Report to Congress on Abnormal Occurrences

Fiscal Year 2023

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 describes nine events in Agreement States and two events involving NRC licensees that were identified as AOs during fiscal year 2023. These events were identified based on the criteria in the NRC policy statement "Abnormal Occurrence Reports," published in Volume 82 of the *Federal Register* (FR), page 45907 (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." Three AOs involved the theft or diversion and recovery of Category 2 radioactive material sources, as defined in 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." The other AO involved a human exposure event. No events at a commercial nuclear power plant met the AO criteria.

Appendix A, "Abnormal Occurrence Criteria," to this report presents the NRC's criteria for identifying AOs. The NRC did not identify any events during fiscal year 2023 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 11 events identified as AOs in fiscal year (FY) 2023, based on the criteria in the NRC policy statement "Abnormal Occurrence Reports" (Volume 82 of the *Federal Register* (FR), page 45907 (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 did not identify any events during FY 2023 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*. 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 on February 24, 1977 (42 FR 10950), followed by 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 2023 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 computer-based data files for more effective collection, storage, retrieval, and evaluation of events.

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 the States' 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 or activities involving the use of radioactive material, whether regulated by the NRC or an Agreement State.

INTERNATIONAL INFORMATION

The NRC exchanges information with various foreign governments 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 other events of interest that occurred during FY 2023.

UPDATES ON PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

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

ABBREVIATIONS

AEA	Atomic Energy Act of 1954, as amended
AO	abnormal occurrence
BRC	Bureau of Radiation Control (Florida)
CCDP	conditional core damage probability
ΔCDP	change in core damage probability
CFR	*Code of Federal Regulations*
Ci	curie(s)
DSHS	Department of State Health Services (Texas)
FR	*Federal Register*
FY	fiscal year
GBq	gigabecquerel(s)
GDC	general design criterion/criteria
Gy	gray(s)
HDR	high dose rate
I	iodine
IMC	inspection manual chapter
Ir	iridium
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
Sv	sievert(s)
TBq	terabecquerel(s)
Tc	technetium
TEDE	total effective dose equivalent
TS	technical specification
Y	yttrium

ABNORMAL OCCURRENCES IN FISCAL YEAR 2023

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, two events were identified as AOs based on the criteria under Category I, “All Licensees,” in Appendix A.

AS23-01 Human Exposure Event at University Hospital & Clinics, Lafayette, Louisiana

Criterion I.A.2 of Appendix A to this report provides, in part, that any unintended radiation exposure (an individual less than 18 years of age) shall be reported as an AO if it results in an annual total effective dose equivalent (TEDE) to a minor of 50 millisieverts (mSv) (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.

Date and Place—October 26, 2022, Lafayette, Louisiana

Nature and Probable Consequences—On January 31, 2023, University Hospital & Clinics Incorporated (the licensee) reported that an embryo/fetus received an unplanned radiation dose. On October 26, 2022, a female patient was administered an activity of 1.11 gigabecquerels (GBq) (30 millicuries (mCi)) of iodine (I)-131 for a therapeutic medical procedure. On January 26, 2023, the licensee was informed by a different physician for the individual that the patient was unknowingly 11–12 weeks pregnant at the time of the I-131 administration in October. A retrospective analysis performed by the medical physicist assigned a dose value to the embryo/fetus of 50 mSv (5 rem). At that time, the patient’s pregnancy continued under the care of an obstetrician and additional specialists due to the patient’s medical history.

Cause(s)—The licensee determined that the cause of the incident was human error. Specifically, while the patient had indicated she was not pregnant when verbally asked before the procedure, two departments of the hospital believed the other had administered a pregnancy test to the patient, but neither had performed the test.

Actions Taken to Prevent Recurrence

Licensee—The licensee changed its policy to require a verified pregnancy test before all I-131 administrations to eliminate this possibility. Additionally, the licensee implemented a policy to require a radiopharmaceutical written directive with all I-131 orders (regardless of quantity) throughout its hospital network.

State—The State of Louisiana Department of Environmental Quality investigated this event and issued an enforcement action and Notice of Potential Penalty to the licensee.

This event is open for the purpose of this report.

NRC23-01 Stolen Industrial Radiography Camera from XCEL NDT, Gretna, Nebraska

Criterion I.C.1 of Appendix A to this report provides, in part, 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.

Date and Place—November 14, 2022, Billings, Montana

Nature and Probable Consequences—On November 14, 2022, XCEL NDT (the licensee) reported the theft and subsequent recovery of a vehicle that contained a locked and shielded industrial radiography exposure device containing 1.94 terabecquerels (TBq) (52.3 curies (Ci)) of iridium (Ir)-192. At the time of the theft, the vehicle was parked at a temporary job site location in Billings, Montana. The vehicle was recovered in the local area within approximately 3 hours of being stolen. Upon recovery of the vehicle, the licensee verified that the exposure device was not accessed, and the device remained locked and undamaged. The licensee's radiation safety officer was immediately notified, as well as the local law enforcement agency in Billings. Local law enforcement investigated the incident but did not identify the perpetrators. No radiological safety consequences are expected as a result of the vehicle theft.

Cause(s)—Although the licensee did not identify a definitive root cause for this event, the licensee (and NRC inspectors) determined that the most likely cause of the vehicle theft was human error in that the licensee radiographer may not have appropriately engaged the vehicle's security-related equipment for the evening when the vehicle was parked at the temporary job site location.

Actions Taken to Prevent Recurrence

Licensee—The licensee completed several corrective actions to prevent recurrence, including repair of the vehicle's security-related equipment, revised procedures for the use and testing of the vehicle's security-related equipment, and retraining of licensee personnel on the revised procedures. The licensee also conducted audits to ensure that the security-related equipment was operating and implemented procedures accordingly across its fleet of vehicles used to transport radiography equipment.

NRC—The NRC issued a Severity Level II violation with an associated $28,000 civil penalty to the licensee.

This event is closed for the purpose of this report.

AS23-02 Stolen Industrial Radiography Camera from Statewide Maintenance Company, Houston, Texas

Criterion I.C.1 of Appendix A to this report provides, in part, 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.

Date and Place—March 8, 2023, Houston, Texas

Nature and Probable Consequences—On March 8, 2023, Statewide Maintenance Company (the licensee) reported that a radiography exposure device, SPEC model 150 containing a 4.48 TBq (121 Ci) Ir-192 source, was stolen from the mobile darkroom of a company truck. This occurred just before midnight while the radiography crew was inside a fast-food restaurant. Initially, it was reported that the crew failed to set the darkroom alarm and left the key to the exposure device transport box in the vehicle. Upon returning to the vehicle, the exposure device was noted as missing, and the licensee's radiation safety officer was contacted. The licensee searched the area but did not locate the missing device. Local law enforcement and the Texas Department of State Health Services (DSHS) were informed of the situation and conducted a search on March 9, 2023, and several days thereafter. Further interviews with the licensee's responsible personnel revealed that the darkroom was not locked because the radiographer had lost the key, and additionally, the source storage box was left unsecured. The Houston Police Department Bomb Squad, Federal Bureau of Investigation, DSHS, and licensee continued to search over several weeks; however, they did not locate the device. Subsequently, on May 23, 2023, the DSHS received a call from a local apartment manager who located the missing device while cleaning a vacated apartment; the licensee was contacted and recovered the device. After recovery, the licensee stated that the source was still fully shielded and that dose rates were normal.

Cause(s)—The cause of the event was attributed to negligence of the personnel responsible for the radiography exposure device in not maintaining appropriate controls over the device.

Actions Taken to Prevent Recurrence

Licensee—The licensee's immediate corrective actions included temporarily suspending the qualifications of all personnel involved and completing repairs to the security-related equipment associated with the vehicle. Subsequently, the licensee required the personnel involved to complete additional new training activities and provided additional training to other employees.

State—The Texas DSHS conducted an onsite investigation with the assistance of the Federal Bureau of Investigation on March 15, 2023. The investigation confirmed that the radiographers had not locked the exposure device inside its transport container and failed to set the alarm for the darkroom door where the device was stored. Multiple violations were cited against the licensee and licensee personnel.

This event is closed for the purpose of this report.

AS23-03 Diverted Industrial Radiography Camera from Industrial Nuclear Company, San Leandro, California

Criterion I.C.1 of Appendix A to this report provides, in part, 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.

Date and Place—April 10, 2023, Doral, Florida

Nature and Probable Consequences—On September 27, 2022, Industrial Nuclear Company (INC, the licensee) shipped three industrial radiography devices each containing a 3.81 TBq (103 Ci) Ir-192 source via a secure common carrier from California to Doral, Florida, for export to an overseas customer. The shipment arrived safely at the Florida warehouse on September 28, 2022, at which time INC erroneously assumed that its responsibility for the security of the shipment ceased. INC believed that its responsibility for the shipment ceased because the overseas customer had hired an export broker who arranged the remaining travel of the shipment. The export broker then transferred the shipment to a freight forwarder, who ultimately transferred the devices to another common carrier (AIRSEATRANS) on October 7, 2022, for delivery to the Miami airport for air shipping to the INC overseas customer on October 9, 2022.

The shipment, however, was not delivered as scheduled because AIRSEATRANS held the shipment at the Miami airport as leverage to recover a debt that AIRSEATRANS believed it was owed by the freight forwarder. INC's overseas customer discovered that the shipment had been diverted in late 2022, but did not initially know where the shipment was being held. On April 10, 2023, INC discovered that the shipment was in AIRSEATRANS possession in the Miami area, and reported the situation to the NRC Operations Center. On that same day, the NRC staff facilitated INC's contact with the Florida Bureau of Radiation Control (BRC). The NRC informed the California Department of Public Health of this event on April 11, 2023.

Upon being notified by the licensee, the BRC immediately initiated an investigation to determine the location of the sources. On April 12, 2023, BRC personnel located the three industrial radiography devices still in the possession of AIRSEATRANS. After determining that the shipping drums containing the three industrial radiography cameras were safe to transport, BRC personnel took custody of the shipping drums and transported them to a BRC radioactive material secure storage location. INC personnel arrived in Florida on April 17, 2023, and arranged secure shipment of the recovered devices to the licensee's facility in LaPorte, Texas. The devices arrived at the licensee's Texas facility on April 18, 2023.

Cause(s)—The BRC's investigation determined that AIRSEATRANS removed the shipment from transit and took possession of the shipment on October 9, 2022, to leverage the shipment for back compensation from the freight forwarder. Additionally, the California Department of Public Health determined that this outcome would not have occurred had INC arranged for the shipment with a secure shipper for the entire domestic portion of the shipment while in transit as required by 10 CFR 37.73(e). In this case, the domestic portion of the shipment would have ceased when the export shipment entered the portion of the Miami airport property that is under

the jurisdiction of another Federal Government agency (e.g., the Federal Aviation Administration or the Department of Homeland Security).

Actions Taken to Prevent Recurrence

Licensee—The licensee modified its procedure for shipping of radiography sources to better reflect the wording of 10 CFR 37.73(e) and related NRC guidance and has trained its shipping personnel in this requirement and guidance.

State—The State of Florida determined that AIRSEATRANS violated Florida regulation 64E-5.201, possession of radioactive material without a license. Florida proposed a Severity Level I violation and fined AIRSEATRANS $185,000.

The State of California cited INC for violating the requirements of 10 CFR 37.73(e) and reminded other known California exporters of radioactive material in Category 1 or 2 quantities of the requirements of 10 CFR 37.73(e).

This event is closed 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, 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.”

AS23-04 Medical Event at Holston Valley Medical Center, Kingsport, Tennessee

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—November 14, 2022, Kingsport, Tennessee

Nature and Probable Consequences—On November 14, 2022, Holston Valley Medical Center (the licensee) reported an event during a cervical cancer treatment with a 327.45 GBq (8.85 Ci) Ir-192 source in an Elekta Model 136149A02 Flexitron-high dose rate (HDR) remote afterloader brachytherapy unit. The written directive prescribed five fractionated treatment doses of 6 Gy (600 rad), for a total of 30 Gy (3,000 rad) for the entire treatment. However, during the first treatment, the medical physicist misread the written directive and administered the total treatment dose of 30 Gy (3,000 rad) instead of the prescribed fractionated dose of 6 Gy (600 rad). The physician notified the patient and began to monitor the patient for adverse health effects. Following the monitoring period, no adverse effects were noted.

Cause(s)—The cause was human error. The licensee uses two treatment planning systems, a main high dose rate planning system and one used as a secondary check. The secondary system displays the total dose prescribed and not the fractionated dose. The medical physicist misread the treatment plan in the secondary system and ran a plan in the main system such that the total dose prescribed as shown in the secondary system was covering the target volume.

Actions Taken to Prevent Recurrence

Licensee—The licensee implemented a program in which one person performs the treatment planning and another person performs the verification plan. Both must then sign off before the treatment is implemented. Additionally, the licensee developed a generic table of expected treatment times based on dose and distance of treatment from the sources. Finally, the licensee contacted Elekta to request a periodic maintenance inspection of the treatment unit and to see if any software or firmware updates were available.

State—The State of Tennessee followed up with the licensee after receipt of the post-event report. Additionally, Tennessee maintained contact with the licensee to verify that no adverse effects to the patient were being reported. Finally, the State reviewed the licensee's corrective actions for this event and found them acceptable. The success of these actions will be reviewed and verified through routine inspections of the licensee.

This event is closed for the purpose of this report.

AS23-05 Medical Event at University of Texas Health Science Center, San Antonio, 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 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—February 13, 2023, San Antonio, Texas

Nature and Probable Consequences—On February 13, 2023, University of Texas Health Science Center (the licensee) reported that a patient received an yttrium (Y)-90 microsphere (Sirtex Medical model SIR-Spheres) treatment to the wrong lobe of the liver. The written directive prescribed an activity of 1.32 GBq (35.74 mCi) to the right lobe of the liver for a dose of 57.57 Gy (5,757 rad). This activity was mistakenly administered to the left lobe of the liver, which resulted in a dose of 106.82 Gy (10,682 rad) due to a smaller tumor volume. The patient was scheduled to receive a dose to the left liver lobe 2 weeks following this administration. Taking this into consideration, the physician and radiologist have concurred that there will be no probable consequences or complications for the patient.

Cause(s)—The medical physicist incorrectly administered the treatment to the wrong lobe of the liver due to human error and a lack of controls before and during the treatment.

Actions Taken to Prevent Recurrence

Licensee—The licensee implemented a new microsphere treatment procedure and provided additional training to personnel. Changes include steps requiring the nuclear medical technologist to read out the lobe written on the directive before administration and the physician to review the directive an additional time before beginning the treatment.

State—The Texas DSHS conducted an inspection to assess the licensee's corrective actions and circumstances of the event. The State verified that the licensee had completed procedural changes and conducted training for all staff. Following the inspection, no violations were cited.

This event is closed for the purpose of this report.

AS23-06 Medical Event at Methodist University Hospital, Memphis, Tennessee

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—February 27, 2023, Memphis, Tennessee

Nature and Probable Consequences—On February 27, 2023, Methodist University Hospital (licensee) reported that during a Y-90 microsphere (MDS Nordion model TheraSphere) treatment, a patient received a dose that was more than 50 percent greater than prescribed. The patient was prescribed two different Y-90 microsphere administrations of 79.95 Gy (7,995 rad) and 474.7 Gy (47,470 rad) to separate liver segments. These administrations were to use activities of 0.8 GBq (21.62 mCi) and 1.93 GBq (52.16 mCi), respectively. When the physician asked for the first treatment dose, they were given the second treatment dose. The physician then verbally read out the dose before administration, connected the radiopharmaceutical, and administered the treatment. Following the completion of the treatment, the physician identified the error and notified the patient of the event. No adverse health effects are expected for the patient because both segments were scheduled to receive treatment.

Cause(s)—The licensee determined that the cause of the event was human error and the lack of procedural checks during the administration process. There was a miscommunication between the physician and the treatment team during the administration process. Even though the dose measurement was read out, neither the physician nor members of the treatment team verbalized which dose was required or had been brought to the table for administration (smaller versus larger).

Actions Taken to Prevent Recurrence

Licensee—The licensee implemented a new education program and updated its procedures before administering a dose. The education program focused on radiation dosing and included event background. A call-back procedure was implemented to be performed before the dose is connected. The call-back procedure requires the sender to provide the order information, the receiver to repeat the order information, and sender to verify before the treatment can be administered.

State—The Tennessee Division of Radiological Health reviewed the licensee's report of the event and its proposed corrective actions and found them both acceptable.

This event is closed for the purpose of this report.

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 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 15, 2023, Baptist Health Medical Center (the licensee) reported that a patient was mistakenly administered an I-131 dosage instead of the intended I-123 radiopharmaceutical. The patient originally arrived for a radioactive iodine thyroid scan using I-123; however, the patient had been scheduled in the electronic medical record system for a total body iodine scan using Thyrogen (a thyroid-stimulating medication). The first dose of Thyrogen was administered on March 13, 2023, and when the patient returned the following day for the second administration, the technologist realized the patient still had their thyroid, and thus had mistakenly received Thyrogen. The technologist contacted the radiologist to inquire how long the patient needed to be off Thyrogen before receiving an I-123 scan. The radiologist instructed the technologist to call the radiopharmacy and ordering provider for clarification. The ordering provider instructed the technologist to continue with the study. On March 15, 2023, the patient returned and was administered 162.8 megabecquerels (MBq) (4.4 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. Because no study of uptake to the thyroid was performed, the health physicist estimated that the patient received a dose of 150 Gy (15,000 rad) to the thyroid. In its follow-up with the licensee, the State of Arkansas reported that the patient's blood test results conducted 6 weeks after the I-131 administration were normal, and no further follow-up 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 of the confusion of the medical records incorrectly stating 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 isotope.

Actions Taken to Prevent Recurrence

Licensee—The licensee created a new form for nuclear medicine technologists to complete, which requires the inclusion of all pathology, surgical reports, and thyroid labs. Additionally, new procedures were implemented that prevent radiologists from signing a written directive without all required reports present, including a valid current procedural terminology code and description of the procedure.

State—The State conducted teleconferences with the licensee and reviewed the licensee's written report for the event, including causal information and planned corrective actions. Based on the information provided, a prompt onsite inspection was determined not to be necessary.

The State will conduct a periodic inspection at the licensee’s facility in early 2024, in which the corrective actions for this event will be evaluated.

This event is open for the purpose of this report.

AS23-08 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 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—June 29, 2023, Unspecified City, New York

Nature and Probable Consequences—On June 29, 2023, the licensee reported that a dose was delivered to the wrong segments of the patient's liver during microsphere (MDS Nordion model TheraSphere) treatment. Posttherapy imaging revealed that some of the activity had been taken up by different segments of the patient's liver. Upon further review, the licensee determined that the administration was performed correctly; however, some activity still transferred due to the complex hepatic artery flow dynamics of the liver. This incident resulted in a dose of 63 Gy (6,300 rad) to unintended segments within the liver. At this time, no consequences are expected for the patient.

Cause(s)—The licensee has indicated that the procedure was administered correctly; however, because of the vascular nature of the liver, there is inherent risk of transport out of the treatment zone.

Actions Taken to Prevent Recurrence

Licensee—The licensee has indicated that the procedure was performed correctly, but the treatment was delivered to adjacent segments of the liver, an accepted risk of the procedure. As such, no actions to prevent recurrence can be taken.

State—The New York State Department of Health has no future plans for this event.

This event is closed for the purpose 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.

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 an HDR intravascular brachytherapy treatment was delivered to the wrong treatment site. The patient was prescribed a dose of 23 Gy (2,300 rad) using a 3.62 GBq (97.84 mCi) strontium-90 source. During treatment, the interventional cardiologist used fluoroscopy to determine that the source had correctly arrived at the treatment site. However, upon further review of the fluoroscopy images, the interventional cardiologist reported that the location of the source could not accurately be assessed. The prescribing physician then determined that the source 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 is expected as a result of this treatment.

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

Actions Taken to Prevent Recurrence

Licensee—The licensee provided additional training to staff involved in these treatments and modified the procedure to better identify source location.

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. On October 20, 2023, the NRC finalized an agreement for a medical physics consultant to provide an independent assessment of the event including an independent estimate of dose to the exposed individual.

This event is open for the purpose of this report.

AS23-09 Medical Event at Ohio State University Medical Center, Columbus, Ohio

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 28, 2023, Columbus, Ohio

Nature and Probable Consequences—On July 28, 2023, the Ohio State University Medical Center (the licensee) reported that a Y-90 microsphere (MDS Nordion model TheraSphere) treatment was delivered to the wrong lobe of the liver. The patient was prescribed an activity of 3.07 GBq (83 mCi) to the right lobe of the liver for a dose of 130 Gy (13,000 rad). Imaging of the patient following the administration of the treatment revealed that the activity had been delivered to the left lobe of the liver. Treatment had been planned for the left lobe of the liver, but not under this written directive. The physician notified the patient of the event. Because future treatment was already planned, no health effects are expected as a result of this procedure.

Causes—The root cause of the event is human error. On July 11, 2023, a planning study was conducted using technetium (Tc)-99m Macroaggregated Albumin (Tc-99m MAA). The Tc-99m MAA predominantly localized to the right hepatic lobe, but the study also noted that Tc-99m MAA was distributed to segment 4 of the left lobe via the right hepatic artery. Based on the planning study, the licensee believed the microspheres would be predominantly distributed to the right lobe of the liver. The licensee followed its treatment protocols, including a time-out before the procedure to verify the patient identity, dose, and treatment location, as well as verifying catheter placement. However, it was discovered after the procedure that the primary distribution was to segment 4 of the left lobe.

Actions Taken to Prevent Recurrence

Licensee—The licensee has directed nuclear medicine to contact interventional radiology and radiation oncology if images indicate any activity in an unintended area. The licensee has also directed the authorized users to consider all distribution pathways discovered during the planning study.

State—The Ohio Department of Health's Bureau of Environmental Health and Radiation Protection conducted a reactive inspection to determine the root cause of the event and if any violations of the administrative code had occurred. The inspection verified that the licensee followed its established protocols and did not identify any noncompliance with State regulations. Also, the State determined that the corrective actions implemented by the licensee were acceptable.

This event is closed for the purpose of this report.

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.

[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 on Intake (ALIs) and Derived Air

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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 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.

[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.

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.

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."

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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.

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.

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).

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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 by the agency or other proper authorities.

8 “Formula quantity” of special nuclear material is defined in 10 CFR 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,” 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).

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).

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.

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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.

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]

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

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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.

(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

(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 one abnormal occurrence (AO) event that the U.S. Nuclear Regulatory Commission reported in NUREG-0090, Volume 45, "Report to Congress on Abnormal Occurrences: Fiscal Year 2022," issued June 2023. This AO involved a medical event at the Comprehensive Cancer Centers of Nevada—Sunset in Las Vegas, Nevada.

AS22-03 Medical Event at Comprehensive Cancer Centers of Nevada, Sunset, Las Vegas, Nevada

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—April 5, 2022, Las Vegas, Nevada

Background—Comprehensive Cancer Centers of Nevada—Sunset (the licensee) reported a medical event in which a patient exceeded their prescribed dose. The incident involved a high dose rate (HDR) remote afterloader and a 333 GBq (9 Ci) Iridium-192 source. The patient was prescribed 10 HDR treatments to breast tissue; however, following four treatments, the licensee discovered that some source catheters had been incorrectly labeled. While this altered the dose distribution and resulted in a higher skin dose than anticipated, the target dose difference did not exceed 50 percent more than the prescription after the licensee replanned the remainder of the patient's treatment to compensate for the erroneous treatments. Initially planned exposure for skin was 26.5 Gy (2,650 rad), and after the adjusted treatments were completed, the resultant dose to the skin was 48.4 Gy (4,840 rad). The licensee determined that no probable consequences were expected from this additional 21.9 Gy (2,190 rad) exposure to the patient's skin.

Update on Actions Taken to Prevent Recurrence

State—The State performed a full inspection of the licensee on March 2, 2023, during which the AO event was discussed. Upon completion of the inspection and discussions of the event, the State issued no violations to the licensee.

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.

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).

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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 website (see https://www.cancer.gov/about-cancer).

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[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.

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

Medical event—as defined in 10 CFR 35.2, an event that meets the criteria in 10 CFR 35.3045(a) or (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

2. *Id.*

3. *Id.*

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 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

4. *Id.*

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."

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
	terabecquerel (TBq)	Ci	0.037
Absorbed dose	gray (Gy)	rad	0.01
Dose equivalent	sievert (Sv)	rem	0.01
	millisievert (mSv)	rem	10
	mSv	millirem (mrem)	0.01