Report to Congress on Abnormal Occurrences

Fiscal Year 2021

United States Nuclear Regulatory Commission
Washington, DC 20555-0001

Enclosure 1

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 six events in Agreement States and two events involving NRC licensees that were identified as AOs during fiscal year 2021. 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). Six AOs were medical events as defined in Title 10 of the Code of Federal Regulations Part 35, "Medical Use of Byproduct Material." There was one event at a medical facility and one event at the National Institute of Standards and Technology (NIST) Center for Neutron Research (NCNR) that involved serious safety significant deficiencies in management or procedural controls. There were no events at a commercial nuclear power plant that met the criteria for AOs.

Appendix A, "Abnormal Occurrence Criteria," to this report presents the NRC's criteria for identifying AOs. In addition, the NRC identified no events during fiscal year 2021 that meet the guidelines for inclusion in Appendix B, "Other Events of Interest." No 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 events identified as AOs in fiscal year (FY) 2021, 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 identified no events during FY 2021 that met the guidelines for inclusion in Appendix B, "Other Events of Interest." During this reporting period, no 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 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 2021 report.

Reviews of and responses to operating experience are essential to ensure that licensees conduct their activities safely. To that end, 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 significant events, including AOs, should they occur.

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

The NRC offers information about events that do not meet the criteria for AOs but are of interest based on the criteria in Appendix B to this report. The NRC identified no other events of interest that occurred during FY 2021.

UPDATES ON PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

Appendix C typically includes updates on previously reported AOs that remain open during the FY addressed in the report or for which significant new information becomes available. However, there are no such updates for this reporting period.

ABBREVIATIONS

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
AO	abnormal occurrence
CCDP	conditional core damage probability
ΔCDP	change in core damage probability
CDPH	California Department of Public Health
CFR	*Code of Federal Regulations*
Ci	curie(s)
CT	computerized tomography
FR	*Federal Register*
FY	fiscal year
GBq	gigabecquerel(s)
Gy	gray(s)
I	iodine
KI	potassium iodide
MBq	megabecquerel(s)
μCi	microcurie(s)
mCi	millicurie(s)
MD	management directive
mSv	millisievert(s)
NIST	National Institute of Standards and Technology
NCNR	NIST Center for Neutron Research
NRC	U.S. Nuclear Regulatory Commission
Sv	sievert(s)
TEDE	total effective dose equivalent
Y	yttrium

ABNORMAL OCCURRENCES IN FISCAL YEAR 2021

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 which met the AO criteria. The identification numbers for the events, which were all reported by Agreement States, start with "AS." Similarly, the identification numbers for all U.S. Nuclear Regulatory Commission (NRC) licensee AO reports start with "NRC."

I. ALL LICENSEES

During this reporting period, no event was identified as an AO based on the criteria under Category I, "All Licensees," in Appendix A.

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, eight 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."

AS21-01 Medical Event at Stanford University, Stanford, California

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 gray (Gy) (1,000 rad), the expected dose to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) from the administration defined in the written directive, and involves a dose or dosage that is at least 50 percent greater than that prescribed.

Date and Place—October 16, 2020, Stanford, CA

Nature and Probable Consequences—On October 16, 2020, Stanford University (the licensee) reported that during an yttrium (Y)-90 microsphere treatment, a patient received a dose that was more than 50 percent greater than that prescribed. The patient had been prescribed 7 Gy (700 rad) to the left lobe of the liver and 17.5 Gy (1,750 rad) to the right lobe of the liver. The patient's left lobe was treated first and mistakenly received the higher dosage intended for the right lobe (1,168 megabecquerels (MBq) (31.57 millicuries (mCi))), resulting in a dose of

17.5 Gy (1,750 rad) to the left lobe of the liver (2.5 times the intended dose). The physician identified his mistake when he went to administer the dosage to the right lobe and realized the prepared dosage was less than he had already administered to the left lobe. After the physician identified the mistake, the correct dosage was administered to the right lobe. The patient and referring physician were notified.

The licensee reported that it did not anticipate any significant adverse impact to the patient from this event.

Cause(s)—The error occurred for two reasons. First, the technician had labeled the containers with the two dosages incorrectly, switching the liver lobes. All other labeling information was correct. Second, the physician administering the dosage failed to verify that the dosage on the container's label matched the dosage prescribed in the written directive for the left lobe.

Actions Taken to Prevent Recurrence

Licensee—The licensee changed its procedures to require a pause after delivery of the dosage to the treatment room, during which all information related to the delivered dosage must be verified to match the written directive prescribing treatment. It also removed the reference to the target organ on the label, to force the comparison of the dosage with the dosage prescribed in the written directive. Additionally, the licensee incorporated a timeout into the procedure to allow the authorized user and health physicist to verify that each dose is identical to that of the written directive. After the timeout, the procedure has the authorized user sign the written directive before administration of the dose(s).

State—The California Department of Public Health (CDPH) reviewed the event and the licensee's proposed corrective actions with licensee personnel, and took enforcement action for the failures that led to the event. The effectiveness of the licensee's corrective actions will be reviewed in future inspections.

This event is closed for the purpose of this report.

NRC21-01 Medical Event at Avera McKennan Nuclear Medicine, Sioux Falls, South Dakota

Criteria III.C.1(b) and III.C.2(b)(i) 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 uses the wrong radiopharmaceutical or unsealed byproduct material.

Date and Place— December 15, 2020, Sioux Falls, SD

Nature and Probable Consequences—On December 23, 2020, Avera McKennan (licensee) notified the NRC of a medical event that had occurred on December 15, 2020. A physician had referred a patient to Avera McKennan for a thyroid scan and uptake (diagnostic) study. Such studies generally use approximately 7.4 MBq (0.2 mCi) of iodine (I)-123. While, the physician referred the patient for a diagnostic dose, the licensee's central scheduling system generated, after miscommunication with the licensee's nuclear medicine department on the diagnostic order, an erroneous written directive, which called for the administration of a therapeutic dose to the thyroid using 555 MBq (15 mCi) of I-131. The administered amount was 584.6 MBq (15.8 mCi) of I-131, which was sufficient to completely ablate the patient's thyroid gland. As such, it is anticipated that the patient will require thyroid hormone replacement therapy for the remainder of their life.

Cause(s)—A miscommunication between the centralized scheduling department and the nuclear medicine representative resulted in the authorized user preparing an erroneous written directive for a therapeutic dose of I-131 instead of the intended diagnostic dose of I-123. The authorized users that prepared and carried out the written directive did not review the patient's clinical situation, including the information from the patient's physician, to determine if the treatment option was appropriate for the patient's situation.

Actions Taken to Prevent Recurrence

Licensee—The licensee performed a detailed review of all I-131 administrations performed in the 6 months preceding the medical event to determine any similar occurrences. The licensee concluded that the event appeared to be isolated in nature. The licensee also revised written procedures to require that, before creating a written directive, the authorized user physically verify the prescribing physician's order for the treatment and also review the patient's electronic medical record, instead of simply relying on the electronic order sent from centralized scheduling to the nuclear medicine department. Finally, the licensee revised the procedure for ordering doses for therapeutic administrations to require an assigned nuclear medicine worker to collect information on the order. This assigned worker would then create a hard-copy folder containing this information and provide it to the authorized user, who would use it to verify that the written directive conforms to the original physician's order.

NRC—The NRC performed a reactive inspection from January 11, 2021, through August 3, 2021, to gather additional information on the event. The report from that inspection documented numerous deficiencies in the licensee's safety program with respect to the receipt, documentation, and transmission of physician requests for patient treatment requiring a written

directive. The inspector discussed his findings with the licensee during the inspection, which informed the licensee's corrective actions described above. The inspection did not identify any violations of NRC regulations.

This event is closed for the purpose of this report.

NRC21-02 National Institute of Standards and Technology, Gaithersburg, Maryland

Criteria III.A.2 and III.A.3 of Appendix A to this report provide, in part, that events at facilities other than nuclear power plants shall be considered for reporting as an AO if it involves:

- a major deficiency in design, construction, control, or operation having significant safety implications that require immediate remedial action, and
- a serious safety-significant deficiency in management or procedural controls.

Date and Place—February 3, 2021, Gaithersburg, MD

Nature and Probable Consequences—On February 3, 2021, the National Institute of Standards and Technology (NIST) Center for Neutron Research (NCNR) test reactor experienced an automatic scram in response to indications of high exhaust stack radiation levels, while operators were performing a startup after a 6-week outage for reactor refueling. Consequently, NIST (the licensee) declared an Alert in accordance with NIST emergency instructions and notified the NRC as required by its emergency plan. The reactor confinement building and control room were evacuated once the reactor was secured. NCNR personnel who were externally contaminated were decontaminated and cleared to go home that day. Monitoring of the contaminated personnel found no significant internal contamination. Later in the day, the licensee downgraded the event to a Notification of Unusual Event in accordance with its emergency instructions. NIST exited the event that evening when samples of effluent gases in the reactor stack met the criteria in the emergency instructions. All response procedures were followed and safety systems functioned as designed.

The NRC monitored the licensee's immediate response to the event to ensure that there was no threat to public health and safety. The NRC also began a special inspection on February 9, 2021, to examine the licensee's response. The licensee held a public meeting on February 10, 2021, with NRC participation, to inform the local community and officials about the event and the NRC's regulatory actions. NIST assessed the release of radioactive material to the environment, and the NRC independently analyzed the same information as part of its special inspection. Both concluded that during the event, potential radiation doses beyond NIST property would have been less than 0.01 millisievert (mSv) (1 millirem (mrem)), which is a very small fraction of the regulatory annual public dose limit of 1 mSv (100 mrem) (a limit roughly equivalent to several chest x-rays) established in 10 CFR 20.1301.

Based on remote visual inspection and radiation conditions in the facility, the licensee notified the NRC on March 2, 2021, that it had exceeded the fuel temperature safety limit in the NCNR technical specifications during the event, causing damage to a fuel element. The fuel element was not fully seated in its normal position and a small amount of melted fuel was deposited on the lower grid plate surfaces near the displaced fuel element nozzle. NIST submitted the written report to the NRC on March 5, 2021. On October 1, 2021, NIST submitted to the NRC a request to restart the NCNR test reactor following completion of corrective actions. NIST also submitted root cause and corrective actions reports to the NRC. In accordance with the requirements of 10 CFR 50.36, "Technical specifications," the licensee cannot resume operation until authorized by the NRC.

Cause(s)—The event occurred because a fuel element was not properly secured in its designated core position during refueling operations. Through interviews and observation of

video footage of the refueling and latch verification evolutions performed by NIST operators, the inspectors determined that a fuel element (S-1175) was not fully latched in the designated core position (J-7) at the end of refueling operations on January 4, 2021. As a result, during plant start-up and ascension to full power operations on February 3, 2021, the fuel element became unlatched out of position in the reactor core and did not receive sufficient coolant flow, resulting in partial melting of the fuel element. The inspectors identified an additional cause that NIST management failed to provide equipment, procedures, and training to support safe operations.

Actions Taken to Prevent Recurrence

Licensee—The licensee revised its procedures to strengthen the fuel latching and latch checks process, to strengthen the oversight role of supervisors, and to ensure that all personnel are trained. The licensee also identified planned actions to: 1) implement a remote display of reactor parameters, 2) implement a change management evaluation process, 3) establish an additional shift of licensed operators, 4) revise supervisor and operator qualifications, 5) enhance proficiency training of reactor operations personnel, and 6) implement design changes for the refueling test stand.

NRC—On March 16, 2022, the NRC issued a special inspection report that identified seven apparent violations of NRC requirements associated with the event. Corrective actions to prevent recurrence will be established during the NRC's enforcement process. The licensee is required to obtain NRC approval prior to restarting the reactor.

This event is open for the purpose of this report.

AS21-02 Columbia Hospital at Medical City Dallas, Dallas, Texas

Criteria III.A.3 of Appendix A to this report provides, in part, that an event shall be considered for reporting as an AO if it results in a serious safety significant deficiency in management or procedural controls.

Date and Place—April 14, 2021, Dallas, TX

Nature and Probable Consequences—On April 14, 2021, Columbia Hospital, doing business as Medical City Dallas, (the licensee) reported that a patient received the wrong radiopharmaceutical for a thyroid diagnostic procedure. The patient had been prescribed 7.4 MBq (200 microcuries (μCi)) of I-123, but instead received 5.55 gigabecquerels (GBq) (150 mCi) of I-131. The licensee discovered the error after the patient was allowed to leave the hospital but recalled the patient back to the hospital to receive potassium iodide (KI) treatment. KI is a thyroid blocking agent administered to either prevent or minimize the uptake of I-131 in the thyroid. The licensee consulted with the Radiation Emergency Assistance Center/Training Site at the Oak Ridge Institute for Science and Education and confirmed that its course of KI treatment was best for the circumstances. The patient stayed 4 days at the hospital and was discharged on April 18, 2021. The licensee followed radiation safety procedures for the administration of the I-131. The calculated dose to the patient's thyroid gland from the intended administration would have been 0.0237 Gy (2.37 rad). The final dose to the patient's thyroid gland is not known because of the interventional treatment with KI. However, calculations by State regulators using conservative assumptions indicate that the patient likely received a dose over 10 Gy (1,000 rad) above the originally intended dose, which is a significant dose beyond what the patient was originally intended to receive, resulting in that ablation of the patient's thyroid (an unintended, serious safety impact to the patient). The patient was placed on a thyroid hormone replacement regimen and is expected to remain on this regimen for the remainder of their life.

Cause(s)—The licensee identified the cause of the event as human error by the nuclear medicine technician preparing the dose. The technician reported to the licensee that the dose was measured in the calibrator, but the technician misread the dose units. The licensee evaluated to determine whether there had been other contributing factors such as inadequate training or barrier design but could not identify any additional contributing factors. The licensee did, however, identify opportunities for procedural enhancements.

Actions Taken to Prevent Recurrence

Licensee—The licensee completed a safety event analysis with members from Patient Safety, Nuclear Medicine, Radiology, and Risk Management, and identified areas in which to strengthen its procedures. The licensee revised all iodine procedures to require verification by two technicians before administration. The licensee also modified the iodine treatment checklist to improve its clarity.

State—The Texas Department of State Health Services, Radiation Control Program did not pursue enforcement action against the licensee but referred the incident to the State medical board for review.

This event is closed for the purpose of this report.

AS21-03 Medical Event at The Ohio State University, 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—May 10, 2021, Columbus, OH

Nature and Probable Consequences—On May 11, 2021, The Ohio State University (the licensee) reported that during a Y-90 TheraSphere treatment, a patient received a dose to the wrong treatment site. The patient was prescribed to receive 2.55 GBq (68.92mCi) to the left lobe of the liver for a dose of 130 Gy (13,000 rad). The catheter placement was verified by angiography and fluoroscopy before treatment, and the catheter had been locked in place to prevent movement. However, it was discovered during posttreatment imaging that the patient received 2.47 GBq (66.76 mCi) to the right lobe of the liver for a dose of 127 Gy (12,700 rad). The licensee believed that the catheter had "kicked out" during treatment. The patient and referring physician were notified of the incorrect dosage to the wrong treatment site. The patient had previously received Y-90 microsphere treatment to the right lobe of the liver and is not expected to experience adverse health effects.

Cause(s)—The licensee investigated the event, and although it believed that the catheter had "kicked out" during treatment, the cause of the event could not be determined. The licensee verified that all steps in the Y-90 administration procedure were followed, including the verification of the catheter position prior to treatment.

Actions Taken to Prevent Recurrence

Licensee—The licensee's corrective action was to modify the Y-90 administration procedure. Prior to this event, the licensee's procedure required catheter placement imaging prior to the vascular patency test. The licensee changed their procedure so that the vascular patency test would be conducted before verifying catheter position.

State—The Ohio Department of Health conducted an investigation on June 3, 2021, but identified no definite cause for the incident. It found that the licensee followed all applicable regulations and internal procedures. As such, no enforcement actions were taken.

This event is closed for the purpose of this report.

AS21-04 Medical Event at Kell West Regional Hospital, Wichita Falls, 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—May 10, 2021, Wichita Falls, TX

Nature and Probable Consequences—On May 12, 2021, Kell West Regional Hospital (the licensee) reported that during a cesium (Cs)-131 prostate seed implant treatment procedure, a patient received a dose to the wrong treatment site. A post-procedure computerized tomography (CT) scan indicated that 63 of the 78 Cs-131 seeds were implanted below the prostate, and the remaining 15 were in the prostate treatment site. The written directive prescribed an activity of 7.34 GBq (198.38 mCi) to the prostate, but the patient received only 1.41 GBq (38.11 mCi). The perineal region below the prostate received a dose of 115 Gy (11,500 rad) and the patient and prescribing physician were notified. The patient did not experience any acute symptoms and was scheduled for long-term follow-up to track their prognosis and any complications.

Causes—The cause of the event was that the ultrasound probe used to guide the seed implantation was not positioned correctly at the prostate gland.

Actions Taken to Prevent Recurrence

Licensee—The licensee revised its procedures to require the establishment of a frame of reference to identify the base and apex of the prostate on the axial and sagittal planes. The licensee also revised implant procedures to include a timeout to verify the location of the prostate and bladder. The licensee implemented a retraining program for the prostate seed program, including, but not limited to, retraining and proctoring by a qualified radiation oncology physician and physicist.

State—The Texas Department of State Health Services, Radiation Control Program, tracked the event and remained in contact with the licensee's medical physics team during evaluation of the event, and determined an onsite inspection was not necessary and that the licensee took all appropriate actions immediately upon discovery of the event.

This event is closed for the purpose of this report.

AS21-05 Medical Event at University of California, Irvine, Medical Center, Orange, California

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 15, 2021, Orange, CA

Nature and Probable Consequences—On June 15, 2021, the University of California, Irvine, Medical Center (the licensee) reported a medical event that involved a patient treated for liver metastases with Y-90 microspheres. The treatment plan prescribed between 0.29 and 0.83 GBq (7.84 and 22.43 mCi) to the left lobe of the liver. The treatment plan specified that the microcatheter be placed in the left hepatic artery near to the branching point with the right artery to ensure that some of the Y-90 microspheres are infused into a small side branch off the left artery. During the treatment, it was discovered that the microcatheter had moved and the right liver lobe received an unintended dose of approximately 20 Gy (2,000 rad). The right lobe had been treated separately with Y-90 microspheres 2 weeks earlier. The patient and prescribing physician were notified. The patient is not expected to experience adverse health effects.

Cause(s)—The licensee determined that the cause was a movement of the microcatheter during the administration due to patient respiration and vascular pulsation.

Actions Taken to Prevent Recurrence

Licensee—The licensee concluded that the movement of the microcatheter had been unavoidable, since it had been necessary to place the microcatheter near the arterial branching point for the two lobes of the liver, but that the movement could have been discovered earlier, which would have reduced the unintended dose to the right lobe. In future cases where patient physiological functions may cause the microcatheter to move, more attention will be directed to detecting such movement. The licensee held a meeting of oncology staff to emphasize the need for such increased attention.

State—The CDPH reviewed the event and the licensee's proposed corrective actions with licensee personnel. Future inspections are planned to verify the effectiveness of the licensee's corrective actions.

This event is closed for the purpose of this report.

AS21-06 Medical Event at Moses Cone Health System, Greensboro, North Carolina

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 26, 2021, Greensboro, NC

Nature and Probable Consequences—On July 26, 2021, Moses Cone Health System (the licensee) reported that during a prostate seed implant treatment, a patient received a dose to the wrong treatment site. The treatment plan was to insert 54 I-125 seeds into the prostate, for a total activity of 1.013 GBq (27.38 mCi), achieving a prescribed dose of 145 Gy (14,500 rad) to the prostate. On August 18, 2021, a follow-up CT scan showed that all 54 I-125 seeds had inadvertently been implanted into the penile bulb. A dose to the penile bulb of approximately 145 Gy (14,500 rad) was received where no dose was intended. The patient and prescribing physician were notified, and the clinical impacts to the patient included severe rectal and perineal pain, the inability to sit upright, and confinement to a bed. The patient received a nerve block for pain from the implantation procedure and all the patient's clinical impacts have been resolved.

Cause(s)—The cause of the event was determined to be human error. After interviews with the medical physicist and radiation safety officer, the inspector ruled out the possibility of a malfunction of the ultrasound unit. The medical physicist's retrospective review indicated that if the catheter was not clearly visible on the ultrasound images, then this could have caused seed implantation in a location other than the prostate.

Actions Taken to Prevent Recurrence

Licensee—The licensee's corrective actions include the addition of a step to the prostate brachytherapy protocol to ensure that personnel clearly identify the prostate gland and the surrounding anatomy.

State—The North Carolina Department of Health and Human Services performed an inspection on August 18, 2021. The investigation found no violations.

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.

I. All Licensees[2]

A. Human Exposure to Radiation from Licensed Material

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

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 Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage,” to 10 CFR Part 20, “Standards for protection against radiation,” unless the licensee has demonstrated compliance with § 20.1301, “Dose limits for individual members of the public,” using § 20.1302(b)(1) or § 20.1302(b)(2)(ii). This criterion does not apply to transportation events.

[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 § 39.2, "Definitions." These sources are only excluded if there is reasonable assurance that the doses from these sources have not exceeded, and will not exceed, the reporting thresholds specified in AO Criteria I.A.1 and I.A.2, and the agency has determined that the risk of theft or diversion is acceptably low.

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

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 § 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 on the part of the agency or other proper authorities.

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

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

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

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

II. Commercial Nuclear Power Plant Licensees

A. Malfunction of Facility, Structures, or Equipment

1. Exceeding a safety limit of a license technical specification (§ 50.36(c)).

2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials that could result in exceeding the dose limits of 10 CFR Part 100, “Reactor site criteria,” or five times the dose limits of General Design Criteria (GDC) 19, “Control Room,” in Appendix A, “General Design Criteria for Nuclear Power Plants,” to 10 CFR Part 50, “Domestic licensing of production and utilization facilities,” could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

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 technical specification that requires immediate remedial action.

2. Personnel error or procedural deficiencies that result in the loss of plant capability to perform essential safety functions such that a release of radioactive materials exceeding the dose limits of 10 CFR Part 100 or five times the dose limits of GDC 19 in Appendix A to 10 CFR Part 50, could

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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” (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13175A294), or initiation of any accident review groups, as described in MD 8.9, “Accident Investigation” (ADAMS Accession No. ML13319A133).

occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod drive mechanism).

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

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

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

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.

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[11] The NRC ROP uses four colors to describe the safety significance of licensee performance. As defined in NRC MD 8.13, "Reactor Oversight Process" (ADAMS Accession No. ML17347B670), green is used for very low safety significance, white is used for low to moderate safety significance, yellow is used for substantial safety significance, and red is used for high safety significance. Reactor conditions or performance indicators evaluated to be red are considered AOs.

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

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

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 § 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 § 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:

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

[15] High-consequence events for facilities licensed under 10 CFR Part 70, "Domestic licensing of special nuclear material," are those that could seriously harm the worker or a member of the public in accordance with § 70.61, "Performance requirements." The integrated safety analysis conducted and maintained by the licensee or applicant of 10 CFR Part 70 fuel cycle facilities identifies such hazards and the safety controls (§ 70.62(c)) applied to meet the performance requirements in accordance with § 70.61(b) through (d).

Fuel cycle facilities licensed under 10 CFR Part 40, "Domestic licensing of source material," or certified under 10 CFR Part 76, "Certification of gaseous diffusion plants," have licensing basis documents that describe facility specific hazards, consequences, and those controls used to prevent or mitigate the consequences of such accidents. For these facilities, a high-consequence event would be a release that has the potential to cause acute radiological or chemical exposures to a worker or a member of the public similar to that defined in Appendix A to Chapter 3, Section A.2, of NUREG 1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications—Final Report," issued June 2015, under "Consequence Category 3 (High Consequences)" (ADAMS Accession No. ML15176A258).

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

(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.

During this reporting period, there were no other events of interest.

APPENDIX C
UPDATES ON PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During this reporting period, there were no updates on previously reported abnormal occurrences.

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 seed implantation for prostate cancer[1]—a form of radiation therapy for prostate cancer. The radioactive seeds are loaded into the designated number of needles in a specific order, and each needle is inserted through the skin in the perineum and into the prostate, using continuous ultrasound guidance. Once accurate needle placement is confirmed, the seeds in that needle are released. This process is continued until all of the radioactive seeds have been implanted.

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, the external whole-body exposure dose equivalent at a tissue depth of 1 centimeter (1,000 milligrams per square centimeter).

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

Dose equivalent (H_T)—as defined in 10 CFR 20.1003, the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest; the units of dose equivalent are the rem and sievert (Sv).

Effective dose equivalent (H_E)—as defined in 10 CFR 20.1003, the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated.

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

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

Fluoroscopy[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.

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2. *Id.*

3. *Id.*

(ii) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following: (A) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure; (B) An administration of a radioactive drug containing byproduct material by the wrong route of administration; (C) An administration of a dose or dosage to the wrong individual or human research subject; (D) An administration of a dose or dosage delivered by the wrong mode of treatment; or (E) A leaking sealed source.

(iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by (A) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and (B) 50 percent or more the expected 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 rems).

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.

4. *Id.*

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.

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.

Vascular patency[5]**—**the degree to which blood vessels are not blocked or obstructed.

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."

5. This definition is based upon the National Library of Medicine's controlled vocabulary thesaurus (see https://www.ncbi.nlm.nih.gov/mesh/?term=vascular+patency).

APPENDIX E
CONVERSION TABLE

Radioactivity and Dose

QUANTITY	FROM METRIC UNITS	TO NON-INTERNATIONAL 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