UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 Allendale Road, SUITE 102
KING OF PRUSSIA, PA 19406-1415

June 22, 2022

EA-22-003
NMED NO. 210483

Tim Martin, Chief Operating Officer
Cabell Huntington Hospital
1340 Hal Greer Boulevard
Huntington, West Virginia 25701

SUBJECT: CABELL HUNTINGTON HOSPITAL - NRC INSPECTION REPORT 03003370/2021001 AND NRC OFFICE OF INVESTIGATIONS REPORT NO. 1-2021-015

Dear Mr. Martin:

This letter refers to a radiation safety inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) at the Cabell Huntington Hospital (Cabell) facilities in Huntington, West Virginia. The routine inspection commenced remotely on May 10, 2021, with continued on-site review on May 17-19, 2021; a limited scope inspection was conducted on-site on November 2, 2021; and reactive inspection activities were conducted on-site on November 16-18, 2021, and February 15-16, 2022.

The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements and with the conditions of your license. The inspection consisted of selected examinations of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel. Additionally, the inspection reviewed one reportable event and one incident that the NRC was made aware of during this time frame: (1) on October 23, 2021, the licensee reported overexposure to an authorized user; and (2) on November 8, 2021, the licensee received licensed material at an unauthorized location. The Inspection Report, Enclosure 1, presents the results of this inspection. The inspectors discussed the preliminary inspection findings, as narratively described in the body of this report, with you and members of your staff at the conclusion of three onsite portions of the inspection on May 19, 2021, November 18, 2021, and February 16, 2022. Inspection findings were also discussed virtually with you and your staff on March 18, 2022. A final exit meeting was conducted virtually with you and your staff on April 27, 2022. Additionally, the apparent violations are provided in Enclosure 2.

In addition to the inspection, an investigation was conducted by the NRC Office of Investigations (OI) between June 21, 2021, and December 22, 2021, to determine whether interventional radiologists who were authorized users of Yttrium-90 (Y-90) at Cabell deliberately failed to wear their supplied dosimetry when administering Y-90, and whether the Radiation Safety Officer deliberately failed to require interventional radiologists to wear their dosimetry during Y-90

procedures. A Factual Summary of OI Investigation Report 1-2021-015 is included in Enclosure 3.

Based on the results of this inspection and investigation, the NRC has identified 14 apparent violations (AVs), of which 11 are being considered for escalated enforcement action, including a civil penalty, in accordance with the NRC Enforcement Policy. In addition, one of the 11 AVs being considered for escalated enforcement appears to have been willful. This violation involved Cabell's failure to monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1502(a)(1), and the apparent willful failure to wear dosimetry by an authorized user of Y-90. Specifically, five authorized users of Y-90 whose occupational exposure exceeded 10 percent of the limits in 10 CFR 20.1201(a) infrequently wore the required dosimetry supplied by Cabell, and one of the authorized users appears to have deliberately failed to wear his dosimetry. These failures to wear dosimetry resulted in Cabell's failure to monitor these individuals' occupational doses from licensed and unlicensed radiation sources under Cabell's control.

The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued at this time. In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. The circumstances surrounding each of these AVs, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and members of your staff at the virtual inspection exit meeting on April 27, 2022.

The AVs are assembled into four groups, three of which are being considered for escalated enforcement. The first group of AVs is related to the development and implementation of your radiation protection program and are discussed in Sections 3, 4, and 5 of the inspection report. This group of violations, which are being considered for escalated enforcement, involves Cabell's failure to:

- develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20
- monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and supply and require the use of individual monitoring devices (as discussed above, this violation involved apparent willfulness)
- provide the Radiation Safety Officer with sufficient management prerogative to identify radiation safety problems and stop unsafe operations
- instruct individuals who are likely to receive in a year an occupational dose in excess of 100 mrem in the applicable provisions of NRC regulations and requirements in its license for the protection of personnel from exposure to radiation and/or radioactive material
- reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person

The second group of AVs is related to Cabell's failure to control occupational dose to three individuals below regulatory limits and are discussed in Section 4 of the inspection report. This group of violations, which are being considered for escalated enforcement, involves Cabell's failure to:

- control the occupational dose to the skin or to any extremity of individual adults to an annual dose limit of 50 rem shallow-dose equivalent
- control the occupational dose to individual adults to an annual dose limit of 5 rem total effective dose equivalent
- control the occupational dose to the lens of the eye of individual adults to an annual dose limit of 15 rem dose equivalent

The third group of AVs is related to Cabell's possession of licensed material at an unauthorized location and are discussed in Section 5 of the inspection report. This group of violations, which are being considered for escalated enforcement, involves Cabell's failure to:

- confine possession and use of byproduct materials to the locations and purposes authorized by its license
- control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage
- comply with the applicable requirements of the Department of Transportation regulations appropriate to the mode of transport

The fourth group of AVs, which are related to Cabell's failures in other radiation safety program areas, is not being considered for escalated enforcement and are described in the inspection report.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) request a pre-decisional enforcement conference (PEC) to discuss the apparent violations, or (2) request alternative dispute resolution (ADR). A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The conference would include an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the AVs. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful.

In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a third party neutral. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help

them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party.

Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

Either the PEC or the ADR would be closed to public observation because the NRC's preliminary findings include information associated with an NRC OI report that has not been publicly disclosed. **Please contact Anne DeFrancisco, Chief, Medical and Licensing Assistance Branch, at 610-337-5078 within 10 days of the date of this letter to notify the NRC of your intent to participate in a PEC or pursue ADR.**

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

If you have any questions concerning this matter, please contact Anne DeFrancisco of my staff at 610-337-5078 or Anne.DeFrancisco@nrc.gov.

Sincerely,

Blake D. Welling

Digitally signed by Blake D. Welling
Date: 2022.06.22 14:33:25 -04'00'

Blake D. Welling, Director
Division of Radiological Safety and Security
Region I

Docket No. 030-03370
License No. 47-00404-02

Enclosures:
1. Inspection Report
2. Apparent Violations
3. Factual Summary of Investigation 1-2021-015

cc w/encls:
James Norweck, M.S., DABR, Radiation Safety Officer
Tera Patton, State of West Virginia

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SUBJECT: CABELL HUNTINGTON HOSPITAL - NRC INSPECTION REPORT 03003370/2021001 AND NRC OFFICE OF INVESTIGATIONS REPORT NO. 1-2021-015 DATED JUNE 22, 2022

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DATE	6/9/22	6/15/22	6/22/22		

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03003370/2021001
Docket No.	030-03370
License No.	47-00404-02
EA No.	EA-22-003
NMED No.	210483
Licensee:	Cabell Huntington Hospital
Locations:	1201 Hal Greer Boulevard Huntington, West Virginia 1340 Hal Greer Boulevard Huntington, West Virginia 1400 Hal Greer Boulevard Huntington, West Virginia 2900 First Avenue Huntington, West Virginia 5170 U.S. Route 60 East Huntington, West Virginia
Inspection Dates:	In-office review: May 10, 2021-April 27, 2022 Onsite inspection: May 17-19, 2021; November 2, 2021; November 16-17, 2021; February 15-16, 2022.
Exit Meeting:	Virtual exit meeting April 27, 2022
Inspectors:	Juan Ayala, Health Physicist Robin Elliott, Senior Health Physicist Patrick-John Hann, Health Physicist Penny Lanzisera, Senior Health Physicist Elizabeth Tindle-Engelmann, Health Physicist
Approved By:	Anne E. DeFrancisco Digitally signed by Anne E. DeFrancisco Date: 2022.06.22 14:12:59 -04'00' Anne DeFrancisco, Chief Medical and Licensing Assistance Branch Division of Radiological Safety and Security

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EXECUTIVE SUMMARY

Cabell Huntington Hospital
NRC Inspection Report No. 03003370/2021001

Cabell Huntington Hospital (CHH) is authorized under United States Nuclear Regulatory Commission (NRC) Materials License 47-00404-02 to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 at its facilities in Huntington, West Virginia.

On May 7, 2021, the NRC announced a routine inspection of CHH that began remotely on May 10, 2021. Onsite inspection occurred on May 17-19, 2021, at CHH. The scope of the inspection was to examine the activities conducted under the license and to confirm compliance with the NRC rules, regulations, and the conditions of the license. The routine inspection identified three apparent violations that are being considered for escalated enforcement regarding the licensee's failure to:

- develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities
- monitor individuals' occupational exposure to radiation from licensed and unlicensed sources of radiation
- provide instruction to occupationally exposed individuals

The inspector discussed the importance of wearing dosimetry with the Radiation Safety Officer (RSO) and one interventional radiology (IR) Authorized User (AU). The routine inspection identified three apparent violations that are not being considered for escalated enforcement regarding the licensee's failure to:

- dispose of Yttrium-90 (Y-90) waste only after it was undistinguishable from background
- maintain required emergency response equipment for high dose rate remote afterloaders (HDRs)
- perform measurements of HDR transfer tubes and applicators

On October 23, 2021, the licensee submitted a written report in accordance with 10 CFR 20.2203, communicating that IR AU number 1 (AU1) received an occupational extremity dose in excess of the regulatory limits in 2021. AU1 conducted activities with licensed material, such as Y-90 microspheres and Technetium-99m (Tc-99m), and unlicensed sources of radiation, such as fluoroscopy (fluoro) and Computed Tomography (CT). On November 2, 2021, a limited scope inspection was conducted to review the circumstances of the licensee's report. To address the reported exposure in excess of NRC's regulatory limits, the licensee initiated the following actions: (1) removing AU1 from licensed activities for the remainder of the calendar year (CY); (2) providing shielding for use while working with unlicensed sources of radiation; and (3) providing radiation safety re-instruction. On November 18, 2021, the NRC issued a Confirmatory Action Letter to CHH reaffirming the actions that were documented in the licensee's written report.

On November 16-18, 2021, the NRC commenced a reactive inspection to review the occupational exposure monitoring program, including evaluation of the licensee's response to the reported overexposure, review of the licensee's dose assessment methodology, and a review of the radiation protection program for compliance with NRC requirements. Four

additional apparent violations were identified and are being considered for escalated enforcement with regard to the licensee's failure to:

- control occupational dose to the extremity of an individual adult below 50 rem
- control occupational dose to individual adults to 5 rem total effective dose equivalent
- control occupational dose to the lens of the eye of an individual adult below 15 rem
- reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person

On February 15-16, 2022, the NRC continued its reactive inspection activities with the review of a November 8, 2021, incident where CHH possessed a 10.11 Curie (Ci) source of Iridium-192 (Ir-192) at an unauthorized location and the review of the licensee's implemented corrective actions for the previously identified apparent violations. The inspectors identified four additional apparent violations which are being considered for escalated enforcement with regard to the licensee's failure to:

- provide the RSO with sufficient management prerogative to identify radiation safety problems and stop unsafe operations
- possess licensed material only at authorized locations
- secure licensed material while not in storage
- comply with Department of Transportation (DOT) regulations while transporting radioactive material

The NRC determined that the failure to control occupational exposures to the regulatory limits and the failure to possess licensed material only at authorized locations were attributed to the licensee's failure to develop and implement a radiation protection program, including policies, procedures, and training programs, commensurate with the scope and extent of licensed activities. The NRC determined this was due to insufficient management oversight and inadequate resources dedicated to the radiation protection program.

The licensee evaluated the root causes of the overexposures and has implemented short term corrective actions to ensure that dosimetry was being worn, that individuals were using As Low As is Reasonably Achievable (ALARA) principles to safely work with licensed and unlicensed sources of radiation, and that radioactive material was not transported offsite. Additionally, the licensee stated that it was working towards creating a new staff position to support the RSO in the effort to regain compliance with NRC requirements. The NRC notes that the licensee did not evaluate the causal factors associated with all of the apparent violations in order to comprehensively evaluate the issues. The licensee has not implemented comprehensive corrective actions to correct the apparent violations and prevent their recurrence.

REPORT DETAILS

1.0 Inspection and Program Scope

1.1 Inspection Scope

The NRC announced a routine inspection of CHH on May 7, 2021. The licensee provided select documents for remote review on May 10-14, 2021. The onsite inspection was conducted on May 17-19, 2021, at CHH's facilities located in Huntington, West Virginia. The scope of the inspection was to examine the activities conducted under the license and to confirm compliance with the NRC rules, NRC regulations, and the conditions of the license. This portion of the inspection is described in Section 2 of this report.

On October 23, 2021, the licensee submitted a written report of an occupational extremity dose in excess of the regulatory limits (Nuclear Material Events Database (NMED) No. 210483, ADAMS Accession No. ML21312A459). The NRC initiated an announced, limited scope inspection at CHH on November 2, 2021, to evaluate the corrective actions that were documented in the report. On November 18, 2021, the NRC issued a Confirmatory Action Letter to CHH reaffirming the corrective actions that were documented in the licensee's written report (ADAMS Accession No. ML21308A550). On November 15, 2021, the NRC chartered a team inspection to review the licensee's radiation protection program with emphasis on their occupational monitoring program. Additionally, the charter tasks included that NRC seek to understand the circumstances that led to the reported overexposure, assess the adequacy of the licensee's response, evaluate the licensee's dose assessment methodology, perform an independent dose estimate, and perform an independent root cause determination. The onsite team inspection occurred on November 16-18, 2021. The team determined there was a need for a retrospective dose evaluation for a group of physicians working with licensed and unlicensed sources of radiation in CYs 2019 to 2021. This evaluation was completed by the licensee on January 24, 2022. On February 23, 2022, the licensee submitted a written report of occupational doses in excess of the regulatory limit for three individuals (NMED No. 210483, ADAMS Accession No. ML22073A220). The occupational monitoring program portion of the inspection is described in Section 3. The overexposure event is described in Section 4.

On December 21, 2021, NRC Region I was made aware of an incident that was reported to the State of Louisiana involving CHH and an Ir-192 source. The incident occurred on November 8, 2021, and involved CHH possessing 10.11 Ci of Ir-192 at an unlicensed facility for over thirty minutes. The inspection team continued the onsite reactive inspection at CHH on February 15-16, 2022, to review the Ir-192 source incident and to review the status of corrective actions for the previously identified apparent violations related to the occupational monitoring program. The Ir-192 source incident is described in Section 5.

In-office review for the entirety of the inspection activities continued through April 27, 2022. The inspection activities were performed in accordance with NRC Inspection Procedures (IP) 87103, 87131, and 87132. Throughout the inspection, inspectors conducted interviews with the licensee's personnel, observed operations, toured facilities, and reviewed select records and documents.

1.2 Program Scope

At the time of the inspection, CHH operated two hospitals, CHH and St. Mary's Medical Center (SMMC), and three clinics under NRC License Number 47-00404-02. The license authorized 10 CFR 35.100-400, 10 CFR 35.600, and Y-90 microspheres under 10 CFR 35.1000. CHH had a Nuclear Medicine (NM) department, Positron Emission Tomography (PET) department, and Radiation Oncology department. SMMC had a NM department, Nuclear Cardiology department, and Radiation Oncology department. The NM departments were responsible for routine nuclear medicine and nuclear cardiology procedures as well as various radiotherapy programs involving the administration of Iodine-131, Radium-223, and Y-90. The Radiation Oncology departments both had established HDR programs. CHH had three outpatient clinics that performed a variety of 35.100-200 activities.

1.3 Management Oversight

CHH and SMMC had separate management structures because they were independent facilities until a change of control occurred in 2018. When CHH acquired SMMC, the SMMC Board of Directors began reporting to the CHH Board of Directors and the CHH Board of Directors became responsible for SMMC. The licensee entered an agreement with Mountain Health Network for management services and was in the process of streamlining processes and policies. Mountain Health provided business direction for CHH and SMMC but reported to the CHH Board of Directors who had oversight of licensed activities.

The licensee operated two Radiation Safety Committees (RSCs), one at CHH and one at SMMC. Both RSCs met on a quarterly basis. The SMMC RSC provided a summary and reported to the CHH RSC which was responsible for overseeing all licensed activities between the two facilities. The licensee had one RSO, a consultant who was onsite weekly and available by phone as needed. The RSO was responsible for program reviews, routine radiation safety tasks, and diagnostic physics services. The RSO was an employee of the interventional radiologists' private practice. The RSO had no staff or additional health physics support. The RSO received support through the RSC members and various department supervisors and managers; however, it appeared that this support was not effective in accomplishing some of the objectives of the radiation protection program.

2.0 Routine inspection

2.1 Inspection Scope

A routine inspection was announced on May 7, 2021. Select records were reviewed remotely on May 10-14, 2021, and an onsite inspection was performed on May 17-19, 2021, at CHH's facilities located in Huntington, West Virginia. The scope of the inspection was to examine the activities conducted under the license and to confirm compliance with the NRC rules, NRC regulations, and the conditions of the license. Aspects of this inspection associated with the licensee's occupational exposure monitoring program are described in Section 3.

2.2 Observations and Findings

During the May 2021 routine inspection, the inspector toured NM, PET, and Radiation Oncology facilities at CHH and SMMC, as well as two outpatient facilities. Throughout the various facilities, the inspector observed tasks including the following: dose calibrator quality control testing, HDR daily spot checks, preparation and administration of doses, receipt of radioactive material, sealed source inventories, and surveys. The inspector reviewed a sample of records including the following items: annual program reviews, decay in storage logs, dose calibrator calibrations, dosimetry results, HDR calibrations, instrument calibrations, RSC meeting minutes, sealed source inventories and leak tests, shipping and receiving logs, surveys, training, and written directives.

2.3 Conclusions

Apparent Violation of 10 CFR 35.92

10 CFR 35.92 allows each licensee to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee monitors the material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding.

During review of the decay-in-storage logs, the inspector determined that the licensee disposed of Y-90 waste that was distinguishable from the background radiation level on two occasions. Specifically, on January 18, 2021, and April 22, 2021, the background radiation level was reported to be 0.02 mR/hr but the waste was distinguishable from background and then disposed of on both dates. On January 18, 2021, waste was determined to be 0.03 mR/hr, and on April 22, 2021, was determined to be 0.04 mR/hr. The inspector interviewed the technologist that surveyed the waste on those two dates. Based on the discussion, it was determined that a background radiation level measurement was appropriately taken and that the waste was surveyed in a low background radiation level area. However, the technologist reported that the survey meter bounced around during the survey which indicated there was residual Y-90 left in the container. The technologist had the understanding that anything below 0.05 mR/hr could be released regardless of the background radiation level. The technologist was not comparing the survey results to the background radiation level measurement to ensure the result was undistinguishable from the background radiation level.

This licensee’s disposal of waste that was distinguishable from background was identified as an apparent violation of 10 CFR 35.92. Based on the small magnitude of the difference between radiation levels for background and the waste, the NRC determined that it is unlikely that any significant amount of Y-90 was released from the facility. As corrective actions, the licensee provided instruction to the technologist on the proper use of survey instruments and clarified the release criteria for radioactive waste streams.

Apparent Violation of Condition 14 of NRC license No. 47-00404-02

Condition 14 of License No. 47-00404-02 requires, in part, that CHH shall conduct its program in accordance with the statements, representations, and procedures contained

in the application dated January 23, 2013, for SMMC and the application dated July 29, 2013, for CHH. The applications dated January 23, 2013, and July 29, 2013, both state that the following emergency equipment for the HDR unit shall be readily available at all times: two pairs of long handled locking forceps, shielding container, heavy-duty wire cutters, emergency personnel dosimeters, portable survey meter, stopwatch or timer, and tape measure.

During the Radiation Oncology facility tours, the inspector determined that the licensee did not have all the required emergency response equipment at CHH or SMMC. Specifically, at both facilities, the licensee did not have two pairs of long handled locking forceps, heavy-duty wire cutters, or a tape measure readily available at either location during the inspection.

The licensee's failure to maintain the emergency response equipment was identified as an apparent violation of Condition 14 of NRC License Number 47-00404-02. As corrective actions, the licensee made an additional pair of long handled locking forceps, heavy-duty wire cutters, and a tape measure available at both facilities.

Apparent Violation of 10 CFR 35.633(a)(2)(i)

10 CFR 35.633(a) requires, in part, that licensees authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit before medical use following replacement of the source and that to satisfy the full calibration requirements, the full calibration measurements must include determination of length of the transfer tubes and determination of the length of the applicators.

Prior to April 27, 2021, the licensee was authorized to use a remote afterloader unit for medical use and did not perform full calibration measurements that included the determination of length of the transfer tubes or the determination of the length of the applicators at SMMC. Specifically, at SMMC, the licensee measured the diameter of the applicator for each treatment but failed to determine the length of the transfer tubes and length of the applicators as part of their full calibration measurements. However, the licensee identified this non-compliance prior to the inspection and began performing the measurements on a quarterly basis on April 27, 2021. The April 27, 2021, measurements of the length of the applicators and transfer tubes were within the acceptable range. Thus, the NRC determined there was no impact to any patient treatments or any medical events.

The licensee's failure to determine the length of the applicators and transfer tubes at SMMC was identified as an apparent violation of 10 CFR 35.633(a)(2)(i).

3.0 Occupational Monitoring Program

3.1 Inspection Scope

The routine inspection of the occupational monitoring program included a review of a sample of records for all of the licensee's facilities and the radiation protection program as it relates to dose monitoring. In office review continued after the onsite routine inspection.

3.2 Observations and Findings

As part of the Y-90 microsphere program, CHH NM and SMMC NM were heavily involved. They received the Y-90, assisted in dose preparation, and handled the waste. The RSO was also present for the majority of the Y-90 administrations due to the complexity of the procedures. The Y-90 procedures were conducted by IR physicians at CHH and SMMC in the IR facilities. There were six Y-90 AUs that were authorized at the time of the inspection. However, two AUs performed the majority of the Y-90 administrations. Table 1 provides the total number of Y-90 administrations performed by each AU between January 1, 2019, and May 26, 2021.

Table 1. Total number of Y-90 administrations for AUs 1-6 at CHH facilities.

AU	01/01/2021-05/26/2021	01/01/2020-12/31/2020	01/01/2019-12/31/2019
AU1	9	21	9
AU2	0	0	0
AU3	7	13	17
AU4	0	1	0
AU5	0	0	0
AU6	0	0	0

In addition to working with Y-90, AUs 1-5 worked with other licensed sources of radiation, such as Tc-99m. AU6 was a Radiation Oncologist and worked with Ir-192 on a regular basis. The dosimetry results for AU6 were as expected based on this individual's job duties; as such, AU6 is not addressed in the remainder of the inspection report. The IR physicians were contracted to the hospital from a private practice. They supported CHH as well as other health care institutions in West Virginia and Kentucky. The AUs 1-5 physicians and one cardiologist worked with licensed sources of radiation and unlicensed sources of radiation at CHH. Occupational exposure to AUs 1-5 from unlicensed source of radiation was primarily from fluoro and CT machines.

On January 15, 2009, CHH implemented a policy titled "Model Occupational Dose Program," the policy was last updated on February 15, 2021. The policy states, in part, that dosimetry is required for individuals likely to receive in 1 year a dose in excess of 10 percent of the applicable regulatory limits. The policy states, in part, that individual monitoring devices for external dose are required for adult individuals likely to receive an annual dose in excess of 0.5 rem deep dose equivalent or 1.5 rem to the lens of the eye or 5 rem to an extremity. In general terms, the policy describes what types of dosimeters will be provided, where they are to be worn, and the frequency with which they should be exchanged. In June of 1994, CHH implemented a policy titled "Radiology Comprehensive Radiation Safety Policy"; the policy was last revised on July 1, 2021. The policy describes what types of dosimeters will be provided, where they are to be worn, and the frequency with which they should be exchanged for individuals receiving occupational exposure while working in the radiology department.

CHH provided a whole-body dosimeter to each individual working with fluoroscopes and/or radioactive material. For fluoro users, the whole-body dosimetry was intended to be worn on the outside of any protective lead equipment on the collar or neck region and the EDE2 correction was then to be applied by the dosimetry vendor. EDE2 correction is

a calculation performed by the dosimetry vendor when one dosimeter is worn outside of a lead apron by multiplying the collar deep dose equivalent by 0.30 to calculate the assigned deep dose equivalent based on the dose reduction from the lead apron. Individuals working with radiopharmaceuticals, such as Y-90 microspheres, were provided an extremity dosimeter that was to be worn on the maximally exposed extremity. AUs 1-5 were assigned a collar dosimeter and an extremity dosimeter at CHH and at SMMC. Both facilities exchanged the dosimeters on a monthly basis for AUs 1-5.

Additionally, the licensee developed a policy titled "Radiology Comprehensive Radiation Safety Policy" in June 1994, and revised the policy last on July 1, 2021. Section 16 states, in part, that individuals that are monitored for exposure to occupational radiation will be required to participate in annual radiation safety training as assigned through the education department's online learning platform. Prior to November 18, 2021, the licensee failed to require all individuals that were monitored for exposure to occupational radiation to participate in annual radiation safety training as assigned through the education department's online learning platform. Specifically, physicians were not enrolled in the online learning platform training module.

3.3 Conclusions

Apparent Violation of 10 CFR 20.1502(a)(1)

10 CFR 20.1502(a)(1) requires, in part, that each licensee shall monitor exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. At a minimum, each licensee shall monitor exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

During the routine inspection in May of 2021, the NRC identified several issues related to the licensee’s occupational exposure monitoring program. Through a review of dosimetry records, it was observed that many of the Y-90 AUs received minimal dose on the monthly reports which indicated dose below the minimum detection threshold of the dosimeter. Alternatively, some physicians’ dosimeters were marked as “unused,” indicating they had not been worn during that period. Table 2 provides a summary of occupational dose of record for AUs 1-5 where M represents “minimal” dose below the detection limit of the dosimeter.

Table 2. Summary of Quarter-to-date (QTD) Dosimeter Results and Annual Dosimeter Results for AUs 1-5 at SMMC and CHH.

AU	2021 QTD SMMC (mrem)	2021 QTD CHH (mrem)	2020 SMMC (mrem)	2020 CHH (mrem)	2019 SMMC (mrem)	2019 CHH (mrem)
AU1	M	Unused	M	67	M	Unused
AU2	M	Unused	M	M	M	M
AU3	M	Unused	M	M	M	M
AU4	M	Unused	M	Unused	M	Unused
AU5	M	382	M	334	M	M

However, the results for AUs 1-5 were inconsistent with the expected dose of this group of physicians. There has been an increase in surgical procedures using CT and Fluoroscopes in the last two decades which has led to increased occupational dose for many practitioners. Additionally, there has been an increase in the number of procedures that require the practitioner to be in or near the radiation beam. This information, in combination with the Y-90 caseload of the facility, indicated that physicians were likely not wearing dosimetry while working with licensed and unlicensed sources of radiation. This was discussed with the RSO on May 18, 2021. On May 19, 2021, the inspector observed AU1 administer Y-90 microspheres at CHH. During the procedure the inspector observed the use of lead aprons and required dosimetry monitoring devices. After the procedure, the inspector spoke with AU1 regarding use of dosimetry. AU1 indicated that he did not always wear dosimetry but would begin wearing dosimetry moving forward. The inspector discussed with AU1 the importance of complying with the licensee's occupational exposure monitoring program and NRC requirements.

RSC meeting minutes were reviewed and the inspector observed that the licensee had historically struggled with dosimetry participants failing to return their dosimeters. At times, the unreturned rate exceeded 10 percent. The licensee created a subcommittee of the CHH RSC to address the high unreturned rate in the first quarter of 2019. The subcommittee had participants from the operating room, the surgery center, and endoscopy. There was no involvement from IR. The inspector reviewed the RSC meeting minutes from 2018 through the first quarter of 2021. The RSC meeting minutes did not mention the abnormally low dosimetry records or that many dosimeters were not used. While onsite, the inspector attended the May 2021 CHH RSC meeting. The inspector observed that the committee discussed pertinent radiation safety topics including the abnormal dosimetry results that the inspector had brought to the attention of the RSO the day prior.

Based on the review of the dosimetry records, RSC meeting minutes, and discussion with AU1 and the RSO, an apparent violation of 10 CFR 20.1502(a)(1) was identified. Although the licensee supplied individual monitoring devices, the licensee failed to require the use of these monitoring devices. This led to the licensee's failure to monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee for adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Apparent Violation of 10 CFR 20.1101(a)

Title 10 CFR 20.1101(a) requires that each licensee develop and implement a radiation protection program commensurate with the scope and extent of licensed activities sufficient to ensure compliance with 10 CFR Part 20.

The licensee developed a policy titled "ALARA Policy" on January 15, 2009, and revised the policy last on February 15, 2021. Section 2 describes the action levels and steps that are to be taken when individuals receive certain occupational doses within a given period. Section 2 states, in part, that if a worker exceeds 375 mrem in a quarter (investigation level II), there will be a written investigation as to the cause and methods to prevent a repeat of a level II exposure.

Contrary to the above, when quarterly reviews were conducted, the licensee did not conduct written investigations for level II exposures to evaluate the unique causes and methods and to prevent recurrence of level II exposures. The licensee provided a generic information sheet on ALARA practices to these individuals with no specific investigation of the causes or methods to prevent repeat level II exposures. While these notifications were distributed to the individuals, individuals frequently failed to reply. When replies were received, they were typically generic responses and few preventative actions to prevent repeated high exposures were described. Other than the generic information sheet, there was no follow-up written evaluation by the licensee regarding the causes and methods to prevent recurrence.

In addition, the licensee failed to include provisions in its ALARA policy to investigate and take action on abnormally low, unused, or unreturned dosimetry. In the ALARA reviews for the first and second quarter of 2019, the third quarter of 2020, and the second and fourth quarter of 2020, the RSO made a note that there were unused dosimeters in the IR series. However, individual dosimetry users were not contacted regarding the unused dosimeters and there was no further effort to monitor occupational exposure for the individuals or to determine the occupational dose to the individuals.

Additionally, annual radiation protection program reviews performed by the licensee did not document that some dosimetry participants had abnormal or nonexistent dosimetry results. The program reviews did not address the dosimetry issues that had been discussed within the RSC meetings or quarterly ALARA reviews. Final conclusions of licensee program audits indicated all items were in compliance with NRC requirements and license conditions.

The licensee's failure to fully develop and implement its policy titled "ALARA Policy" was identified as an apparent violation of 10 CFR 20.1101(a). An additional example of the apparent violation of 10 CFR 20.1101(a) is discussed in Section 4 of the inspection report.

Apparent Violation of 10 CFR 19.12(a)

10 CFR 19.12(a) requires that all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem shall be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of the NRC regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material.

Specifically, AUs 1-5 who were working in IR, and who in the course of their employment were likely to receive in a year an occupational dose in excess of 100 mrem, were not instructed in the applicable provisions of NRC regulations and CHH's license for the protection of personnel from exposure to radiation and/or radioactive material. The licensee failed to provide these individuals with adequate instruction regarding the regulatory requirement for use of dosimeters and engineering controls, which contributed to their failure to properly wear dosimetry, to the licensee's failure to monitor their exposure to occupational radiation, and to multiple exceedances of annual dose limits. The licensee believed that AUs 1-5 were aware of the requirements to wear dosimetry and to use engineering controls based on the elements of their prior training and experience. Because of this, no formal instruction was provided by the licensee. Although the licensee stated that it provided various memorandums to AUs 1-5 on the

topic of “Proper Use of Radiation Dosimeters,” which discussed the requirement to wear dosimetry when receiving work-related radiation exposure, the licensee could not verify that the memorandums were received or read by the individuals. Additional guidance on how and where to wear the dosimeters was provided in the memorandums. However, the NRC determined that the use of memorandums was an ineffective training methodology. Additionally, AUs 1-5 participated in an electronic learning training on the topic of safe fluoro practices. Based on the NRC’s review of the training module, occupational dose limits were discussed but instruction on proper monitoring was not provided in the electronic learning content.

The licensee’s failure to provide instruction in the applicable provisions of the NRC regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material was identified as an apparent violation of 10 CFR 19.12(a).

4.0 Overexposure Event Follow-up

4.1 Inspection Scope

On November 2, 2021, the NRC began a limited scope inspection to follow-up on the licensee’s written report dated October 23, 2021, which stated AU1 exceeded the extremity occupational dose limit for 2021 (ADAMS Accession No. ML21312A459). On November 18, 2021, the NRC issued a Confirmatory Action Letter to CHH reaffirming the corrective actions that were documented in the written report (ADAMS Accession No. ML21308A550). On November 15, 2021, a reactive team inspection was chartered to review to the licensee’s occupational exposure monitoring program. The charter tasks included understanding the circumstances that led to the reported overexposure, assessing the adequacy of the licensee’s response, evaluating the licensee’s dose assessment methodology, performing an independent dose estimate, and performing an independent root cause determination. The team reviewed the circumstances surrounding the overexposure and the implementation of the licensee’s occupational dose monitoring program through interviews, evaluation of controls, direct observation of work activities, review of records and procedures, and a retrospective evaluation of occupational doses for multiple AUs.

4.2 Observations and Findings

AU1 began wearing dosimetry consistently after the routine inspection in May of 2021. As such, measurable exposure was recorded for AU1. On September 24, 2021, the RSO contacted NRC Region I to discuss a possible extremity overexposure. On October 23, 2021, the licensee submitted a written report pursuant to 10 CFR 20.2203 describing that AU1 had received an estimated 122 rem to the extremities for CY 2021 Year-To-Date (YTD) (ADAMS Accession No. ML21312A459). The written report included a description of the actions taken by the licensee to respond to the event, including: prohibiting AU1 from handling licensed material for the remainder of the CY, the addition of engineering controls, reinstruction on ALARA practices, and deterring the AU1 from placing their hands near radiation beams.

On November 2, 2021, an NRC inspector conducted interviews of the RSO and AU1. The purpose of the interview of AU1 was to collect preliminary information surrounding the reported overexposure and the disproportionally high extremity dose. Based on the interview, the NRC came to the understanding that AU1’s extremity dose likely came

from a workflow practice specific to positioning patients while the beam was on for biopsies and ablations. The AU stated that this practice was learned in medical training. AU1 expressed concern regarding the high dose and was unaware of the magnitude of the extremity dose. The NRC determined that AU1 was occupationally exposed at four other facilities in addition to his work at CHH and SMMC. The inspector observed that implementation of the actions described in the written report had been initiated.

4.3 Retrospective Dose Evaluation

During the November 2021 reactive inspection, the NRC determined that the magnitude of AU1's extremity dose was likely much higher than 122 rem based on several considerations. For example, AU1's dosimetry results indicated that individual frequently conducted activities with their hand near or in the beam. Additionally, AU1's extremity dose was a factor of 10 higher than the whole-body dose readings. Observations of a representative sample of fluoroscopic procedures amongst all AUs demonstrate that no direct exposure to the extremities occurred during fluoroscopic procedures; however, direct extremity exposures for AU1 were observed for 24 CT-fluoro guided cryo-ablations and biopsy procedures. In these cases, AU1's hand(s) were observed to be in the primary beam.

As a result of the deficiencies identified in CHH's occupational exposure monitoring program, interviews, observations, facility tours, and record review, the NRC determined that the licensee's dose evaluation was likely incorrect and that a revised dose evaluation was needed to assess the occupational dose for AUs 1-5 for the years 2019-2021. The licensee began working on a revised dose evaluation on November 18, 2021, for the total effective dose equivalent (whole-body dose) and lens of the eye dose received by AUs 1-5 at all the facilities where the AUs had medical privileges and a revised extremity evaluation for AU1 at all the facilities where the AUs had medical privileges.

On January 24, 2022, the licensee completed their assessment. Their methodology included collecting the total number of procedures performed by each AU at all facilities where medical procedures were performed during that CY at all facilities. The procedures were binned into groups based upon similarities of the procedure scope and complexity. The licensee reviewed all the CHH procedures from October 1, 2021, to December 31, 2021, to establish the average patient dose indicator for each group of procedures. This information was converted to occupational dose using conservative assumptions, physician use of engineering controls, and direct measurements.

Methodology for the licensee's data collection and calculation is as follows for whole-body and lens of eye dose evaluations:

- For each group of procedures, the 25th percentile, 75th percentile, and mean cumulative air kerma and Computed Tomography Dose Index volume (CTDIvol) was recorded for fluoro and CT procedures in mGy, respectively. The data was obtained for all CHH fluoro and CT procedures from October 1, 2021, to December 31, 2021.
- During the NRC inspection, the licensee created an experimental set up to measure the scattered dose per patient dose indicator. To measure the scatter for both fluoro and CT procedures, a 24 cm of solid water phantom was placed in the beam of representative interventional fluoro and CT units and a calibrated

handheld digital ion chamber was used to measure the accumulated exposure at the usual physician position. An mR per mGy of indicated air kerma (AK) conversion factor was determined for fluoroscopy and mR per CTDIvol (mGy) for CT guided procedures. This factor was multiplied by the number of procedures performed. The factors were as follows:
    - fluoro scatter: 0.093 mR/mGy
    - CT Scatter: 0.015 mR/mGy
- Correction factors were applied to account for the use of protective lead equipment such as lead aprons, lead eyewear, and ceiling-mounted shields based on observed practices on an individual AU basis. The factors considered dose reduction from wearable lead garments, leaded eye wear, and ceiling-mounted shields.
- For Y-90 microsphere procedures, pre-procedure 4-sided dosage measurements were used to determine the dose to the physician.

Methodology for the licensee's data collection and calculation is as follows for AU1's extremity dose evaluations:

- It was assumed that the physician's hand was on the surface of the patient during CT biopsies and ablations.
- During the NRC inspection, a patient dose indicator to occupational dose conversion factor was established for extremity doses by directly measuring the exposure on the surface of a 32-centimeter acrylic phantom, simulating the physician's hand on the surface of the patients' skin at the time of occupational exposure. The factor was determined to be 69 mR/mGy CTDIvol
- A correction factor of 30 percent was applied for the percentage of procedures that the physician's hand was observed in the CT beam.
- A correction factor of 30 percent was applied for the percentage of time during each procedure the physician's hand was observed in the CT beam.

The NRC performed an independent retrospective dose evaluation. The NRC's results were on the same order of magnitude as the licensee's. Since the NRC found the licensee's approach to be reasonable, the inspection findings are based on the licensee's calculations.

4.4 Conclusions

The results indicated occupational doses in excess of the regulatory limit for various time periods between 2019 and 2021 for AUs 1-3. The licensee submitted a written report in accordance with 10 CFR 20.2203 on February 23, 2022, reporting the results of the retrospective dose evaluation (ADAMS Accession No. ML22073A220).

Apparent Violations of 10 CFR 20.1201(a)

The results of the licensee's retrospective dose evaluation are summarized in the Tables 3-5. The highlighted values represent occupational doses in excess of limits found in 10 CFR 20.1201(a).

Table 3. Results of the Licensee's Retrospective Dose Evaluation for Extremity Dose

	Extremity Dose per Calendar Year (rem)		
AU	**2021**	**2020**	**2019**
AU1	475.526	560.880	571.294
AU2	24.815	26.873	28.301
AU3	13.774	14.270	18.321
AU4	25.748	23.325	30.151
AU5	10.552	9.739	14.926

Table 4. Results of the Licensee's Retrospective Dose Evaluation for Total Effective Dose Equivalent (TEDE)

	Total Effective Dose Equivalent per Calendar Year (rem)		
AU	**2021**	**2020**	**2019**
AU1	10.202	12.051	11.670
AU2	7.445	8.062	8.490
AU3	4.132	4.281	5.496
AU4	3.984	3.614	4.675
AU5	3.165	2.922	4.478

Table 5. Results of the Licensee's Retrospective Dose Evaluation for Lens of the Eye Dose

	Lens of the Eye Dose per Calendar Year (rem)		
AU	**2021**	**2020**	**2019**
AU1	17.003	20.085	19.449
AU2	12.408	13.436	14.150
AU3	6.887	7.135	9.161
AU4	6.640	6.023	7.792
AU5	5.276	4.869	7.463

Based on the licensee's retrospective evaluation of the occupational dose to AUs 1-5, the following conclusions can be made: (1) there are three examples of an apparent violation of 10 CFR 20.1201(a)(2)(ii) where the licensee failed to control occupational dose to an individual adult's extremity to 50 rem; (2) there are seven examples of an apparent violation of 10 CFR 20.1201(a)(1)(i) where the licensee failed to control occupational dose to individual adults to 5 rem total effective dose equivalent; and (3) there are three examples of an apparent violation of 10 CFR 20.1201(a)(2)(i) where the licensee failed to control occupational dose to an individual adult's lens of the eye to 15 rem. It is also notable that AU1 had doses in excess of the NRC's occupational dose limits in all three categories: lens of the eye, extremity, and TEDE, for all three years reviewed.

The licensee stated that it intends to provide the calculated occupational doses to the dosimetry vendor to revise the individuals' doses of record.

Apparent Violation of 10 CFR 20.1201(f)

10 CFR 20.1201(f) requires licensees to reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

Prior to the reactive inspection, CHH had not attempted to reduce the occupational dose to AUs 1-5 by the amount of occupational dose AUs 1-5 received at other facilities where they worked with unlicensed sources of radiation. During the inspection, the RSO and AU1 informed the inspector that AUs 1-5 also performed IR procedures at facilities other than those on the CHH license. While procedures were typically less complex than those performed at CHH, AUs 1-5 still received occupational exposure at those facilities. Additionally, AUs 1-5 were listed as AUs on multiple other NRC licenses for activities conducted under 10 CFR 35.100 and 10 CFR 35.200. The inspectors visited another NRC licensee where AUs 1-5 were listed as AUs, and determined that AUs 1-5 did not receive exposure to licensed sources of radiation at that facility, but they did receive exposure to unlicensed sources of radiation. As such, their exposure at CHH should have been reduced by the amount of occupational dose received while working at the other facilities.

This is an apparent violation of 10 CFR 20.1201(f) which requires licensees to reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose they received while employed by any other person.

5.0 Ir-192 Source Incident Follow-up

5.1 Inspection Scope

On December 21, 2021, the NRC virtually met with CHH regarding a notification from the State of Louisiana involving CHH and an Ir-192 source. An onsite inspection was conducted on February 15-16, 2022, to review the incident and to determine if the licensee had conducted their activities in accordance NRC rules, NRC regulations, and the conditions of the license. The inspection included the following elements: facility tours of CHH and the unauthorized location; interviews with CHH personnel, a vendor,

and personnel from the unauthorized location; and reenactments of specific elements of the incident.

5.2 Observations and Findings

Incident Background

On December 21, 2021, NRC Region I was made aware of an incident that was reported to the State of Louisiana involving CHH and the delivery of a Ir-192 source on November 8, 2021. A labor strike began at CHH on November 3, 2021. Prior to the strike, it was determined that some delivery drivers would not cross the strike line to make deliveries. As part of the contingency plan for the strike, a CHH senior manager was tasked with determining how materials would get to the facility during the strike. As a 300-bed hospital, CHH receives hundreds of packages per day including various types of hazardous materials. The senior manager contacted various local businesses and organizations to determine if they would be able to receive packages on behalf of CHH. A verbal agreement was made between CHH management and the management of a local organization for CHH deliveries to be made to the organization's facility while the labor strike was in effect. Once packages were at the alternate location, the local organization's staff would palletize the packages and CHH would retrieve the packages in a box truck. Two of CHH's senior managers stated they considered hazardous materials in their contingency plan; the local organization's management stated they agreed to receive special materials, such as hazardous materials, on behalf of CHH. The contingency plan was not communicated beyond the CHH executive leadership team and the staff that were directly impacted by the change such as the individual assigned to drive the box truck and other supply chain personnel.

Incident Summary

On October 26, 2021, a member of the CHH Radiation Oncology department was sent an electronic letter from Alpha-Omega Services, a State of Louisiana radioactive source manufacturing licensee, stating that an Ir-192 source cable for HDR brachytherapy was scheduled to arrive at CHH on November 8, 2021. On November 8, 2021, the shipper delivered a blue Type A shipping container to the alternate location at the local organization in accordance with the strike contingency plan. The package contained a 10.11 Ci Ir-192 sealed source in special form. The container was left on the exterior dock of the local organization's facility. The local organization's staff found the container on their dock around 9:15 AM. The local organization's staff recognized the radioactive trefoil and called CHH to immediately retrieve the package. While waiting for CHH, a member of the local organization's staff stayed with the package at a distance of approximately 1 meter. CHH staff retrieved the Ir-192 source, along with other packages, secured it on the box truck and drove it to CHH's facility on public highways. Once at CHH, the package was received in accordance with their internal procedures for opening radioactive material and secured until December 10, 2021, when the service provider was onsite to perform the HDR source exchange. The service provider noted that the security tab on the package was missing but that it did not appear that any tampering of the source occurred. Additionally, the shipping papers and packing list were not affixed to the shipping container when the package arrived at the CHH facility.

Based on the circumstances of the incident there was no indication that any members of the public received doses above NRC regulatory limits. Additionally, although the security tab was removed from the shipping container, there was no indication that the source was accessed by anyone other than the authorized service provider on December 10, 2021. It is presumed that the source remained locked within the interior shield of the shipping container during transit and storage. Specifically, the key needed to access the source was not shipped with the source; the key remained secure at the licensee's facility until the service provider arrived.

The inspectors identified four apparent violations regarding the licensee's failure to: (1) provide the RSO with sufficient management prerogative to identify radiation safety problems and stop unsafe operations; (2) possess licensed material only at authorized locations; (3) secure licensed material while not in storage; and (4) comply with DOT regulations while transporting radioactive material. Additionally, the inspectors identified a second example of the licensee's failure to develop and implement a radiation protection program commensurate with the scope and extent of licensed activities.

5.3 Conclusions

Apparent Violation of 10 CFR 35.24(g)

10 CFR 35.24(g) requires licensees to provide the RSO with sufficient authority, organizational freedom, time, resources, and management prerogative to identify radiation safety problems, initiate, recommend, or provide corrective actions, stop unsafe operations, and verify implementation of corrective actions.

Throughout the strike contingency planning, licensee senior management failed to involve the RSO in elements that would impact the radiation protection program. Management did not provide the RSO with sufficient management prerogative to identify radiation safety problems or stop unsafe operation when the contingency plan was developed or implemented. Specifically, through the inspection, the NRC determined that the RSO was not informed of the alternative delivery plan until December 15, 2021. The licensee's management did not include the RSO in the development or implementation of the alternative delivery plan for materials coming into its facility during the labor strike which led to the delivery of an Ir-192 source to an unauthorized location on November 8, 2021. Additionally, while the RSO had a delegation of authority from licensee management, pursuant to 10 CFR 35.24(b) which outlined the RSO's duties and responsibilities, by not involving the RSO in the alternative delivery plan, management circumvented the RSO's ability to fulfil the duties and responsibilities outlined in the delegation of authority. This shows the failure of the licensee to provide the RSO with sufficient management prerogative to identify radiation safety problems or stop unsafe operations.

The licensee's failure to involve the RSO in the contingency planning was identified as an apparent violation of 10 CFR 35.24(g).

Apparent Violation of 10 CFR 30.34(c)

10 CFR 30.34(c) requires that licensees confine their possession and use of byproduct materials to the locations and purposes authorized in the license.

CHH's materials license (NRC License No. 47-00404-02) specifically lists two locations in Huntington, West Virginia, where CHH is authorized to conduct activities, such as possession of Ir-192. The local organization was not an authorized location for CHH to possess Ir-192 or any type of specifically licensed byproduct material. However, on November 8, 2021, CHH possessed a 10.11 Ci Ir-192 source at an unauthorized location when, at the direction of CHH senior management, the shipper delivered the Ir-192 source to a local organization which was not an authorized location for CHH to possess byproduct material.

The licensee's failure to confine their possession and use of byproduct materials to the locations and purposes authorized in the license was identified as an apparent violation of 10 CFR 30.34(c).

Apparent Violation of 10 CFR 20.1802

10 CFR 20.1802 requires that a licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

On November 8, 2021, the licensee failed to control and maintain constant surveillance of a 10.11 Ci Ir-192 source that was not in storage. Specifically, at the licensee's direction, a shipper delivered the Ir-192 source to a local organization's exterior loading dock, where it was unattended by licensee personnel for approximately 90 minutes. The source was unattended for approximately 1 hour and then attended by a member of the public for approximately 30 minutes. CHH created a security vulnerability by diverting the Ir-192 source to the unauthorized location. They risked loss or theft while the source was unattended for an unknown period of time, less than one hour. Further, the source was then attended by the local organization's staff member, who was a member of the public, for approximately thirty minutes.

The licensee's failure to control or maintain surveillance of the licensed material was identified as an apparent violation of 10 CFR 20.1802.

Apparent Violation of 10 CFR 71.5(a)

10 CFR 71.5(a) requires that licensees who transport licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the DOT in Title 49 of the Code of Federal Regulations (49 CFR) Parts 107, 171-180, and 390-397.

On November 8, 2021, CHH failed to comply with multiple requirements of the DOT regulations in 49 CFR Parts 172, 177, and 173. 49 CFR 172.101, radioactive material is classified as hazardous material. Specifically, the following areas of non-compliance were identified:

- 49 CFR 172.702 requires that each hazmat employer shall ensure that each hazmat employee is trained and tested, and that no hazmat employee performs any function subject to the requirements of 49 CFR Parts 171-177 unless trained, in accordance with Subpart H of 49 CFR Part 172. On November 8, 2021, an individual, that had not been trained or tested in accordance 49 CFR Part 172, performed functions subject to the requirements of 49 CFR Parts 171-177.

Specifically, the individual transported 10.11 Ci of Ir-192 from the unauthorized location to CHH on public highways.

- 49 CFR 177.817(a) requires that a person cannot accept hazardous material for transportation or transport a hazardous material by highway unless the person has received shipping papers prepared in accordance with 49 CFR 172.200-203. On November 8, 2021, the licensee transported a 10.11 Ci Ir-192 source from the unauthorized location to CHH without a shipping paper.
- 49 CFR 172.600 (c) states, that no person to whom Subpart G of Part 172 applies may offer for transportation, accept for transportation, transfer, store or otherwise handle during transportation a hazardous material unless emergency response information conforming to this subpart is immediately available for use at all times the hazardous material is present. On November 8, 2021, the licensee transported a 10.11 Ci Ir-192 source from the unauthorized location to CHH without emergency response information accompanying the shipment.
- 49 CFR 173.475 requires that before each shipment of any radioactive materials package, the offeror must insure by examination or appropriate tests, that the external radiation and contamination levels are within the allowable limits in 49 CFR Parts 171-178. On November 8, 2021, the licensee transported a package which contained 10.11 Ci or Ir-192 but failed to determine the non-fixed contamination level prior to transporting it from the unauthorized location to CHH.

The licensee's failure to comply with DOT regulations while transporting radioactive material was identified as an apparent violation of 10 CFR 71.5(a).

Apparent Violation of 10 CFR 20.1101(a)

10 CFR 20.1101(a) requires, in part, that each licensee develop and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with 10 CFR Part 20.

The licensee developed a policy titled "Ordering and Receiving Radioactive Material" on January 15, 2009, and revised the policy last on February 15, 2021. Section 2 states, in part, that the RSO will establish and maintain a system for ordering and receiving radioactive material.

Contrary to the above, as of November 8, 2021, the licensee had not established or maintained a system for ordering and receiving Ir-192 sealed sources. During the inspection, it was determined that multiple individuals were involved in the ordering and receipt of Ir-192 including a contracting individual, radiation oncology leadership, contract medical physicists, PET staff, and supply chain staff. Because the licensee had failed to establish a system for ordering and receiving radioactive materials that are received infrequently, such as Ir-192 sources, the individuals involved in this task were unable describe the process and there was confusion as to who was responsible for certain elements of the process such as managing the purchase order. The lack of defined roles, responsibilities, and actions for ordering and receiving such materials contributed to the delivery of an Ir-192 source to a local organization not authorized on the license, to that source being unattended at the local organization after it was delivered, and to the failure of the RSO and the Radiation Oncology Department at CHH to be aware of that delivery until approximately one month later, when the service provider who was onsite to exchange the Ir-192 source for the HDR unit noticed irregularities in the packaging.

The licensee's failure to fully develop and implement their policy titled "Ordering and Receiving Radioactive Material" was identified as a second example of an apparent violation of 10 CFR 20.1101(a).

6.0 Causal Evaluation

The NRC determined that the most likely root cause of the of the apparent violations was a programmatic breakdown of the licensee's radiation protection program. The licensee failed to develop and implement a radiation protection program commensurate with the scope of their activities which led to the failure to control occupational dose to the regulatory limits and the failure to possess licensed material only at authorized locations. For example, due to the inadequate development and implementation of a radiation protection program, the licensee failed to properly monitor personnel for occupational exposure to radiation, evaluate abnormal dosimetry results, and assess the contribution from outside employment in determining total occupational exposure which led to their failure to control occupational doses to the limits prescribed in 10 CFR 20.1201(a). Additionally, due to the inadequate development and implementation of a radiation protection program, the licensee failed to establish and maintain a system for ordering and receiving radioactive material commensurate with the scope of licensed activities such that a process for ordering and receiving Iridium-192 was not developed.

The NRC determined the most likely cause of the programmatic breakdown of CHH's radiation protection program was a lack of adequate resources and adequate management oversight. This determination was based on a review of RSC meeting minutes, program reviews, internal communications, and personnel interviews (CHH staff, physicians, CHH management, CHH executive management).

The failure to provide adequate resources was evident in the licensee staff's workload, delay in response to requests for information, and inability to implement prompt and comprehensive corrective actions for the apparent violations. The RSO was a consultant RSO that had many responsibilities associated with diagnostic medical physics work and as an RSO for other NRC licensees. The RSO had minimal assistance from other staff. The support that the RSO received was from supervisors and managers of specific departments that had competing priorities and no official responsibility for implementation of the radiation protection program. Aside from Y-90 administrations, the various programs were required to be self-sufficient due to the lack of resources. The RSO was involved in Y-90 administrations due to the complexity of the procedure which included patient dosimetry planning and contamination control.

The failure of CHH management to provide an appropriate level of oversight was indicated by the content of the RSC meetings regarding occupational monitoring and the licensee's diversion of licensed material to an unauthorized location. From 2018 through 2021, a series of RSC meeting discussions were captured, ideas were proposed, and draft policies were discussed in an attempt to address the issue of physician noncompliance with occupational monitoring program requirements with specific focus on the failure to return dosimetry, not the failure to wear dosimetry. No corrective actions were implemented that addressed the licensee-identified deficiencies and no program of greater oversight, scrutiny, or verification was established as a result of these meetings and discussions. Finally, when the licensee diverted incoming shipments to an unauthorized location, the licensee failed to consider whether it was appropriate to divert

hazardous materials to a different location. During the contingency planning, the licensee failed to provide management oversight of the radiation protection program by not considering NRC requirements and license conditions during the planning.

CHH communicated that they believe the root cause for the overexposures was due to high workload and poor use of ALARA engineering controls such as radiation shielding devices by the physicians. The licensee has not performed a root cause analysis for the Ir-192 source incident; however, they have determined that the precipitating factors were the ongoing labor strike and a lack of departmental awareness of the contingency plan. As of April 27, 2022, the licensee had not provided the NRC with a comprehensive root cause or assessment of the causal factors for each of the apparent violations presented by the NRC.

7.0 Corrective Actions

As of April 27, 2022, the licensee had not provided the NRC with comprehensive corrective actions or comprehensive preventative actions for each of the apparent violations. However, they implemented several short-term corrective actions to address the event and incident that occurred. Additionally, they have communicated numerous ideas for long term corrective actions such as creating a new full-time position to assist the RSO with the radiation protection program implementation.

With regard to the occupational exposure monitoring program the licensee implemented the following corrective actions:

- The licensee developed a centralized radiation safety policy titled “Mountain Health Network Comprehensive Radiation Safety Policy” that applies to all CHH facilities. The policy includes instructions on the use of dosimetry, compliance requirements with the licensee’s occupational monitoring program, and additional detail on indicators of improper dosimeter use.
- The licensee developed and assigned an electronic training module to the IR AUs that provides instruction on the proper use of dosimetry.
- For IR procedures, the licensee implemented a time out prior to procedure commencement where all individuals are required to affirm that they are wearing their dosimetry.
- The licensee posted signage on entry points to IR suites indicating that dosimetry is required beyond that point.

With regard to controlling occupational doses to the regulatory limits, the licensee implemented the following corrective and preventative actions:

- AU1 was not permitted to work with licensed material for the remainder of CY2021.
- Leaded gloves were procured and made available for use by practitioners.
- Additional portable lead shielding was ordered and usage of currently available shielding increased.
- The licensee posted signage on CT machines indicating hands should not be placed in the beam.

With regard to possession of licensed material at an unauthorized location, the licensee believed there is a very low risk of recurrence due to the abnormal circumstances of the

labor strike that contributed to the incident. The licensee implemented the following preventative actions:

- The licensee provided in-person instruction to supply chain and security staff instructing them to not transport radioactive material to or from CHH facilities.
- The licensee is in the process of creating an electronic learning module that will be assigned to all staff and communicate that radioactive material is not to be transported to or from CHH facilities by staff.
- The licensee revised their policy titled “Ordering and Receiving Radioactive Material” to include additional communication information and cautions. However, the policy has not been revised to include a system for ordering Ir-192 sources.
- The licensee revised their policy titled “Safety Opening Radioactive Material Packages” to include how to receive Ir-192 sources.

8.0 Independent Radiation Measurements

Independent radiation surveys were conducted at the inspected facilities. The survey results were consistent with the licensee’s postings, the licensee’s results, and applicable regulatory limits. Due to the extended nature of the inspection, the instrumentation had varying calibration dates. All instruments utilized for independent verification were within the proper calibration window at the time of their utilization.

Instrumentation:

Model: RadEye G
Serial Number: 30846
Calibration Expiration: October 12, 2021

Model: RadEye G
Serial Number: 30650
Calibration Expiration: June 28, 2022

Model: Ludlum 2401P
Serial Number: 281358
Calibration Expiration: April 12, 2022

9.0 Conclusions

Through this inspection, 14 apparent violations of NRC requirements were identified. Based on NRC review, five of the apparent violations were related to the programmatic failure of the licensee’s radiation protection program, three of the apparent violations were related to individuals exceeding occupational dose limits, three of the apparent violations were related to the possession of licensed material at an unauthorized location, and three apparent violations were associated with other radiation safety program elements. The first three groups are being considered for escalated enforcement while the last group is not being considered for escalated enforcement. The apparent violations are described in Sections 2, 3, 4, and 5 of the inspection report and presented in Enclosure 2.

As of April 27, 2022, the licensee had not provided the NRC with a root cause, corrective actions, or comprehensive actions to prevent recurrence for all of the apparent violations presented by the NRC. The NRC notes that the licensee performed a root cause

assessment for the overexposure event and has implemented short term corrective actions as described in Sections 6 and 7.

10.0 Exit Meeting

An inspection briefing was held onsite on May 19, 2021, with licensee senior management, to provide a summary of the apparent violations identified as part of the routine inspection as well as a discussion regarding the open items. An inspection briefing was held onsite on November 18, 2021, with senior management, to provide a summary of the apparent violations identified as part of the team inspection as well as a discussion regarding the retrospective dose evaluation. An inspection briefing was held onsite on February 16, 2022, with licensee senior management, to provide a summary of the apparent violations identified during the entire inspection. A final inspection briefing was held virtually on March 23, 2022, to provide an update on NRC in office review.

Upon completion in-office review, a virtual exit meeting was held on April 27, 2022, with senior management to present the inspection findings. The NRC discussed the content of the inspection report, described the NRC's enforcement process, and described the options that are available to the licensee.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

+	Cynthia Adkins, SMMC Accreditation and Clinical Patient Safety Officer
#+*	Jeff Adkins, SMMC Assistant Director of Radiology
	Holly Blatt, CHH Interventional Radiology Nursing Supervisor
	Paul Blom, M.D.
+*	Hoyt Burdick, M.D., Chief Medical Officer
+	Todd Campbell, SMMC Chief Executive Officer
	Larry Dial, Mountain Health Chief Clinical Officer
*	J.K. Fife, CHH Director of Supply Chain
#+	Denise Gabel-Comeau, CHH Director of Quality/Patient
#+*~^	Nancy Godby, CHH Director of Radiology
#*	Angie Hayes, CHH Manager of Radiation Oncology
*	Chris Hoffman, CHH Executive Director of Edwards Comprehensive Cancer Center
#+*	James Kellar, SMMC Director of Radiology
#+*~^	Tim Martin, CHH Chief Operating Officer
#+*~^	James Norweck, RSO
+	Barbara Padgett, SMMC Interventional Radiology Nursing Supervisor
+*~	Tera Patton, Chief Radiological Health State of West Virginia
	James Reynolds, M.D.
*	Raymond Rodebaugh, Ph.D, CHH Chief Medical Physicist
+	Vera Rose, M.D., SMMC Vice President Clinical Services
	Kathy Scaggs, CHH Regulatory Readiness Manager
#+*~^	Tina Shoemaker, CHH NM Supervisor
	Daniel Snavely, M.D.
#	Jill Stevens, SMMC NM Supervisor
#	Abby Wood, Ph.D., CHH Medical Physicist
*	Bill Wright, Radiology Inc. Administrator
+*	Kevin Yingling, M.D., Mountain Health Chief Executive Officer

#	Individual(s) present for onsite inspection briefing on May 19, 2021
+	Individual(s) present for onsite inspection briefing on November 18, 2021
*	Individual(s) present for onsite inspection briefing on February 16, 2022
~	Individual(s) present for remote inspection briefing on March 18, 2022
^	Individual(s) present for remote exit meeting on April 27, 2022

INSPECTION PROCEDURES USED

IP 87103, Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing
IP 87131, Nuclear Medicine Programs, Written Directive Required
IP 87132, Brachytherapy Programs

LIST OF ACRONYMS USED

ALARA: As Low As is Reasonably Achievable
AU: Authorized User
CHH: Cabell Huntington Hospital
Ci: Curie
CT: Computed Tomography
CY: Calendar Year
CPT: Current Procedural Terminology
CTDIvol: Computed Tomography Dose Index volume
DOT: Department of Transportation
Fluoro: Fluoroscopy
HDR: high dose rate remote afterloader
IP: Inspection Procedure
IR: Interventional Radiology
Ir-192: Iridium-192
NM: Nuclear Medicine
NMED: Nuclear Material Events Database
NRC: United States Nuclear Regulatory Commission
PET: Positron Emission Tomography
QTD: Quarter to Date
RSC: Radiation Safety Committee
RSO: Radiation Safety Officer
SMMC: St. Mary's Medical Center
Tc-99m: Technetium-99m
TEDE: Total Effective Dose Equivalent
YTD: Year to Date
Y-90: Yttrium-90
10 CFR: Title 10 of the *Code of Federal Regulations*
49 CFR: Title 49 of the *Code of Federal Regulations*

APPARENT VIOLATIONS

APPARENT VIOLATIONS BEING CONSIDERED FOR ESCALATED ENFORCEMENT

Apparent Violation of 10 CFR 20.1101(a)

10 CFR 20.1101(a) requires, in part, that each licensee develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20.

Section 2 of the licensee's Policy 2-005, "ALARA Policy" (last revised February 15, 2021), which is part of the licensee's radiation protection program, describes the action levels and steps that are to be taken when maximum permissible levels of occupational exposures to radiation are exceeded. Section 2 states, in part, that if a worker exceeds 375 mrem in a quarter (investigation level II), there will be a written investigation as to the cause and methods to prevent a repeat of a level II exposure.

Section 2 of the licensee's Policy 2-010, "Ordering and Receiving Radioactive Material" (last revised February 15, 2021), which is part of the licensee's radiation protection program, states, in part, that the Radiation Safety Officer will establish and maintain a system for ordering and receiving radioactive material.

Contrary to the above, between May 2018 and May 2021, the licensee failed to develop and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20. Specifically, the licensee failed to include in its ALARA Policy provisions to investigate and take action on abnormally low, unused, or unreturned dosimetry. Furthermore, the licensee failed to perform written investigations for level II exposures that evaluated the unique causes and methods to prevent recurrence of level II exposures. Finally, as of November 8, 2021, the Radiation Safety Officer (RSO) failed to establish a system for ordering and receiving infrequently-received radioactive materials, which contributed to the delivery of an Ir-192 source to an unauthorized location and to the failure of the RSO and the Radiation Oncology Department at CHH to be aware of that delivery until approximately one month later.

Apparent Violation of 10 CFR 20.1502(a)(1)

10 CFR 20.1502(a)(1) requires, in part, that each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Contrary to the above, for periods between May 2018 and May 2021, the licensee failed to monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and did not require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a). Specifically, five authorized users of Yttrium-90 whose occupational exposure to licensed and unlicensed sources of radiation exceeded

10 percent of the limits in 10 CFR 20.1201(a) often failed to wear their supplied dosimetry, thereby preventing the licensee from monitoring their occupational exposures.

Apparent Violation of 10 CFR 35.24(g)

10 CFR 35.24 (g) states, in part, a licensee shall provide the Radiation Safety Officer with sufficient management prerogative to identify radiation safety problems and stop unsafe operations.

Contrary to the above, prior to November 8, 2021, the licensee failed to provide the Radiation Safety Officer (RSO) with sufficient management prerogative to identify radiation safety problems or stop unsafe operations. Specifically, the licensee failed to include the RSO in the development and implementation of an alternative delivery plan for radioactive materials during a labor strike, which resulted in a 10.11 Ci Iridium-192 source being delivered to an unauthorized location.

Apparent Violation of 10 CFR 19.12(a)

10 CFR 19.12(a) requires, in part, that all individuals who in the course of their employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) shall be instructed in, and required to observe, to the extent within the workers control, the applicable provisions of NRC regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material.

Contrary to the above, as of November 18, 2021, adult authorized users of Yttrium-90, and who in the course of their employment were likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv), were not instructed in the applicable provisions of NRC regulations and CHH's license for the protection of personnel from exposure to radiation and/or radioactive material. Specifically, the licensee failed to provide adequate instruction on the regulatory requirement for use of dosimeters to five occupational workers, which contributed to their failure to wear dosimetry and the licensee's failure to monitor the workers' exposure to occupational radiation.

Apparent Violation of 10 CFR 20.1201(f)

10 CFR 20.1201(f) requires, in part, that the licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

Contrary to the above, as of November 18, 2021, the licensee failed to reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. Specifically, during 2019, 2020, and 2021, the licensee did not reduce the allowable maximum occupational doses for three adult authorized users of Yttrium-90 by the doses they received at other institutions.

Apparent Violation of 10 CFR 20.1201(a)(2)(ii)

10 CFR 20.1201(a)(2)(ii) requires, in part, that the licensee control the occupational dose to the skin or to any extremity of individual adults to an annual dose limit of 50 rem (0.5 Sv) shallow-dose equivalent.

Contrary to the above, during calendar years 2019, 2020, and 2021, the licensee failed to limit the annual dose to the extremity of an adult authorized user of Yttrium-90 to 50 rem (0.5 Sv) shallow-dose equivalent. Specifically, the licensee concluded that an authorized user received 475 rems shallow-dose equivalent to the hand for the period January 1, 2021, to December 31, 2021; 560 rems shallow-dose equivalent to the hand for the period January 1, 2020, to December 31, 2020; and 571 rems shallow-dose equivalent to the hand for the period January 1, 2019, to December 31, 2019.

Apparent Violation of 10 CFR 20.1201(a)(1)(i)

10 CFR 20.1201(a)(1)(i) requires, in part, that the licensee control the occupational dose to individual adults to an annual dose limit of 5 rems (0.05 Sv) total effective dose equivalent.

Contrary to the above, during calendar years 2019, 2020, and 2021, the licensee failed to limit the annual occupational dose to individual adults to 5 rems (0.05 Sv) total effective dose equivalent. Specifically, one authorized user of Yttrium-90 received an estimated 10.202 rems, total effective dose equivalent, for the period January 1, 2021, to December 31, 2021; 12.051 rems, total effective dose equivalent, for the period January 1, 2020, to December 31, 2020; and 11.670 rems, total effective dose equivalent, for the period January 1, 2019, to December 31, 2019. A second authorized user received an estimated 7.445 rems, total effective dose equivalent, for the period January 1, 2021, to December 31, 2021; 8.062 rems, total effective dose equivalent, for the period January 1, 2020, to December 31, 2020; and 8.490 rems, total effective dose equivalent, for the period January 1, 2019, to December 31, 2019. A third authorized user received an estimated 5.496 rems, total effective dose equivalent, for the period January 1, 2019, to December 31, 2019.

Apparent Violation of 10 CFR 20.1201(a)(2)(i)

10 CFR 20.1201(a)(2)(i) requires, in part, that the licensee control the occupational dose to the lens of the eye of individual adults to an annual dose limit of 15 rems (0.15 Sv) dose equivalent.

Contrary to the above, for calendar years 2019, 2020, and 2021, the licensee failed to limit the annual dose to the lens of the eye of an adult authorized user of Yttrium-90 to 15 rems (0.15 Sv) dose equivalent. Specifically, an authorized user received, to the lens of the eye, an estimated 17.003 rems, dose equivalent, for the period January 1, 2021, to December 31, 2021; 20.085 rems, dose equivalent, for the period January 1, 2020, to December 31, 2020; and 19.449 rems, dose equivalent, for the period January 1, 2019, to December 31, 2019.

Apparent Violation of 10 CFR 30.34(c)

10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct materials to the locations and purposes authorized in the license.

Condition No. 10 of License No. 47-00404-02 requires that licensed material be used or stored only at 1201 Hal Greer Boulevard, 1340 Hal Greer Boulevard, 1400 Hal Greer Boulevard, 1249 15th Street Suite 4000, 2900 First Avenue, and 5170 U.S. Route 60 East in Huntington, West Virginia.

Contrary to the above, on November 8, 2021, the licensee possessed byproduct material at a location in Huntington, West Virginia, that was not authorized in its license. Specifically, on November 8, 2021, at the direction of licensee senior management, a shipper delivered a 10.11 Ci Ir-192 source to a local organization which was not an authorized location for the licensee to possess byproduct material.

Apparent Violation of 10 CFR 20.1802

10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Contrary to the above, on November 8, 2021, the licensee failed to control and maintain constant surveillance of licensed material that was in an unrestricted area and not in storage. Specifically, at the licensee's direction, a shipper delivered a 10.11 Ci Ir-192 source to a local organization's exterior loading dock, where it was unattended by licensee personnel for approximately 90 minutes.

Apparent Violation of 10 CFR 71.5(a)

10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 107, 171-180, and 390-397.

Four examples of the licensee's failure to comply with applicable requirements of the DOT regulations were identified:

(1) 49 CFR 172.702 requires that each hazmat employer shall ensure that each hazmat employee is trained and tested, and that no hazmat employee performs any function subject to the requirements of 49 CFR Parts 171-177 unless trained, in accordance with Subpart H of 49 CFR Part 172.

Hazmat employer, as defined in 49 CFR 171.8, includes a person who employs or uses at least one hazmat employee and who transports hazardous materials in commerce or causes hazardous materials to be transported in commerce. Hazmat employee, as defined in 49 CFR 171.8, includes a person who is employed by a hazmat employer and

who in the course of that employment directly affects hazardous materials transportation safety.

49 CFR 172.101 designates radioactive material as a hazardous material for purposes of transportation.

Contrary to the above, on November 8, 2021, the licensee, a hazmat employer, failed to provide training for its hazmat employees as required by Subpart H to 49 CFR Part 172. Specifically, the licensee transported an Iridium-192 source from a local organization's facility to the licensee's facility using personnel who had not received hazmat training.

(2) 49 CFR 177.817(a) states that a person may not accept hazardous material for transportation or transport a hazardous material by highway unless it is accompanied by shipping papers prepared in accordance with 49 CFR 172.200-203.

49 CFR 172.101 designates radioactive material as a hazardous material for purposes of transportation.

Contrary to the above, on November 8, 2021, the licensee transported an Iridium-192 source by highway without a shipping paper. Specifically, the licensee transported an Iridium-192 source on public highways from a local organization's facility, which was not an authorized location on the license, to the licensee's facility without a shipping paper.

(3) 49 CFR 172.600(c) states, in part, that no person to whom Subpart G of Part 172 applies may offer for transportation, accept for transportation, transfer, store or otherwise handle during transportation a hazardous material unless emergency response information conforming to this subpart is immediately available for use at all times the hazardous material is present

Contrary to the above, on November 8, 2021, the licensee transported an Iridium-192 source outside the confines of the authorized locations on its license without emergency response information to accompany the shipment. Specifically, the licensee transported an Iridium-192 source by public highway from a local organization's facility to the licensee's facility without emergency response information accompanying the shipment.

(4) 49 CFR 173.475 requires, in part, that before each shipment of any Class 7 (radioactive) materials package, the offeror must ensure, by examination or appropriate tests, that the external radiation and contamination levels are within the allowable limits in 49 CFR Parts 171-178.

Contrary to the above, on November 8, 2021, the licensee transported a radioactive materials package without first examining or conducting appropriate tests on the package to ensure external radiation and contamination levels were below applicable limits. Specifically, the licensee failed to determine the non-fixed contamination level for an Iridium-192 source prior to transporting the source from a local organization's facility that was not an authorized location on the license to the licensee's facility.

APPARENT VIOLATIONS NOT BEING CONSIDERED FOR ESCALATED ENFORCEMENT

Apparent Violation of 10 CFR 35.92

10 CFR 35.92 states, in part, that a licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding.

Contrary to the above, on January 18, 2021, and April 22, 2021, the licensee monitored byproduct material at the surface before disposal, determined that its radioactivity could be distinguished from background radiation level, and then disposed of the byproduct material without further decay-in-storage. Specifically, on both occasions, the licensee monitored Yttrium-90 waste at the surface before disposal, determined that its radioactivity was greater than background, and disposed of the Yttrium-90 waste. On January 18, 2021, the survey result was 0.03 mR/hr and on April 22, 2021, the survey result was 0.04 mR/hr while background was 0.02 mR/hr on both occasions.

Apparent Violation of Condition 14 of License No. 47-00404-02

Condition 14 of License No. 47-00404-02 requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the application dated January 23, 2013 for St. Mary's Hospital and application dated July 29, 2013, for Cabell Huntington Hospital.

The applications dated January 23, 2013, and July 29, 2013, both state, in part, that the following emergency equipment for the HDR unit shall be readily available at all times: two pairs of long handled locking forceps, shielding container, heavy-duty wire cutters, emergency personnel dosimeters, portable survey meter, stop watch or timer, and tape measure.

Contrary to the above, on May 18, 2021, at St. Mary's Hospital and on May 19, 2021, at Cabell Huntington Hospital, the licensee failed to conduct its program in accordance with statements, representations, and procedures contained in the applications dated January 23, 2013, and July 29, 2013. Specifically, the licensee did not have two pairs of long handled locking forceps, heavy-duty wire cutters, or a tape measure readily available at either location.

Apparent Violation of 10 CFR 35.633(a)(2)(i)

10 CFR 35.633(a)(2)(i) states, in part, that a licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit before medical use following replacement of the source. 10 CFR 35.633(b)(6) states, in part, that to satisfy the requirements of paragraph (a) of this section full calibration measurements must include determination of length of the transfer tubes and length of the applicators.

Contrary to the above, prior to April 27, 2021, the licensee was authorized to use a remote afterloader unit for medical use and failed to perform full calibration measures that included determination of length of the transfer tubes and length of the applicators. Specifically, the licensee measured the diameter of the applicator for each treatment but failed to determine the length of the transfer tubes and length applicator as part of their full calibration measurements.

Factual Summary of NRC Office of Investigations Case No. 1-2021-015

On June 21, 2021, the U.S. Nuclear Regulatory Commission (NRC), Office of Investigations (OI), Region I, initiated an investigation to determine whether two interventional radiologists (IRs) who were authorized users of Yttrium-90 (Y-90) at Cabell Huntington Hospital (Cabell or the licensee) deliberately failed to wear their supplied dosimetry when administering Y-90, and whether the Radiation Safety Officer deliberately failed to require interventional radiologists to wear their dosimetry. The investigation arose out of a May 2021, NRC inspection at Cabell, during which the NRC inspector learned that some IRs had not been wearing their dosimetry during Y-90 procedures. The investigation was completed on December 22, 2021, and was documented in the subject OI report.

Cabell is a materials licensee authorized to use of Yttrium-90 (Y-90) at two facilities, Cabell and St. Mary's Medical Center. Cabell is authorized to possess and use Y-90 at both facilities as permitted by 10 CFR 35.1000. IR1 and IR2 are board-certified radiologists who are listed as authorized users (AUs) for Y-90 on CHH's license.[1]

Section 3.4.2 of CHH's "Radiation Safety Policy Procedure Y-90 Microsphere Therapy" (RSPP for Y-90) states that "[a]ll personnel will wear radiation dosimeters" and that "[p]ersonnel who handle radioactive materials must wear an extremity dosimeter in the maximally exposed location." The RSO confirmed during the OI investigation that physicians who use Y-90 are issued both a radiation dosimeter (whole-body dosimeter) as well as a ring dosimeter, and that the dosimeters are collected and read monthly.

The RSO told OI that he had observed IR1 and IR2 not wearing dosimetry during Y-90 procedures and that he had verbally reminded them about wearing dosimetry after some of those procedures. The RSO also told OI that he had sent memos to IRs stressing the importance of wearing dosimetry, but the licensee could not verify that the IRs had received or read the memos. IR1 and IR2 both acknowledged to OI that they failed to comply with the requirement to wear dosimetry during the 2018 through April 2021 timeframe.

IR1 stated during his OI interview that he was aware during the 2018-2021 time period of the requirement to wear dosimetry during Y-90 procedures. IR1 also acknowledged receiving training on the requirement during residency and reminders from the RSO during his time at Cabell. IR1 claimed that he sometimes wore dosimetry and that when he failed to do so the reason was inattention or forgetfulness. However, IR1's dosimetry records indicate that he had not worn his dosimetry at all, at either Cabell or St. Mary's, from 2018 through April 2021.

IR2's dosimetry records indicate that he seldom wore dosimetry at Cabell or St. Mary's from 2018 through April 2021. IR2 told OI that he believed prior to May 2021 that wearing dosimetry was recommended, but not required. IR2 acknowledged receiving reminders from the RSO for about a year that they needed to wear dosimetry, but stated

[1] In NRC Inspection Report No. 03003370/2021001, IR1 corresponds to AU 3 and IR2 corresponds to AU 1.

that he viewed the reminders as a recommendation for his personal safety. IR2 also stated that a reason he did not wear dosimetry at the time was concern about having to stop working if he exceeded occupational dose limits, and that if dosimetry was only a recommendation, he was not going to do it if he would be unable to provide care for his patients.

Based on the evidence obtained through the OI investigation, it appears that IR1 violated 10 CFR 30.10(a)(1) by deliberately failing to wear required dosimetry while performing Y-90 administrations. IR1's failure to wear dosimetry appears to have caused Cabell to be in violation of 10 CFR 20.1502(a)(1). In addition, IR2's failure to wear dosimetry and the RSO's inability to enforce the wearing of dosimetry, although apparently not willful, also appear to have caused Cabell to be in violation of 10 CFR 20.1502(a)(1).