Report to Congress on Abnormal Occurrences

Fiscal Year 2022

United States 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 eight events in Agreement States and one event involving an NRC licensee that were identified as AOs during fiscal year 2022. 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." The other two events involved non-medical overexposures. No events at a commercial nuclear power plant met the criteria for AOs.

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 2022 that met the guidelines for inclusion in Appendix B, "Other Events of Interest." One event met the guidelines for inclusion in Appendix C, "Updates on Previously Reported Abnormal Occurrences." Appendix D, "Glossary," defines terms used throughout this report. Appendix E, "Conversion Table," presents conversions commonly used when calculating doses.

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EXECUTIVE SUMMARY

INTRODUCTION

Section 208 of the Energy Reorganization Act of 1974, as amended (Public Law 93-438), defines an abnormal occurrence (AO) as an unscheduled incident or event that the U.S. Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66) changed the AO reporting frequency from quarterly to annual.

This report describes nine events identified as AOs in fiscal year (FY) 2022, 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 2022 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 oversight authority primarily ~~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 2022 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 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

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 2022.

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

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
~~AMC~~	~~Aurora Medical Center of Oshkosh~~
AO	abnormal occurrence
AU	authorized user
CCDP	conditional core damage probability
ΔCDP	change in core damage probability
CFR	*Code of Federal Regulations*
Ci	curie(s)
CT	computed tomography
FR	*Federal Register*
FY	fiscal year
GBq	gigabecquerel(s)
Gy	gray(s)
HDR	high dose rate
IMC	inspection manual chapter
MBq	megabecquerel(s)
mCi	millicurie(s)
MD	management directive
MDH	Minnesota Department of Health
mrem	millirem(s)
mSv	millisievert(s)
NCNR	NIST Center for Neutron Research
NIST	National Institute of Standards and Technology
NRC	U.S. Nuclear Regulatory Commission
ROP	Reactor Oversight Process
Sv	sievert(s)
TEDE	total effective dose equivalent
TS	technical specification
Y	yttrium

ABNORMAL OCCURRENCES IN FISCAL YEAR 2022

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.

NRC22-01 Overexposure at Cabell Huntington Hospital, Huntington, West Virginia

Criteria I.A.1(f) of Appendix A to this report provides, in part, that any unintended exposure to radiation from licensed material to an adult (any individual 18 years of age or older) shall be reported as an AO if it results in an annual shallow dose equivalent to the skin or extremities of 2,500 millisieverts (mSv) (250 rem) or more.

Date and Place—January 1, 2019 – December 31, 2021, Huntington, WV

Nature and Probable Consequences—During a reactive inspection at Cabell Huntington Hospital (licensee), the NRC reviewed the facts and circumstances surrounding the report submitted by the licensee to the NRC of a dose exceeding the occupational extremity dose limit. The individual who received the overexposure was an authorized user (AU) of yttrium (Y)-90 microspheres. During this inspection, the NRC determined that the magnitude of the overexposure was likely much higher than the dose of 1,220 mSv (122 rem) originally reported to the NRC. After a retrospective dose evaluation, the licensee estimated that the extremity doses for the AU were 4,755 mSv (475.5 rem) in 2021, 5,609 mSv (560.9 rem) in 2020, and 5,713 mSv (571.3 rem) in 2019. A very large majority of the dose is likely attributed to x-ray radiation emitted from machine sources for computed tomography (CT) and fluoroscopy procedures not licensed by the NRC. However, the AU also performed ~~9, 21, and 9~~ Y-90 procedures licensed by the NRC (9 in 2021, 21 in 2020, and 9 in 2019) that contributed to the overexposures ~~in 2021, 2020, and 2019, respectively~~.

Cause(s)—The NRC attributed the primary cause of the event to a programmatic breakdown of the licensee's radiation protection program due to a lack of resources and adequate management oversight.

Actions Taken to Prevent Recurrence

Licensee—As corrective actions, the licensee (1) developed a centralized radiation safety policy to include instructions on the use of dosimetry and compliance with the occupational monitoring program, (2) developed an electronic training module that provides training on the proper use of dosimetry, (3) did not permit the AU who exceeded dose limits in 2021 to continue working with licensed material, and (4) restructured the Radiation Safety Committee such that it is now a single committee with oversight over all locations of use.

NRC—Between May 10, 2021, and April 27, 2022, the NRC performed a series of onsite inspections and in-office reviews in response to this event. In addition to the inspections, the NRC Office of Investigations ~~conducted an investigation to assess~~investigated any potential wrongdoing associated with this event. As a result of the inspections and investigation, the NRC identified 14 violations and issued a confirmatory order to the licensee on November 10, 2022. The violations that involved occupational exposure limits exceedance include exposures from both NRC-licensed and non-licensed sources of radiation.

This event is closed for the purpose of this report.

AS22-01 Overexposure at Northwest Community Hospital, Arlington Heights, Illinois

Criteria I.A.2 of Appendix A to this report provides, in part, that any unintended radiation exposure to any minor (an individual less than 18 years of age) shall be reported as an AO if it results in an annual total effective dose equivalent ~~to a minor~~ of 50 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—March 2, 2022, Arlington Heights, IL

Nature and Probable Consequences—On March 2, 2022, Northwest Community Hospital (the licensee) reported that a patient, not known to be pregnant at the time of the administration, received 3.7 gigabecquerels (GBq) (100 millicuries (mCi)) of iodine-131. A pregnancy test was performed in advance of the administration and the results were negative (i.e., that the patient was not pregnant). However, on April 13, 2022, the Radiation Safety Officer received a notification that the patient was determined to be 7 days pregnant when the administration occurred. The licensee estimated the dose to the embryo/fetus through 12 weeks of development ~~at~~ was 266 mSv (26.6 rem). The patient's neonatal specialist determined that there ~~is~~ would be no expected risk of fetal death or anatomical malformation due to this administration. The licensee did not ~~notified~~ notify the Illinois Emergency Management Agency of the event ~~on~~ until May 31, 2022, and submitted a written report on June 12, 2022.

Cause(s)—The licensee's pregnancy testing policy did not account for very early stage (i.e., first week of gestation) pregnancies that standard pregnancy tests cannot detect.

Actions Taken to Prevent Recurrence

Licensee—The licensee revised its pregnancy testing policy to include patient instruction to abstain from sexual intercourse for at least 10 days before administration of iodine-131.

State—The Illinois Emergency Management Agency performed a reactive inspection on June 2, 2022. The State's staff determined that the licensee's corrective actions regarding the updated pregnancy testing policy and patient instruction were adequate. However, the licensee was cited for failing to comply with the reporting and notification requirements for an event of this nature, where the licensee must report the event no later than the next calendar day after discovery and submit a written report within 15 days after discovery. Corrective actions to prevent the recurrence of late incident reporting will be pursued through the enforcement process.

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."

AS22-02 Medical Event at Aurora Medical Center of Oshkosh, Oshkosh, Wisconsin

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—November 19, 2021, Oshkosh, WI

Nature and Probable Consequences—Aurora Medical Center of Oshkosh (licensee) reported that a patient received a dose in excess of the treatment plan. The patient was prescribed two different Y-90 microsphere administrations of 126 Gy (12,600 rad) and 138 Gy (13,800 rad) to separate liver segments. These administrations were to use activities of 1 GBq (27 mCi) and 2.72 GBq (73.5 mCi); however, the licensee has estimated that the activities used were 2.18 GBq (58.9 mCi) and 4.4 GBq (118.9 mCi), resulting in administered doses of 256 Gy (25,600 rad) and 294 Gy (29,400 rad). These doses were 103 percent and 113 percent greater than those prescribed. The patient received additional laboratory work in November 2021 and February 2022 that indicated no adverse effects had occurred and none are expected.

Cause(s)—The apparent cause of this event was a communication error that resulted in the ordering of doses with an incorrect calibration date of November 22, 2021. Additionally, the licensee failed to confirm that the prescribed dose matched the measured dose activity during its preprocedural checks.

Actions Taken to Prevent Recurrence

Licensee—The licensee instituted corrective actions, including updating its Y-90 case worksheet to add new verification of the dose in hand versus the written directive. It has also updated its dose ordering process by requiring that the technologist ordering the dose complete a written document template provided by the manufacturer and that a second person sign off on the completed form to verify the order.

State—The Wisconsin Department of Health Services initiated a reactive inspection and interviewed the manufacturer. The State's review of the event and the licensee's program identified four violations. The effectiveness of the licensee's corrective actions will be reviewed in future inspections.

This event is closed for the purpose of this report.

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 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, NV

Nature and Probable Consequences—Comprehensive Cancer Centers of Nevada—Sunset (licensee) reported a medical event in which a patient received a dose that exceeded their prescribed dose by more than 50 percent. The incident involved a high -dose-rate (HDR) remote afterloader and a 333 GBq (9,000 mCi) iridium-192 source. The patient was prescribed 10 HDR treatments to breast tissue; however, the licensee subsequently discovered that some source catheters had been incorrectly labeled and were positioned incorrectly during the initial four treatments ~~fractions~~. While this altered the dose distribution and resulted in a higher ~~skin~~ dose to the skin than anticipated, the target dose difference did not exceed 50 percent of the dose prescribed after the licensee replanned the remainder of the patient's treatments to compensate for the erroneous treatments. The initially planned exposure ~~for~~ to the 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), which exceeded the planned exposure by 21.9 Gy (2,190 rad). The licensee determined that no ~~probable consequences~~significant adverse effects were expected from this additional exposure to the patient's skin, though the patient will be seen by his/her physician for follow-up more regularly than typically advised to monitor for skin reactions.

Cause(s)—The preliminary apparent cause of the event appears to be human error and lack of proper review for catheter identification and placement by the licensee physicists.

Actions Taken to Prevent Recurrence

Licensee—The licensee updated its HDR procedures to further emphasize the review of catheter identification before treatment and modified the treatment planning process to include a review by a second licensee physicist before administration. The licensee staff also received additional training on correct catheter identification.

State—The Nevada Department of Health and Human Services plans to perform an inspection in 2023 to review the event and associated corrective actions with the licensee.

This event is open for the purpose of this report.

AS22-04 Medical Event at Loma Linda University Health, Loma Linda, 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 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, Loma Linda, CA

Nature and Probable Consequences—On April 5, 2022, Loma Linda University Health (licensee) reported that during a palliative Y-90 microsphere treatment, a patient received a dose that was more than 50 percent greater than that prescribed. The patient (Patient A) was prescribed a dose of 120 Gy (12,000 rad) to two smaller segments of the liver. However, Patient A was administered a dose of 736.6 Gy (73,660 rad) to the two segments of the liver. The licensee had scheduled two patients for microsphere treatments on that same day. A nuclear medicine technologist erroneously selected one of the dose vials for Patient B to use for Patient A's treatment. Due to miscommunication during a nuclear medicine technologist shift change, the erroneous dose vial was taken to the therapy suite by a second nuclear medicine technologist without having been assayed on the dose calibrator to verify it was within 10 percent of the written directive ~~dose~~activity, and ~~it~~ this vial was administered to Patient A, likely resulting in ablation of two small segments of the liver. However, since the affected segments together comprised less than 10 percent of the patient's liver, no negative effects on the patient were anticipated.

Cause(s)—The licensee identified the cause of the event as human errors by the two certified nuclear medicine technologists and the AU, who collectively failed to follow the licensee's Y-90 administration standard operating procedure by (1) not appropriately recording the pretreatment dose calibrator Y-90 activity measurement, (2) not verifying that the dose vial activity was within 10 percent of the written directive activity before it was delivered to the therapy suite, and (3) not appropriately completing the time-out review (conducted in the therapy suite just before treatment) to verify that the dose calibrator activity measurement was within 10 percent of the written directive activity.

Actions Taken to Prevent Recurrence

Licensee—The licensee instituted revisions to its Y-90 administration standard operating procedure to require the signed verification of dose vial activity by two technologists, with an interim requirement that a supervisor or manager complete one of those verifications. Also, all dose vials must now be reverified when transferred between certified nuclear medicine technologists. Licensee nuclear medicine staff and AUs were trained on the updated Y-90 administration standard operating procedure. Additionally, for 90 days, a supervisor was required to check the dose vial information for accuracy before transport to the therapy suite. Finally, the licensee performed monthly audits of Y-90 administration documentation for 3 months to assess the effectiveness of the corrective actions and will continue to perform quarterly audits.

State—The California Department of Public Health investigated the incident and cited the licensee for three instances of noncompliance with the licensee's Y-90 administration standard operating procedure.

This event is closed for the purpose of this report.

AS22-05 Medical Event at the University of Pennsylvania, Philadelphia, Pennsylvania

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 18, 2022, Philadelphia, PA

Nature and Probable Consequences—On May 18, 2022, the University of Pennsylvania (licensee) reported an incident involving a dose to the incorrect treatment site during a Gamma Knife® Stereotactic Radiosurgery treatment. The patient underwent treatment of four lesions in the brain using cobalt-60. After the treatment, it was discovered that targeting had been inaccurate by 0.5 centimeters for all four lesions. The prescribed dose to target tissue was between 20 and 21 Gy (2,000 and 2,100 rad). With the error in treatment positioning, the delivered dose to target tissue was estimated to be between 8 and 15 Gy (800 and 1,500 rad). The expected dose to surrounding healthy tissue as prescribed ranged between 2.68 and 5.79 Gy (268 and 579 rad). The error in treatment position resulted in a maximum dose range to unintended healthy tissue of approximately 21.82 - 27.09 Gy (2,182 - 2,709 rad). No adverse effects to the patient are expected due to this event, but the patient will continue to be monitored.

Cause(s)—Due to an ~~unknown~~ apparent treatment planning system limitation, the revised coregistration (aligning) of the images shifted the intended target but not the treatment parameters. This was discovered after the surgery, and it was determined that all treatment applications were 0.5 centimeters off target.

Actions Taken to Prevent Recurrence

Licensee—As corrective action, the licensee updated its treatment procedures to include the review and approval of the treatment plan by two of the three team members (AU, authorized medical physicist, neurosurgeon) before treatment for cases that involve a coregistration of CT/magnetic resonance images. In addition, the licensee ~~planned to contact~~reported the ~~manufacturer to discuss the system limitation~~ problem with the treatment planning software to the manufacturer.

State—From May 25 through June 27, 2022, the Pennsylvania Department of Environmental Protection conducted a reactive inspection in response to this event. No violations were identified as a result of this inspection. The system limitation that caused the event was unknown to the licensee at the time.

This event is closed for the purpose of this report.

AS22-06 Medical Event at an Unspecified 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 03, 2022, ~~Unspecified City,~~ NY

Nature and Probable Consequences—A New York State medical licensee reported that a patient received an iridium-192 treatment to the wrong site using an HDR unit. The ~~male~~ patient was diagnosed with basal carcinoma of the skin of the left scalp. The patient was administered a total of 36 Gy (3,600 rad) over 6 weeks (6 Gy (600 rad) per week). On June 3, 2022, the licensee determined that the physician/AU ~~determined that he~~ had misidentified the treatment site.

Per the radiation oncologist, the recurrence of the basal cell carcinoma at the biopsy site is a potential consequence of this event. The patient was offered an additional course of radiation therapy to the correct site, additional surgery, or observation by a dermatologist. The patient choose observation by ~~his~~ a dermatologist.

Cause(s)—The treatment site was ~~misidentified~~ incorrectly identified because the photographs were taken right after the lesion was biopsied by the dermatologist. No photographs were taken of the treatment site before the biopsy. When the patient started radiation therapy the biopsied lesion had completely healed and the correct treatment site could not be identified from the photographs, pathology reports, consult requests, or the patient's recollection.

Actions Taken to Prevent Recurrence

Licensee—The licensee created an HDR planning policy for dermal brachytherapy. In addition, the licensee updated its Commitment to Quality Care Policy to state that HDR skin cancer sites will be reviewed at a peer review meeting before treatment begins. Furthermore, better photographs of treatment site(s), including pre-biopsy photographs, will be required before beginning radiation therapy. Ambiguous information will require a request to verify the correct treatment site.

State—The New York State Department of Health reviewed the circumstances of the event and determined that the licensee's corrective actions were adequate.

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 AO that it reported and informed the NRC that withholding this information is consistent with New York State Public Health Law § 2805-l.

AS22-07 Medical Event at University of Minnesota, Minneapolis, Minnesota

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—June 14, 2022, Minneapolis, MN

Nature and Probable Consequences—The University of Minnesota (licensee) reported that a patient received ~~more~~ a dose greater than prescribed during a Y-90 microsphere treatment. The licensee ordered a stock quantity of microspheres and received 5.14 GBq from the pharmacy. Rather than drawing the prescribed dose for this procedure, the entire stock quantity was taken to interventional radiology for administration. The dose was administered to the patient without verifying the activity in the ~~Nalgene~~ storage jar or ~~seeing~~ reading the activity listed on the label. The patient was prescribed 2.2 GBq (59.46 mCi) for a dose of 150 Gy (15,000 rad) to the right lobe of the liver but was administered 5.07 GBq (137 mCi) for a dose of 340 Gy (34,000 rad). The AU signed the written directive after the procedure with 5.14 GBq (139 mCi) prescribed and 5.07 GBq (137 mCi) delivered. The prescribing physician (interventional radiologist) realized the error the next day when reading the post report. There have been no unexpected or adverse clinical symptoms, signs of radiation-induced liver injury, or other systemic effects observed in the patient due to this event.

Cause(s)—This event was caused by human error; the licensee did not verify that the dose administered to the patient matched the prescribed dose.

Actions Taken to Prevent Recurrence

Licensee—The licensee developed and implemented a new procedure that requires the AU to review and sign the written directive before the therapy is administered. The licensee has also updated the written directive form and retrained staff on the procedure.

State—The Minnesota Department of Health (MDH) performed a reactive inspection on June 30, 2022. During the inspection, the MDH staff identified that the AU was minimally involved in this type of procedure and was signing the written directive after the administration. As a result of the inspection, MDH issued a violation, and enforcement action was taken against the licensee.

This event is closed for the purpose of this report.

AS22-08 Medical Event at HCA-HealthONE, Aurora, Colorado

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 24, 2022, Aurora, CO

Nature and Probable Consequences—On June 24, 2022, HCA-HealthONE (licensee) reported that a Y-90 microsphere treatment dose was delivered to the wrong location. The patient was prescribed a dose of 148 Gy (14,800 rad) to the right lobe of the liver. However, imaging after the administration indicated that the activity was incorrectly delivered to the left lobe of the liver for an estimated dose of 240 Gy (24,000 rad). The physician notified the patient of the misadministration to the incorrect liver lobe. The licensee reported that the radiation dose to the left lobe is unlikely to cause any permanent damage.

Causes—The suspected cause of the event was that the microcatheter shifted when the licensee connected the microsphere administration kit after the correct location was verified with contrast fluoroscopy but before the delivery of the treatment. A contributing cause was that the patient's left hepatic artery was very close to the treatment area.

Actions Taken to Prevent Recurrence

Licensee—The licensee updated its administration procedure such that a reference image from the last fluoroscopic image using contrast showing flow to the appropriate vasculature will be saved and displayed side-by-side with real-time fluoroscopy. This will help identify and correct small changes in the location of the tip of the microcatheter before administration of the Y-90 microspheres.

State—The Colorado Department of Public Health & Environment investigated the incident and identified one violation for the licensee's failure to follow the written directive in that the Y-90 dosage was administered to the left liver lobe rather than the right liver lobe as directed.

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 2010 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 3710 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 (TS) (§ § 50.36(c)).

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

3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials that could result in exceeding the dose limits of 10 CFR part 10010 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 5010 CFR Part 50, “Domestic licensing of production and utilization facilities,” could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy.

1. Discovery of a major condition not specifically considered in the safety analysis report or TS that requires immediate remedial action.

2. Personnel error or procedural deficiencies that result in the loss of plant capability to perform essential safety functions such that a release of radioactive materials exceeding the dose limits of 10 CFR Part 100 or 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 ASP 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.

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 44, "Report to Congress on Abnormal Occurrences: Fiscal Year 2021," issued in August 2022. This AO involved an event at the National Institute of Standards and Technology (NIST) Center for Neutron Research (NCNR) test reactor in Gaithersburg, Maryland.

Event at the National Institute of Standards and Technology in Gaithersburg, Maryland
(previously reported as NRC21-02 in NUREG-0090, Volume 44)

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

Background—On February 3, 2021, the 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~~placed in a safe condition. 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~~ The licensee 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~~ The licensee assessed the release of radioactive material to the environment, and the NRC independently analyzed the same information as part of its special inspection. Both ~~assessments~~ 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 Title 10 of the *Code of Federal Regulations* (10 CFR) Section 20.1301, "Dose limits for individual members of the public."

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 licensee determined that the fuel element was not ~~fully~~ properly seated in its normal position, causing a localized loss of cooling. ~~and~~ As a result, ~~a small amount of~~ melted fuel was deposited on the lower grid plate surfaces near the displaced fuel element nozzle. NIST submitted a written report to the NRC on March 5, 2021. During subsequent inspections, the NRC observed that the damaged fuel element nozzle was almost completely blocked by melted fuel. On

October 1, 2021, NIST submitted to the NRC a request to restart the NCNR test reactor following the completion of corrective actions. NIST also submitted root cause and corrective action 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 startup 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 NRC inspectors found that the NIST operators did not follow technical specifications for refueling and did not have adequate procedures for emergency response, refueling, or reactor startup. Moreover, NIST management did not provide the equipment, procedures, and training necessary to support safe operation, which led directly to a violation of the technical specification safety limit for fuel and ultimately to the partial melting of nuclear fuel.

Update on 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 display of reactor parameters in the control room for operators to identify mechanical anomalies during reactor startup, (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 changes for the refueling tasks and latch verification procedures.

NRC—The NRC’s March 16, 2022, special inspection report (ADAMS Accession No. ML22056A361) associated with the event identified seven apparent violations of NRC requirements, the most significant being an apparent violation of NCNR Technical Specification 2.1, “Safety Limit,” which states that the reactor fuel cladding temperature shall not exceed 842 degrees Fahrenheit for any operating conditions of power and flow. The NRC inspectors observed ~~once-molten material~~failed fuel in and around a fuel element, indicating that the fuel cladding temperature safety limit had been exceeded. The NRC special inspection team also identified weaknesses in the NIST root cause reports. A public meeting was also held to discuss the inspection results.

In accordance with the NRC’s Enforcement Policy, the NRC and NIST participated in an alternative dispute resolution mediation session on May 10, 2022, to resolve the issues identified during ~~by~~ the special inspection. On August 1, 2022, the NRC issued a confirmatory order (ADAMS Accession No. ML22206A213) to NIST outlining robust and comprehensive corrective actions required to be implemented at NCNR to address concerns associated with the apparent violations. Because NIST agreed to the corrective actions and timelines in the confirmatory order, the NRC did not issue a civil penalty to NIST and will not pursue further enforcement action for the violations identified in the special inspection report.

On August 1, 2022, the NRC also issued a supplemental inspection plan (ADAMS Accession No. ML22206A008) to NIST. The purpose of the plan is to (1) establish NRC oversight of the NCNR test reactor following the extended shutdown due to the event and subsequent notification that the fuel temperature safety limit was exceeded; (2) ensure that the NRC communicates its oversight in a clear and predictable manner to the licensee, the public, and other stakeholders; (3) document the required licensee corrective actions taken to support re-start readiness; and (4) provide reasonable assurance of adequate protection of public health and safety during and following the NIST reactor restart. The supplemental inspections of corrective actions and improvements made by NIST ~~will~~ informed the NRC's decision to authorize restart of the reactor.

A public meeting was held on March 2, 2023, which outlined ~~The~~ the NRC's technical review of NIST's request to restart. ~~remains ongoing. The NRC determined that~~ the additional NRC inspections of the NIST corrective actions ~~are~~ necessary to support a decision on restart authorization, and additional NRC supplemental inspections that would occur following the restart. On March 9, 2023, the NRC authorized the restart of the NCNR test reactor (ADAMS Accession No. ML23040A337).

This event is closed for the purpose of this report.

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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).

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).

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

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

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

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

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

Fluoroscopy[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

2. *Id.*

3. *Id.*

prescribed dosage range; or (C) The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more.

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

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

4. *Id.*

Source material—as defined in 10 CFR 40.4, "Definitions," (1) uranium or thorium, or any combination thereof, in any physical or chemical form, or (2) ores that contain by weight 1/20th of 1 percent (0.05 percent) or more of (i) uranium, (ii) thorium, or (iii) any combination thereof. Source material does not include special nuclear material.

Special nuclear material—as defined in 10 CFR 70.4, "Definitions," (1) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission, pursuant to the provisions of section 51, "Special Nuclear Material," of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but not including source material, or (2) any material artificially enriched by any of the foregoing, but not including source material.

Technical specification—part of an NRC license authorizing the operation of a nuclear production or utilization facility that establishes requirements for items such as safety limits, 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 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