Sv).

Effective dose equivalent (H_E)—as defined in 10 CFR 20.1003, 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.

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

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

Fluoroscopy[1]—an x-ray procedure that makes it possible to see internal organs in motion.

Gray (Gy)—as defined in 10 CFR 20.1004, "Units of radiation dose," the International System's unit of absorbed dose; 1 Gy is equal to an absorbed dose of 1 joule per kilogram (100 rad).

Interstitial[2]—situated within, but not restricted to or characteristic of, a particular organ or tissue; used especially with fibrous tissue.

Medical event—as defined in 10 CFR 35.2, an event that meets the criteria in 10 CFR 35.3045(a) or 10 CFR 35.3045(b). Regulations in 10 CFR 35.3045(a) state the following:

> A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which—
>
> (1) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in—
>
> (i) 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 (A) the total dose delivered differs from the prescribed dose by 20 percent or more; (B) the total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or (C) the fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more.
>
> (ii) 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: (A) an administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure; (B) an administration of a radioactive drug containing byproduct material by the wrong route of administration; (C) an administration of a dose or dosage to the wrong individual or human research subject; (D) an administration of a dose or dosage delivered by the wrong mode of treatment; or (E) a leaking sealed source.
>
> (iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by: (A) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and (B) 50 percent or more the expected

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1. These terms are not defined in Title 10 of the *Code of Federal* Regulations or a U.S. Nuclear Regulatory Commission (NRC) management directive, inspection procedure, or policy statement. Rather, these definitions are based on those on the National Institutes of Health–National Cancer Institute Web site (see https://www.cancer.gov/about-cancer).

2. *Id.*

dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

(2) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in—

(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(iii) An administration that includes any of the following: (A) the wrong radionuclide; (B) the wrong individual or human research subject; (C) sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or (D) a leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

Regulations in 10 CFR 35.3045(b) state the following:

> 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.

Prescribed dosage—as defined in 10 CFR 35.2, 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 10 CFR 35.100, “Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required,” and 10 CFR 35.200, “Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.”

Prescribed dose—as defined in 10 CFR 35.2, (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.

Rad—as defined in 10 CFR 20.1004, the special unit of absorbed dose; 1 rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 Gy).

Radiation (ionizing radiation)—as defined in 10 CFR 20.1003, 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, “Standards for Protection

Against Radiation," does not include nonionizing radiation (such as radio waves or microwaves) or visible, infrared, or ultraviolet light.

Radiation therapy (radiotherapy)[3]—the treatment of disease with radiation (e.g., x-rays).

Reactive inspection—as defined in NRC Inspection Manual Chapter 2800, "Materials Inspection Program," and Management Directive 8.10, "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility," an inspection performed in response to an event to obtain additional information.

Rem—as defined in 10 CFR 20.1004, the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

Shallow dose equivalent (H_S)—as defined in 10 CFR 20.1003, for the external exposure of the skin of the whole body or the skin of an extremity, the dose equivalent at a tissue depth of 0.007 centimeter (7 milligrams/square centimeter).

Sievert (Sv)—as defined in 10 CFR 20.1004, the International System's unit of any of the quantities expressed as dose equivalent; the dose equivalent in Sv is equal to the absorbed dose in Gy multiplied by the quality factor (1 Sv = 100 rem).

Source material—as defined in 10 CFR 40.4, "Definitions," (1) uranium or thorium, or any combination thereof, in any physical or chemical form, or (2) ores that contain by weight 1/20 of 1 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, "Definitions," (1) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission, pursuant to the provisions of AEA Section 51, "Special Nuclear Material," determines to be special nuclear material, but not including source material, or (2) any material artificially enriched by any of the foregoing, but not including source material.

Technical specification—part of an NRC license authorizing the operation of a nuclear production or utilization facility that establishes requirements for items such as safety limits, limiting safety system settings, limiting control settings, limiting conditions for operation, surveillance requirements, design features, and administrative controls.

Therapeutic dose—as defined in 10 CFR 35.2, 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, the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Written directive—as defined in 10 CFR 35.2, 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 10 CFR 35.40, "Written directives."

3. *Id.*

APPENDIX E
CONVERSION TABLE

Radioactivity and Dose

QUANTITY	FROM METRIC UNITS	TO NONINTERNATIONAL SYSTEM UNITS	DIVIDE BY
Radioactivity	megabecquerel (MBq)	curie (Ci)	37,000
	gigabecquerel (GBq)	Ci	37
Absorbed dose	gray (Gy)	rad	0.01
Dose equivalent	sievert (Sv)	rem	0.01
	millisievert (mSv)	rem	10
	mSv	millirem (mrem)	0.01