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Protecting People and the Environment

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Volume 47

Report to Congress on Abnormal Occurrences

Fiscal Year 2024

Office of Nuclear Regulatory Research

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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) 2024 describes seven events involving Agreement State licensees and one event involving an NRC licensee. These events were identified based on the criteria in the NRC policy statement "Abnormal Occurrence Reports" (82 FR 45907; October 2, 2017). Seven AOs were medical events as defined in Title 10 of the *Code of Federal Regulations* Part 35, "Medical Use of Byproduct Material." The other AO involved two criteria: (1) a substantial breakdown of physical security, cybersecurity, or material control and accountability programs that significantly weakens protection against loss, theft, diversion, or sabotage, and (2) a serious safety–-significant deficiency in management or procedural controls. 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 2024 that met the guidelines for inclusion in Appendix B, "Other Events of Interest." Two events 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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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 eight events identified as AOs in fiscal year (FY) 2024, based on the criteria in the NRC policy statement "Abnormal Occurrence Reports" (82 FR 45907; October 2, 2017). 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 2024 that met the guidelines for inclusion in Appendix B, "Other Events of Interest." During this reporting period, two events 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*. 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 *Federal Register* (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 October 2, 2017 (82 FR 45907); the revised criteria became effective on that date. The NRC staff used these criteria to define AOs for this FY 2024 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 to identify deficiencies and ensure 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 39 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 2024.

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, two events met the guidelines for inclusion in Appendix C.

ABBREVIATIONS

AEA	Atomic Energy Act of 1954, as amended
AO	abnormal occurrence
CCDP	conditional core damage probability
ΔCDP	change in core damage probability
CDPH	California Department of Public Health
CDPHE	Colorado Department of Public Health and Environment
CFR	*Code of Federal Regulations*
Ci	curie(s)
DSHS	Department of State Health Services (Texas)
FR	*Federal Register*
FY	fiscal year
GBq	gigabecquerel(s)
GI	gastrointestinal
Gy	gray(s)
HDR	high dose rate
I	iodine
IMC	inspection manual chapter
MAA	macroaggregated albumin
MBq	megabecquerel(s)
mCi	millicurie(s)
MD	management directive
mrem	millirem(s)
mSv	millisievert(s)
NRC	U.S. Nuclear Regulatory Commission
ROP	Reactor Oversight Process
RSO	Radiation Safety Officer
Sv	sievert(s)
Tc	technetium
TEDE	total effective dose equivalent
TS	technical specification(s)
Y	yttrium

ABNORMAL OCCURRENCES IN FISCAL YEAR 2024

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, one event was identified as an AO based on the criteria under Category I, “All Licensees,” in Appendix A.

AS24-01 Security Event at ARC Inspection Services LLC, Krum, Texas

Criterion I.C.4 in Appendix A to this report, provides, in part, that an event shall be considered for reporting as an AO if there was any substantial breakdown of physical security or material control (e.g., of access control containment or accountability systems) that significantly weakened the facility’s protection against theft, diversion, or sabotage. Additionally, criterion III.A.3 in Appendix A to this report provides, in part, that an event at any facility other than a nuclear power plant shall be considered for reporting as an AO if it involves a serious safety-significant deficiency in management or procedural controls.

Date and Place—August 7, 2024, Krum, Texas

Nature and Probable Consequences—On August 4, 2024, the Texas Department of State Health Services (DSHS) received information alleging a radiography licensee (ARC Inspection Services, LLC), abandoned a truck carrying Category 2 radioactive sources and that the vehicle was previously under the control of an individual who was not designated by the company’s security program as trustworthy and reliable. The DSHS conducted investigations of the licensee’s facilities in Krum, Texas, from August 7 to 9, 2024. Though the investigations did not substantiate that Category 2 radioactive sources had been abandoned, the DSHS found that the licensee had not completed background checks for multiple personnel. Background checks are required to determine whether employees are trustworthy and reliable prior to being assigned access to licensed radioactive material sources. Further, DSHS found (1) numerous instances where security related information and equipment associated with the Category 2 material were accessed by unauthorized licensee personnel before the trustworthy and reliability process was completed; (2) the licensee exceeded their radioactive material possession limit without prior approval from DSHS; (3) the licensee failed to maintain appropriate records and information associated with background checks for personnel and inventories of radioactive materials; and (4) the licensee appeared to have conducted radiography activities in surrounding states without

obtaining appropriate regulatory approvals through licensing or reciprocity. Despite the violations identified, DSHS found no indication that any individual would have received an exposure to radiation that would have exceeded any regulatory limits.

Cause(s)— The primary root cause for the violations identified by DSHS was the licensee's Radiation Safety Officer (RSO) not adequately implementing the licensee's security plans and procedures. In particular, DSHS determined that several of the licensee's employees were performing duties associated with the RSO role, without authorization.

Actions Taken to Prevent Recurrence

Licensee—The licensee reorganized its organizational structure and appointed a single individual as RSO. In addition, by early September 2024, the licensee sufficiently corrected the violations identified by DSHS in its initial investigation activities to comply with the Texas Radiation Act and applicable rules.

State—The DSHS initiated a prompt investigation, identifying numerous violations of the Texas Radiation Act and applicable rules associated with the licensee's activities. On August 26, 2024, DSHS issued an impound order to the licensee which reclaimed all the licensee's radioactive sources and radiography devices until satisfactory corrective actions had been taken. On September 5, 2024, the impound order was rescinded following DSHS' determination that the licensee had satisfactorily completed corrective actions. The DSHS further heightened its oversight of the licensee's activities, requiring the licensee to provide frequent reporting of its activities, and increasing the frequency of inspections. Ultimately, DSHS issued an administrative penalty to the licensee of $235,500 with conditions associated with nine violations of the Texas Radiation Act.

This event is closed for the purposes 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, seven 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."

AS24-02 Medical Event at Providence Sacred Heart Medical Center, Spokane, Washington

Criteria III.C.1(b) and III.C.2(a) 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 a dose that exceeds, by 10 grays (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 dose or dosage that is at least 50 percent greater than that prescribed.

Date and Place—June 14, 2023, Spokane, Washington

Nature and Probable Consequences—On June 14, 2023, the Providence Sacred Heart Medical Center (licensee) reported an event during a high dose rate (HDR) brachytherapy treatment with an iridium-192 source. The written directive prescribed a series of three fractionated treatments for two separate skin lesions. The two locations were supposed to receive 5 Gy (500 rad) and 4 Gy (400 rad) per fractionated treatment, for total doses of 15 Gy (1,500 rad) and 12 Gy (1,200 rad), respectively. During the first treatment however, all 15 Gy (1,500 rad) and 12 Gy (1,200 rad) to the respective locations were administered to the patient. After treatment, the physician noticed that the incorrect doses had been administered and immediately notified the patient. No adverse health effects were expected for the patient because the total doses did not exceed the treatment plan.

Cause(s)— The primary cause was a breakdown in communication. Because of the high volume of treatments scheduled for that day, the medical physicist initially planning the treatment was called to the operating room, and a second medical physicist finished the treatment planning. The first medical physicist failed to communicate that the treatment was supposed to be fractionated, and the second medical physicist instead planned 15 Gy (1,500 rad) and 12 Gy (1,200 rad) for the respective locations in one treatment. The authorized user reviewed the treatment plan and failed to notice the deviation from the written directive.

Actions Taken to Prevent Recurrence

Licensee—The licensee revised the HDR policy to specify that a single medical physicist should be present and accountable throughout the planning and treatment process. The revised policy also details a formal plan for the handoff procedure should a transition between medical physicists need to occur during planning or treatment. Lastly, the revised HDR policy now

includes a timeout before the start of the treatment, during which all involved staff are verbally briefed on the treatment plan to confirm that there are no concerns before proceeding.

State—The Washington Department of Health conducted an investigation of the licensee 30 days after the incident. The investigation resulted in the issuance of a Notice of Correction enforcement action, which required, in part, that the licensee complete an independent third-party audit of the facility's radioactive materials program. The Washington Department of Health reviewed the results of the independent audit and other corrective actions, including its revised HDR policies and protocols, as part of onsite inspections taking place through July 2024 and determined that the revised policies and protocols adequately addressed the program's deficiencies.

This event is closed for the purposes of this report.

AS24-03 Medical Event at an Unspecified Medical Licensee, Unspecified City, New York[1]

Criteria III.C.1(b) and III.C.2(b)(iii) 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 a dose that exceeds, by 10 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—November 6, 2023, Unspecified City, New York

Nature and Probable Consequences—On November 6, 2023, the licensee reported that a dose was delivered to the wrong treatment site during a gamma knife radiosurgery treatment. The patient was intended to receive a single dose of 80 Gy (8,000 rad) to the left-side trigeminal nerve (a cranial nerve). The full treatment dose was delivered to the right-side trigeminal nerve. The patient was immediately notified, and no adverse health consequences are expected.

Cause(s)—The medical physicist incorrectly identified the right-side trigeminal nerve as the treatment site. Both the neurosurgeon and the radiation oncologist reviewed the treatment plan and failed to notice the incorrectly labeled treatment site. All three individuals then signed off on the treatment plan before administration.

Actions Taken to Prevent Recurrence

Licensee—The licensee implemented new procedures for gamma knife radiosurgery treatments, including a medical physics check to determine laterality, an additional peer review by a gamma knife-trained radiation oncologist, and a verbal timeout, during which the treatment plan is confirmed by attending staff, for all cases before the plan is signed by the appropriate medical professionals.

State—The State conducted an inspection for this event and a related complaint on April 19, 2024. There were no enforcement actions as a result of the inspection and the State closed the event.

This event is closed for the purposes of this report.

[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.

NRC24-01 Medical Event at Saint Francis Medical Center, Cape Girardeau, Missouri

Criteria III.C.1(b) and III.C.2(a) 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 a dose that exceeds, by 10 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 dose or dosage that is at least 50 percent greater than that prescribed.

Date and Place—May 6, 2024, Cape Girardeau, Missouri

Nature and Probable Consequences—On May 7, 2024, the Saint Francis Medical Center (the licensee) reported an event associated with an yttrium (Y)-90 microsphere administration. On May 6, 2024, during a palliative treatment of a liver tumor, the patient received a dose to the treatment site approximately 300 percent greater than the prescribed dose. The written directive prescribed a dose of 90 Gy (9,000 rad) to the left lobe of the liver; however, the patient received 360 Gy (36,000 rad). The authorized user planned a treatment consisting of one dosage of an activity of 7.0 gigabecquerels (GBq) (190 millicuries (mCi)), with a calibration date of Sunday, April 28, 2024, or a second dosage option of 3.0 GBq (82 mCi), with a calibration date of Sunday, May 5, 2024. Either of these single dosages would have delivered the prescribed dose of 90 Gy to the treatment site. However, the authorized user provided unclear instructions to the nuclear medicine staff, who interpreted the treatment plan to include both dosages. As of January 27, 2025, the patient's referring physician indicated that the patient did not have any identifiable health effects on the liver as a result of the procedure and the patient continued with their cancer treatment plan.

Cause(s)— When planning the treatment, the authorized user listed two treatment dosage options on the same worksheet and the nuclear medicine staff interpreted the treatment as needing both administrations. The computerized version of the worksheet that the authorized user worked with did not include an alert or prompt to warn the staff that these combined dosages would result in a dose to the treatment site exceeding the prescribed dose.

Actions Taken to Prevent Recurrence

Licensee—Corrective actions from the licensee included closing the Y-90 microsphere program.

NRC— The NRC conducted an inspection on May 14, 2024, and May 15, 2024, and the licensee is continuing to monitor the patient for potential health effects. On March 20, 2025, the NRC notified the licensee of a Notice of Violation for four violations, including failure to have written directives dated and signed by an authorized user prior to a therapeutic administration of radiation from byproduct material; failure to develop, implement, and maintain written procedures; failure to provide training to individuals involved in Y-90 microsphere administrations; and failure to ensure that radiation safety activities are performed in accordance with licensee-approved procedures. Updates received from the licensee regarding patient outcome will be provided in future reports.

This event is closed for the purposes of this report.

AS24-04 Medical Event at Rose Medical Center, Denver, Colorado

Criteria III.C.1(b) and III.C.2(b)(iii) 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 a dose that exceeds, by 10 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—May 13, 2024, Denver, Colorado

Nature and Probable Consequences—On May 16, 2024, the Rose Medical Center (licensee) reported an event during an administration of Y-90 microspheres. The written directive prescribed an activity of 0.610 GBq (16.5 mCi) to the liver for a dose of 515 Gy (51,500 rad). A dosage of 0.613 GBq (16.6 mCi) of Y-90 microspheres was administered on May 13, 2024. Follow up imaging analysis conducted on May 15, 2024, revealed an unanticipated migration of microspheres to the gastrointestinal (GI) system with an estimated dose of 14–20 Gy (1,400–2,000 rad). The patient was notified on May 16, 2024, and underwent several follow up appointments to verify that there were no adverse health effects to the GI system.

Cause(s)—The licensee assessed the likely cause of the event as the complex vascularity of the individual's liver. Two mapping studies were performed before the administration of the Y-90 microspheres. The first mapping study indicated that there was potential flow to the GI system. However, on the day of the Y-90 microsphere administration, the licensee completed recommended imaging activities, including a second technetium (Tc)-99m macroaggregated albumin (MAA) mapping study initiated from a different arterial location, which indicated that there would be no potential flow to the GI system. Because of the advanced nature of the patient's condition, a third mapping study was not conducted. Thus, the Y-90 microspheres were administered using the arterial pathway from the second mapping procedure, which did not show flow to the GI system. The licensee hypothesized that because the second mapping study was conducted the same day as the administration of the Y-90 microspheres, it was possible that the Tc-99m MAA particles (which consists of larger particles than the Y-90 microspheres) may have partially blocked the patient's tumoral vessels, thereby altering the flow dynamics of the microspheres.

Actions Taken to Prevent Recurrence

Licensee—The licensee and the patient's physician monitored the patient for potential adverse complications due to the unintended dose to the GI system; none were identified. Subsequently, the licensee made no formal changes or additional commitments to its license for administration procedures, given that the administration of the Y-90 microspheres had been conducted in accordance with the manufacturer's recommendations.

State—The Colorado Department of Public Health and Environment (CDPHE) conducted a reactive inspection onsite at the facility on July 16, 2024, with follow up activities through July 31, 2024. Based on the inspection, CDPHE determined that the licensee appeared to have conducted the Y-90 microsphere administration consistent with the manufacturer's recommendations, licensee procedures, and NRC licensing guidance. Consequently, CDPHE identified no violations during the inspection.

This event is closed for the purposes of this report.

AS24-05 Medical Event at University of California, Los Angeles, Medical Center, Los Angeles, California

Criteria III.C.1(b) and III.C.2(b)(iii) 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 a dose that exceeds, by 10 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—July 26, 2024, Los Angeles, California

Nature and Probable Consequences—On August 2, 2024, the University of California, Los Angeles (the licensee), reported an event that occurred on July 26, 2024, during a Y-90 microsphere administration intended for the left lobe of the liver. The written directive prescribed an activity of 0.720 GBq (20 mCi) for an intended dose of 179 Gy (17,900 rad) to the left lobe of the liver. One week before the treatment, a mapping study using Tc-99m MAA was performed. The study did not indicate flow of the Tc-99m MAA to the GI system. On the day of the Y-90 microsphere treatment, the licensee conducted an angiogram to verify that the microcatheter placement for the treatment was in the same position that had been used during the mapping study. However, posttreatment imaging revealed that the Y-90 microspheres migrated to the GI system, resulting in an unintended dose of 199 Gy (19,900 rad), while the liver received no dose during the Y-90 microsphere treatment. The patient was notified of the incident and warned of the potential for adverse effects. Over the next several months, the patient was monitored by a team of specialists and was treated for adverse effects to the GI system, including GI-related pain, loss of appetite, vomiting, gastritis, and ulcers. As of the most recent patient exam, in November 2024, the patient appeared to be recovering.

Cause(s)—The licensee was not able to definitively determine why the Y-90 microspheres migrated to the GI system, when the Tc-99m MAA had not flowed to the stomach during the mapping study one week earlier. The licensee hypothesized that characteristics of the blood flow to the patient's liver may have been different because of the immunotherapy and angiogenesis treatment that the patient completed approximately one month before the Y-90 microsphere administration.

Actions Taken to Prevent Recurrence

Licensee—The licensee updated its Y-90 microsphere treatment guidance to specify that when pretreatment mapping studies suggest abnormal arterial structure, cone beam computed tomography should be used during arteriography to augment the pretreatment mapping studies. Also, the licensee gave clear instructions to authorized users concerning the reporting requirements, due to the fact that the event was not reported to the California Department of Public Health (CDPH) until seven days after the administration.

State—The CDPH met with the licensee several times to discuss the suspected cause of the unintended dose to the patient, corrective actions to preclude recurrence, and the late reporting of the medical event. A Notice of Violation was issued to the licensee for the late reporting of the medical event, and the State determined that the licensee took appropriate corrective actions to preclude recurrence. CDPH will conduct a followup inspection in early 2025 to verify the licensee's implementation of the corrective actions.

This event is closed for the purposes of this report.

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 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 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 was delivered to the wrong treatment site during a Y-90 microsphere administration. The written directive prescribed an activity of 1.31 GBq (35.3 mCi) 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 migrated to the patient's GI system. A dose assessment indicated that a majority of the dose was delivered to the GI system. The patient was notified immediately and experienced severe health consequences.

Cause(s)—The medical event was caused by human error. The treatment team did not perform a pretreatment mapping study before administration. The patient was scheduled to receive treatment in a two-pronged approach, with one dose to each lobe of the liver. In the pretreatment Tc-99m MAA mapping with angiogram for the right lobe of the liver (performed on June 20, 2024), no flow to the GI system was noted. The treatment, encompassing the right lobe of the liver, was completed on July 11, 2024. On September 4, 2024, the treatment encompassing the left lobe of the liver was completed, without performing pretreatment Tc-99m MAA mapping to determine risk of flow of Y-90 microspheres to the GI system.

Actions Taken to Prevent Recurrence

Licensee—All of the licensee's interventional radiologists that are involved with Y-90 microsphere administrations are undergoing additional education, which includes a discussion of this case. The licensee has implemented a new formal process for the treatment team to review current TC-99m MAA and angiography mapping techniques, including cone beam computed tomography.

State—The investigation is ongoing; however, the State expects to take escalated enforcement action.

This event is open for the purposes of this report.

AS24-07 Medical Event at an Unspecified Medical Licensee, Unspecified City, New York[2]

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 a dose that exceeds, by 10 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 23, 2024, Unspecified City, New York

Nature and Probable Consequences—On September 24, 2024, the licensee reported that a dose was delivered to the wrong treatment site during a Y-90 microsphere administration. The written directive prescribed a dosage of 2.18 GBq (59 mCi), however, during treatment, only 0.925 GBq (25 mCi) was administered. During follow up, it was determined that some of the Y-90 microspheres migrated to the GI system, resulting in an unintended dose of 99 Gy (9,900 rad). The patient was admitted for observation and held until September 27, 2024. At the time of discharge, the patient remained asymptomatic. The patient's cancer treatment was placed on hold. The patient is being monitored for any adverse health effects from the unintended dose to the GI system.

Cause(s)—The licensee identified the likely cause of this event as a blockage and subsequent rupture of the microcatheter used for the Y-90 microsphere administration. The physician noted resistance during administration and attempted to flush the microcatheter, resulting in the rupture.

Actions Taken to Prevent Recurrence

Licensee—The licensee used a compatible microcatheter per the manufacturer's recommendations and followed administration protocol. As such, no changes to the program are being made. The licensee, however, has taken steps to prevent recurrence, including (1) advising interventional radiology authorized users of this issue at the associated morbidity and mortality conference; (2) notifying the vendor of the event; and (3) determining if medical device reporting is required.

State—The State confirmed that the licensee followed manufacturer's recommendations for both the administration and equipment. The State has no further actions planned in response to this event.

This event is closed for the purposes of this report.

[2] 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-I.

APPENDIX A
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, or 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.

The NRC provided the criteria below for identifying AOs, as well as the guidelines for "other events of interest," in a policy statement published in Volume 82 of the *Federal Register*, page 45907 (82 FR 45907; October 2, 2017).

Abnormal Occurrence Criteria

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

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:

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[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.

[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 Title 10 of the *Code of Federal Regulations* (10 CFR) 35.3045, "Report and notification of a medical event," which are considered in AO criterion III.C.

(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 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 10 CFR 20.1301, “Dose limits for individual members of the public,” using 10 CFR 20.1302(b)(1) or 10 CFR 20.1302(b)(2)(ii). This criterion does not apply to transportation events.

[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.

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 10 CFR 39.2, "Definitions." These sources are excluded only 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 10 CFR 73.2, "Definitions."

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[8] that is judged to be caused by theft or diversion.

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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 10 CFR 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.

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 by the agency or other proper authorities.

8 "Formula quantity" of special nuclear material is defined in 10 CFR 70.4, "Definitions."

4. Any substantial breakdown[9] of physical security, cybersecurity, 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) (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 that could result in exceeding the dose limits of 10 CFR Part 100, "Reactor Site Criteria," or 5 times the dose limits of General Design Criterion (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).

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 5 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).

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[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," approved June 25, 2014 (Agencywide Documents Access and Management System Accession No. ML13175A294), or initiation of any accident review groups, as described in MD 8.9, "Accident Investigation," approved April 11, 2014 (ML13319A133).

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 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]

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.

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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" (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 has 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," dated November 25, 2019 (ML19256A191), or under NRC IMC 0350, "Oversight of Reactor Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns," dated March 1, 2018 (ML17116A273). This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

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]

1. A medical event, as defined in 10 CFR 35.3045, which results in a dose that:

   (a) 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) Exceeds, by 10 Gy (1,000 rad), the expected dose to any other organ or tissue from the administration defined in the written directive; and

2. A medical event, as defined in 10 CFR 35.3045, which involves:

   (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

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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 10 CFR 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 (10 CFR 70.62(c)) applied to meet the performance requirements in accordance with 10 CFR 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)" (ML15176A258).

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

(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.

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 that 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 two abnormal occurrences (AOs) that the U.S. Nuclear Regulatory Commission (NRC) reported in NUREG-0090, Volume 46, "Report to Congress on Abnormal Occurrences: Fiscal Year 2023," issued June 2024. These AOs involved medical events at Baptist Health Medical Center, in Little Rock, Arkansas, and Henry Ford Hospital, in Detroit, Michigan.

AS23-07 Medical Event at Baptist Health Medical Center, Little Rock, Arkansas

Criteria III.C.1(b) 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 a dose that exceeds, by 10 grays (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 uses the wrong radiopharmaceutical or unsealed byproduct material.

Date and Place—March 15, 2023, Little Rock, Arkansas

Nature and Probable Consequences—On March 21, 2023, Baptist Health Medical Center (the licensee) reported that a patient was administered iodine (I)-131 instead of I-123 in error. The patient was inadvertently scheduled in the electronic medical record system for a total-body iodine scan using I-131 and Thyrogen (a thyroid-stimulating medication) and not a thyroid scan using I-123 as intended. On March 15, 2023, the patient was administered 162.8 megabecquerels (4.4 millicuries (mCi)) of I-131. When the patient returned for imaging on March 17, 2023, the radiologist realized the wrong study had been performed and the patient was administered the incorrect radiopharmaceutical. The health physicist estimated that the patient received a dose of 150 Gy (15,000 rad) to the thyroid. In its followup with the licensee, the State of Arkansas reported that the patient's blood test results conducted six weeks after the I-131 administration were normal, and no further followup with the patient was conducted. No long-term health effects for the patient were anticipated.

Cause(s)—The licensee determined that the cause of this event was human error, in that the protocol to have all pertinent reports and lab work completed before starting the procedure was not followed. Additionally, because the medical records incorrectly stated that the patient needed a total-body iodine scan, the radiologist lacked sufficient information to prescribe the correct treatment. When signing the written directive, the radiologist was told only that a total-body iodine scan had been ordered for the patient, leading to the administration of I-131 instead of the intended I-123 radiopharmaceutical.

Update on Actions Taken to Prevent Recurrence

State—In May 2024, the State conducted a periodic review, including an onsite review with the licensee's management to ascertain the details of the event, the determined root cause(s), corrective actions taken, and adverse health effects to the patient. The licensee improved communications between the departments that are responsible for scheduling, ordering, and administering nuclear medicine radiopharmaceuticals, and also improved the process for written directive approvals. The State reviewed the corrective actions taken by the licensee and

determined that they were adequate to prevent future recurrence.

This event is closed for the purposes of this report.

NRC23-02 Medical Event at Henry Ford Hospital, Detroit, Michigan

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 a dose that exceeds, by 10 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—July 11, 2023, Detroit, Michigan

Nature and Probable Consequences—On July 11, 2023, Henry Ford Hospital (the licensee) reported that a high dose rate (HDR) intravascular brachytherapy treatment was delivered to the wrong treatment site. The patient was prescribed a dose of 23 Gy (2,300 rad) to the left circumflex artery using a 3.62 gigabecquerel (97.8 mCi) strontium-90 source. During treatment, the interventional cardiologist used fluoroscopy to determine that the source had correctly arrived at the treatment site. Upon further review of the fluoroscopic images, however, the interventional cardiologist reported that the location of the source could not accurately be assessed. The prescribing physician then determined that the source had failed to reach the correct target and instead provided the prescribed dose (23 Gy) to another part of the vasculature proximal to the treatment location. No permanent damage was expected as a result of the treatment.

Cause(s)—This event was caused by human error; the interventional cardiologist misread the fluoroscopic images because of their quality and visual complexity. These images were obscured by the presence of brachytherapy equipment, preexisting medical devices, and interventional equipment.

Update on Actions Taken to Prevent Recurrence

NRC—On July 18, 2023, the NRC performed a reactive inspection to evaluate the circumstances of the event and to assess its root and contributing causes, as well as the actions taken by the licensee in response to the event. The NRC thereafter retained the services of a medical physics consultant to provide an independent assessment of the event, including an independent estimate of the dose to the exposed individual.

In a summary of findings, dated February 14, 2024, the consultant concluded that the licensee's dose estimate was reasonable, its corrective actions were appropriate, and the dose was insufficient to cause harm to the patient. The NRC characterized the isolated failure to implement written procedures providing high confidence that treatments were in accordance with written directives as a noncited violation in accordance with its Enforcement Policy, and no enforcement action was taken because: (1) the licensee demonstrated initiative in identifying the violation and its root cause for failing to implement its written procedures, (2) the licensee implemented adequate corrective actions to prevent recurrence of a similar violation, (3) the violation was not repetitive as a result of inadequate corrective action, and (4) the violation was not willful.

This event is closed for the purposes 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.

Catheter[1]—a flexible tube used to deliver fluids into or withdraw fluids from the body.

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

1. This term is 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, this definition is based on those on the National Institutes of Health—National Cancer Institute website (see https://www.cancer.gov/about-cancer).

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[2]—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[3]—situated within, but not restricted to or characteristic of, a particular organ or tissue; used especially of 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 that 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

2. *Id.*

3. *Id.*

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 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)[4]**—**the treatment of disease with radiation (such as 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 1/20th 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 section 51, "Special Nuclear Material," of the Atomic Energy Act of 1954, as amended, 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,

4. *Id.*

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."

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

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(See instructions on the reverse)

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10. SUPPLEMENTARY NOTES

NRC Project Manager, Rigel Flora

11. ABSTRACT (200 words or less)

Section 208 of the Energy Reorganization Act of 1974, as amended, defines an abnormal occurrence (AO) as an unscheduled incident or event that the NRC determines to be significant from the standpoint of public health or safety. The Federal Report Elimination and Sunset Act of 1995 requires that AOs be reported to Congress on an annual basis. This report includes those events that the NRC has determined to be AOs during the Fiscal Year 2023.

This report describes seven events involving Agreement States and one event involving an NRC licensee. The NRC identified no events at NRC licensed facilities during Fiscal Year 2023 that met the guidelines for inclusion in Appendix B, “Other Events of Interest.” Two events met the guidelines for inclusion in Appendix C, “Updates of Previously Reported Abnormal Occurrences.”

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)

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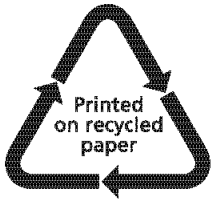

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