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

October 6, 2023

Tim Martin, MBA, ACHE
Chief Operating Officer
Cabell Huntington Hospital
1340 Hal Greer Boulevard
Huntington, WV 25701-0195

SUBJECT: NRC INSPECTION REPORT 030-03370/2023-001 AND NOTICE OF VIOLATION

Dear Tim Martin:

This letter refers to the announced inspection conducted onsite from July 18-20, 2023, at your facilities in Huntington, West Virginia, with in-office review through September 1, 2023. The inspection was an examination of activities conducted under your license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's rules, regulations, and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel. The preliminary inspection findings were discussed with you and your staff following the conclusion of the onsite portion of the inspection on July 20, 2023. A final exit briefing was conducted telephonically with you and representatives of your staff on September 7, 2023. The enclosed reports present the results of the inspection (Enclosure 2).

While the inspection acknowledged and reviewed your current compliance with requirements associated with the violations identified in the NRC Inspection Report 030-03370/2021-001, this report does not address your compliance with the resulting Order (EA-22-003). Your compliance with the Order will be dispositioned in a separate correspondence under a parallel inspection effort (NRC Inspection Report 030-03370/2023-002).

Based on the results of the inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy, which can be found at the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation is cited and described in the enclosed Notice of Violation (Notice) (Enclosure 1) because it was identified by the NRC during the inspection. The violation involved the failure to administer diagnostic nuclear medicine dosages within the range prescribed by an Authorized User.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance will be achieved is already adequately addressed on the docket in the enclosed inspection report. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter, its enclosures, and your response, should you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room located at NRC Headquarters in Rockville, MD, and from the NRC's document system, the 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 or proprietary information so that it can be made available to the Public without redaction.

If you have any questions concerning this matter, please contact Mr. Jason vonEhr of my staff at (610) 337-5256, or the undersigned at (610) 337-5078.

Sincerely,

Anne E. DeFrancisco

Digitally signed by Anne E. DeFrancisco
Date: 2023.10.06 07:26:39 -04'00'

Anne DeFrancisco, Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

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

Enclosures:
1. Notice of Violation
2. NRC Inspection Report 030-03370/2023-001

cc:
Tera Patton, State of West Virginia

NRC INSPECTION REPORT 030-03370/2023-001 AND NOTICE OF VIOLATION – DATED OCTOBER 6, 2023.

Distribution:
P. Krohn, DRSS, RI
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K. Trotter, NRAN
B. Klukan, RI
R1Enforcement
Region I OE Files (with concurrences)

ADAMS ACCESSION NUMBER:

☒SUNSI Review: By: JEV	ADAMS: ☒ Yes ☐ No	☐ Non-Publicly Available ☒ Publicly Available	☒ Non-Sensitive ☐ Sensitive	Keyword: N/A

OFFICE	RI:DRSS	RI:DRSS	RI:DRSS	RI:DRSS		
NAME	VStowell	KTrotter	JvonEhr	ADeFrancisco		
SIGNATURE	VAS	KRT	JEV	AED		
DATE	10/02/23	10/03/23	10/03/23	10/04/23		

OFFICAL RECORD COPY

NOTICE OF VIOLATION

Cabell Huntington Hospital
Huntington, WV

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

During a routine inspection conducted on July 18-20, 2023, with in-office review through September 1, 2023, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 35.63(d) requires that, unless otherwise directed by an Authorized User, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.
>
> Contrary to the above, on numerous occasions between April 20, 2023, and July 19, 2023, the licensee failed to ensure that dosages were not used when they did not fall within the prescribed dosage range or if the dosage differed from the prescribed dosage by more than 20 percent, and the dosage or dosage range was not otherwise directed by an Authorized User. Specifically, in at least 45 instances identified by the NRC between April 20, 2023, and July 19, 2023, the licensee administered dosages which were not within the prescribed dosage range and were not otherwise directed by an Authorized User at three of its facilities in Huntington, West Virginia.
>
> This is a Severity Level IV violation (NRC Enforcement Policy Section 6.3.d.3).

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance will be achieved is already adequately addressed on the docket in the enclosed inspection report (Enclosure 2). Therefore, you are not required to respond unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be made available electronically for public inspection in the NRC Public Document Room and on the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, it should, therefore, not include any personal privacy or proprietary information so that it can be made publicly available without redaction.

If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal

privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 6th day of October 2023.

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Docket:	030-03370
License:	47-00404-02
Report:	2023-001
Licensee:	Cabell Huntington Hospital
Locations Inspected:	Cabell Huntington Hospital, 1340 and 1400 Hal Greer Boulevard, Huntington, WV St. Mary's Medical Center, 2900 First Avenue, Huntington WV, and Marshall Cardiology Erma Ora Byrd Clinical Center, 1249 15th Street, Suite 4000, Huntington, WV
Inspection Dates:	July 18-20, 2023, with in-office review through September 1, 2023

Inspectors: *Jason vonEhr* 10/03/2023
Jason vonEhr, Senior Health Physicist — Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Valerie Stowell 10/02/2023
Valerie Stowell, Health Physicist — Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Approved By: *Anne DeFrancisco* 10/06/2023
Anne DeFrancisco, Chief — Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Attachment: Supplemental Inspection Information

Table of Contents

EXECUTIVE SUMMARY

Cabell Huntington Hospital
NRC Inspection Report 030-03370/2023-001

An announced routine inspection and escalated enforcement follow-up was performed of Cabell Huntington Hospital on July 18-20, 2023, with in-office review through September 1, 2023. The inspection was an examination of activities conducted under the license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules, regulations, and with the conditions of the license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel.

While the inspection acknowledged and reviewed the current compliance with requirements associated with the violations identified in the NRC Inspection Report 030-03370/2021-001 (Section 4), this report does not address the licensee's compliance with the resulting Order (EA-22-003). The compliance with the Confirmatory Order will be addressed in a separate NRC correspondence under a parallel and ongoing inspection effort (NRC Inspection Report 030-03370/2023-002). The violations from 2021 are not considered closed, with the exception of those violations which were not considered for escalated enforcement, as they are not part of the Confirmatory Order (Section 4).

Program Overview

Cabell Huntington Hospital is authorized by the NRC Materials License 47-00404-02 to use sealed and unsealed byproduct material for medical use, including diagnostic and therapeutic uses authorized by Title 10 of the *Code of Federal Regulations* 35.100-400, 35.600, and 35.1000. Storage and use of NRC-licensed byproduct materials was authorized at the licensee's facilities in Huntington and Point Pleasant, West Virginia. (Section 1)

Inspection Findings

One Severity Level IV violation of NRC requirements was identified. The violation involved the failure to administer diagnostic nuclear medicine dosages within the range prescribed by an Authorized User. (Section 3)

Corrective Actions

Cabell Huntington Hospital committed to and began implementing several actions both to address the immediate failure as well as some of the contributing factors. These actions included:

- Immediate communications to staff reminding staff of the underlying requirement and associated licensee policy and procedure;
- Development of refresher training to incorporate reminders to staff of the requirement;
- Revising the master exam list for the nomenclature for nuclear medicine studies; and
- Developing a single corporate-wide dose protocol that will apply to all facilities and ensuring clarity in the isotope, drug, and permissible activity or activity range.

Together, these actions appear to address the violation, and thus provide a basis for confidence that the licensee can prevent recurrence of the violation. (Section 3.2.7)

REPORT DETAILS

1. Program Overview

Cabell Huntington Hospital (CHH) was authorized by the U.S. Nuclear Regulatory Commission (NRC) Materials License 47-00404-02 to use sealed and unsealed byproduct material for medical use, including diagnostic and therapeutic uses authorized by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.100-400, 35.600, and 35.1000. Storage and use of NRC-licensed byproduct materials was authorized at the licensee's facilities in Huntington and Point Pleasant, West Virginia.

The license was amended nine times since the last routine inspection (performed in three phases from May 10, 2021, through February 16, 2022). Amendments 75, issued May 17, 2021, through Amendment No. 83, issued February 28, 2023, was limited to the addition and removal of Authorized Users (AUs) and Authorized Medical Physicists (AMPs), or the expansion of their associated authorizations. The exception to this was Amendment No. 80, issued September 30, 2022, which merged Pleasant Valley Hospital, previously licensed under NRC License No. 47-17286-01, into the CHH NRC license.

2. Summary of NRC Inspection Report 030-03370/2021-001

The NRC's inspection efforts related to the routine inspection performed in May 2021, with two further reactive inspection efforts in November 2021 and February 2022, were collectively documented in the NRC's inspection report issued on June 22, 2022 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML22173A063[1]). The inspection report described fourteen apparent violations of NRC requirements. The apparent violations were assembled into four groups which are described below.

Group 1 - Apparent violations associated with the development and implementation of the radiation protection program, which involved the apparent 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;
- 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 millirem 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; and

[1] NRC Agencywide Documents Access and Management System (ADAMS) Accession Numbers listed in this report may be accessible using the hyperlink below with the associated ADAMS Accession Number inserted in place of the "ML" at the end. https://www.nrc.gov/docs/ML

- 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.

Group 2 - Apparent violations associated with the apparent failure to control occupational dose to individuals working under the CHH license, which involved the apparent 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; and
- Control the occupational dose to the lens of the eye of individual adults to an annual dose limit of 15 rem dose equivalent.

Group 3 - Apparent violations associated with the possession of licensed material at an unauthorized location and its associated deficiencies, which involved the apparent 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; and
- Comply with the applicable requirements of the Department of Transportation regulations appropriate to the mode of transport.

Group 4 - Apparent violations that were not considered for escalated enforcement, which included the apparent failures to:

- Monitor and dispose of short-lived byproduct material in accordance with the decay-in-storage requirements;
- Possess and maintain emergency response equipment for the High Dose Rate Afterloader (HDR); and
- Perform an element of the full calibration measurements for the HDR.

Following the issuance of the above-described findings, the licensee engaged in alternative dispute resolution with the NRC. This process successfully concluded and the results of which were documented in a Confirmatory Order (hereafter: Order) issued on November 10, 2022 (ADAMS Accession No. ML22313A116). This Order described legally binding actions for CHH along with timelines and junctures for NRC review and approval of select CHH actions. The NRC's terms and conditions included that the apparent violations described in the June 22, 2022, were described as violations, but were not issued in a separate Notice of Violation, and that one of these violations was determined to involve willfulness (Group 1, Bullet 2, above).

3. Observations and Findings – Routine Inspection

3.1. Inspection Scope

The scope of the routine inspection included an examination of activities conducted under the NRC license as they relate to public health and safety, to confirm compliance with the NRC's rules, regulations, and with the conditions of the CHH license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel.

3.2. Observations and Findings

This inspection included observations at several CHH facilities, including the two primary locations of NRC-licensed activities: the Cabell Huntington Hospital located at 1340 and 1400 Hal Greer Boulevard, Huntington, West Virginia, and St. Mary's Medical Center located at 2900 First Avenue, Huntington, West Virginia. In addition, the inspection included observations at the Marshall Cardiology at Cabell Huntington Hospital, Erma Ora Byrd Clinical Center at 1249 15th Street, Huntington, West Virginia.

The inspectors toured all areas where licensed material was used at the above-described facilities and observed the following activities: package receipt, dose calibrator quality control, dose preparation, dose administration, patient interaction, radiation surveying, and waste management. Additionally, independent confirmatory surveys were performed and found to be consistent with licensee postings and within regulatory limits.

The Pleasant Valley Hospital located at 2520 Valley Drive, Point Pleasant, West Virginia was recently merged into the CHH license (Amendment No. 80, issued September 30, 2022). However, this facility was recently inspected by the NRC prior to this license merger. This inspection occurred on July 18, 2022, and concluded with no violations identified. The licensed activities at this facility were limited to nuclear medicine operations under 10 CFR 35.100 and 200.

3.2.1. Licensee Oversight

The radiation safety program operated under the direction of a Radiation Safety Committee (RSC). While the scope and implementation of its oversight mission by the RSC has changed significantly since the last inspection, the review of the RSC charter and the implementation of this charter are associated with the NRC's parallel inspection effort reviewing the licensee's compliance with the Order. Nonetheless, the RSC appeared to be well-attended, with representation from each of the different physical facilities (as committed to by the licensee in recent letters tied to the license via License Condition 14) and from each medical modality addressed in 10 CFR Part 35. Given the extensive breadth of the program, the licensee organized sub-committees to address more specific program areas with commensurate attention, such as dosimetry.

The consultant Radiation Safety Officer (RSO) for the license was assisted by a full-time Assistant RSO. The two individuals provided direct and indirect oversight, with some program areas having more autonomy and other program areas having direct involvement by the RSO or Assistant RSO.

3.2.2. Diagnostic Nuclear Medicine Program

The nuclear medicine and positron emission tomography (PET) programs were inspected at Cabell Huntington Hospital, St. Mary's Medical Center, and Marshall Cardiology. Records reviews included the two further licensed locations of use (Pleasant Valley Hospital and the Cabell Surgery Center). The three physical locations with onsite inspection activities represent five of the seven nuclear medicine groups/departments performing activities under the NRC licensee. Cabell Huntington Hospital had one nuclear medicine department and one PET while St. Mary's had a general nuclear medicine department and dedicated cardiac nuclear medicine department, and Marshall Cardiology was limited to a cardiac nuclear medicine department.

The most routinely used radionuclides included technicium-99m and flourine-18. While other lesser-used radionuclides were available and approved for use, only iodine-123 appeared with any regularity over the preceding months of licensed activities across the reviewed facilities. Each department had an average of ten administrations per day of operation, with busier days seeing closer to twenty administrations in a single day.

The inspectors observed multiple instances where nuclear medicine technologists received packages, performed quality assurance/quality control checks, and prepared dosages for administration. When time allowed, staff and supervisors were interviewed and all were knowledgeable about licensee processes and procedures. Postings and required NRC forms around the hot labs and administration areas were deemed adequate. No issues were identified outside of a single violation described below in Section 3.2.8.

3.2.3. Therapeutic Nuclear Medicine Program

The nuclear medicine's unsealed radioactive material therapeutic program was inspected at Cabell Huntington Hospital and St. Mary's Medical Center, the only two locations authorized for these activities. The CHH program used radium-223 Xofigo and iodine-131 most frequently. The staff and supervisors that were interviewed were knowledgeable of the program's policies and procedures. Patient administrations across the licensed facilities averaged a 5-10 administrations per quarter between Xofigo and iodine. A sample of recent administrations' documentation, including written directives and patient release calculations, were reviewed and found adequate. The licensee staff walked through the processes with the inspectors from referral, ordering, receipt, administration, and discharge of patients, with no issues of concern identified.

3.2.4. Manual Brachytherapy Program

The NRC license authorized manual brachytherapy program only at St. Mary's Medical Center. The inspectors reviewed the program at this facility with knowledgeable staff and physicians. The activities performed under this program were limited to two cases performed since the last NRC inspection. The licensee had no plans to discontinue this program.

The two procedures that were completed were reviewed from initial referral, treatment planning and dose mapping, seed determination, ordering, and receipt, written directive approval, administration, and release of the patient. The inspectors observed and

performed surveys of the room where excess seeds were stored. Postings and signage were found to be adequate.

The inspectors interviewed with staff, supervisors, AMPs, and an AU who were involved in the performance of the administrations. The inspectors discussed best practices with regards to medical event identification within the program. No issues were identified across the manual brachytherapy program.

3.2.5. High Dose Rate Afterloader Program

Under this NRC license, St. Mary's Medical Center and Cabell Huntington Hospital were each authorized for their own HDR programs. While on site, the inspectors conducted personnel interviews, performed records reviews, and observed both actual and simulated patient treatment processes. The inspectors reviewed records such as written directives, patient treatment plans, HDR calibrations, and daily spot checks for both locations.

At St. Mary's Medical Center, no patients were scheduled during the onsite inspection period. Therefore, the licensee demonstrated a walkthrough of patient treatment steps and daily spot checks for the inspectors. The inspectors verified the availability of emergency response equipment and the security of the device and keys to the console and device. Confirmatory surveys were consistent with the licensee's results and postings were appropriate.

At Cabell Huntington Hospital, one patient was scheduled to receive a treatment during the inspection period. A daily spot check was performed using the HDR unit prior to patient treatment. The inspectors were able to observe the treatment after receiving consent from the patient. Both an AU and AMP were present for the duration of the patient treatment, and a post-treatment survey was performed. Emergency response equipment was available within the HDR room, and emergency procedures were posted by the operating console. Signs and postings for the suite were found to be adequate and commensurate with the associated radiation hazard. No issues or items of concern were identified with respect to the licensee's HDR program.

3.2.6. Yttrium-90 Microsphere Program

The NRC license granted authorization to use yttrium-90 microspheres, both Nordion Model TheraSpheres and Sirtex Medical Limited Model SIR-Spheres, at both the Cabell Huntington Hospital facility and St. Mary's Medical Center. The inspectors reviewed the licensee's microsphere program with staff and physicians. This review included patient referral, treatment planning, ordering and receipt of the radioactive material, manipulation (in the case of SIR-Spheres), administration, and patient release. Surveys were performed of the patient and the residual microspheres. Medical event criteria was reviewed and no reportable medical events occurred. Written directives were sufficiently detailed, staff were knowledgeable of licensee policies and manufacturer procedures, and the cases were well-documented.

A sample of cases performed since the last inspection were reviewed at both of the authorized facilities, with no concerns or issues identified.

3.2.7. Violation of 10 CFR 35.63(d)

In the course of the NRC's July 2023 inspection, one violation of NRC requirements was identified. The violation concerned the use of dosages that were either administered outside of the AU-approved dosage range or greater than 20 percent outside of AU-approved dosage, contrary to 10 CFR 35.63(d).

During the NRC inspection, an NRC inspector traveled to Marshall Cardiology, one of the satellite facilities authorized on the CHH license. The inspector noted multiple instances in a limited sampling of prior administrations where dosages were recorded as administered to patients outside of the associated cardiac study dosage range. Based on interviews, some staff at the facility appeared to have an incorrect understanding of the NRC's regulation in that they believed that the dose protocol included a 20 percent acceptability range beyond the AU-approved dosage range, rather than the regulation's language, which in contrast provides for a dosage range or a 20 percent acceptability range.

The inspectors performed an extent-of-condition review of recent administrations across all of CHH's facilities, including an expanded review of the initial facility, to identify whether this issue was limited to one facility and how frequent the instances were. This included a 100 percent review of nuclear medicine administrations, both PET and general nuclear medicine, for the prior four months. The inspectors found some instances at Cabell Huntington Hospital nuclear medicine and PET departments (representing approximately less than one percent of total number of administrations over the reviewed period) and at St. Mary's Medical Center (representing approximately one percent of administrations). No instances of noncompliant dosages were identified at the Pleasant Valley Hospital or the Cabell Surgery Center. At least 40 instances of noncompliant dosages were positively identified at Marshall Cardiology representing approximately 10 percent of administrations.

It is critical to note that during this review, only a single instance (a PET dosage) was identified where a dosage was recoded as beyond 20 percent from the approved dosage range. In this single instance a dosage of 6.17 millicuries of gallium-68 was assayed and recorded as administered, whereas the approved range for this study was between 2 and 4.5 millicuries. Given the limited radiation exposure associated with diagnostic nuclear medicine studies, no patient harm is believed to have resulted from these noncompliant dosages.

The inspectors noted that the records system inhibited a full and accurate independent review at the time of the inspection by the nature of the way the nuclear medicine studies were recorded, the way the acceptable protocols were documented, and the diversity of protocols across the multi-facility CHH license. Some examples of this included the labeling of studies in the exam master list which did not always have sufficient information to differentiate whether a study was a cardiac rest test versus a cardiac stress test, potential confusion to the acceptable radioactive 'tag' or drug of use in the master protocol list, and the fact that the multiple facilities (merged over the last few years into a health system) retained independent protocol lists, often with differing acceptable dosages.

In addition, a specific diagnostic protocol with a large range of acceptability was noted and CHH staff retrieved and reviewed the original approval for this study and determined

that a typo in the placement of the decimal point in the protocol's acceptability range appeared to allow for a far lower acceptable activity than the original approval. In a second example, one of the satellite facilities on the CHH license had its single study incorporated into the Cabell Huntington Hospital protocol list, but it did not provide for what the tagging agent or drug would be for that study (using the facility name in place of this information), and the dosage range for this facility differed from the Cabell Huntington Hospital dosage range for the same study.

Finally, it was noted that, while in the second example above there were two facilities on the same dosage protocol, other facilities (e.g. St. Mary's Medical Center) had their own separate and independent dosage protocol. The inspectors noted that there is no regulatory requirement for these elements, as the dosage protocols need only be approved by a sufficiently credentialed AU. Nonetheless, the inspectors observed an instance when a first-of-a-kind study was performed at one CHH facility (St. Mary's Medical Center) for which no dosage protocol could be identified at this facility. Yet a dosage protocol did exist for the nuclear medicine department at Cabell Huntington Hospital for this same diagnostic study. Note: the administration at St. Mary's Medical Center was within the Cabell Huntington Hospital protocol's dosage range, and therefore was deemed compliant.

As a result of the instances identified above where dosages were administered to patients outside of the acceptable dosage range or beyond 20 percent of an approved dosage, a violation of 10 CFR 35.63(d) was identified. The violation is identified and described in the enclosed Notice of Violation (Enclosure 1).

The licensee has committed to and begun implementing several corrective actions:

- Immediate communications to staff reminding staff of the underlying requirement and associated CHH policy and procedure;
- Development of refresher training to incorporate reminders to staff of the requirement;
- Revising the master exam list for the nomenclature for nuclear medicine studies; and
- Developing a single corporate-wide dose protocol that will apply to all facilities and ensuring clarity in the isotope, drug, and permissible activity or activity range.

3.3. Conclusions

The NRC inspection identified one violation of greater-than-minor significance related to the licensee's implementation of its nuclear medicine dosing protocol. Specifically, this violation dealt with numerous instances identified in the period from April 20, 2023, and July 19, 2023, in which diagnostic nuclear medicine dosages were administered outside the dosage range approved by an AU. This violation is described in the accompanying Notice of Violation (Enclosure 1).

4. Observations and Findings – Escalated Enforcement Review

4.1. Inspection Scope

The second portion of the 2023 inspection consisted of a review of the licensee's current compliance with the regulations and license commitments associated with violations during the NRC's last inspection and described in the NRC's communications dated June 22, 2022, and November 10, 2022.

The 2021 inspection resulted in fourteen findings, grouped into four functional areas as described in Section 2 of this report. The NRC's final review and, if appropriate, closure of the first three groups of violations associated with the 2021 inspection findings will be part of the NRC's parallel and ongoing inspection effort (NRC Inspection Report 030-03370/2023-002). The review completed during the July 2023 inspection is described below for each of the four functional areas.

4.2. Group 1: Violations Associated with the Radiation Protection Program

The 2021 inspection identified five violations associated with CHH's development and implementation of its radiation protection program. These included violations against 10 CFR 20.1101(a), 10 CFR 20.1502(a)(1), 10 CFR 35.24(g), 10 CFR 19.12(a), and 10 CFR 20.1201(f).

4.2.1. Review of Violation of 10 CFR 20.1101(a)

Regarding the licensee's radiation protection program under 10 CFR 20.1101(a), the NRC's 2021 inspection described the CHH written ALARA (As Low As Reasonably Achievable) Policy and CHH's failures to implement portions of this policy as it pertained to occupational exposure investigations as well as CHH's failure to develop a sufficient program to investigate abnormally low, unused, or unreturned dosimetry. The NRC's 2023 inspection reviewed the licensee's RSC meeting records, including the sub-committee devoted to dosimetry, discussed its scope, review, and practices with committee members, interviewed radioactive materials users, and performed an independent review of staff and physician occupational exposure records, including ALARA investigations for staff involved in NRC-licensed activities.

The licensee expanded existing processes and created new processes to manage the approximately 2,500 badged employees (only a small fraction of which work directly with or in proximity to NRC-licensed activities). CHH delegated many reviews down to supervisor or managerial level staff, who better understand the scope and frequency of work of the applicable staff or physician. In the sample review, records were complete and investigations well documented. No overexposures were identified by CHH or by the NRC inspectors. The inspectors reviewed dosimetry results for staff and physicians involved with high-exposure activities, each of which had satisfactory explanations and were within regulatory requirements. Both the licensee's RSC and sub-committee were empowered to question and review results presented.

While not specifically discussed in terms of the licensee's established radiation protection program, the NRC's 2021 inspection identified the apparent gap in that CHH had not attempted to determine the occupational exposure of five physicians as a result

of occupational duties occurring outside of the CHH license. This is discussed below in Section 4.2.5.

No substantial and systematic programmatic weaknesses were identified. The inspectors provided feedback and best practices for the licensee's consideration, such as the relatively limited scope and depth of the investigations into abnormal dosimetry results. Overall, no regulatory non-compliances were identified.

4.2.2. Review of Violation of 10 CFR 20.1502(a)

The second violation associated with this group of violations involved 10 CFR 20.1502(a): the licensee's failure to monitor occupational exposure from licensed and unlicensed sources under of radiation the control of the licensee and to supply and require the use of individual monitoring devices (dosimeters). In one of the instances identified, the NRC determined the violation to be willful. This violation was closely related to the violation involving 10 CFR 20.1101(a). In the course of the NRC's 2023 inspection, staff and physicians in appropriate functional areas were observed using dosimeters throughout the facilities during the NRC's inspection. The inspectors interviewed nuclear medicine staff, physicians, supervisors, and managers to gain an understanding of dosimeter use and practices. CHH implemented new steps in its 'timeout' process for interventional radiology, a functional area central to the 2021 occupational exposure findings, to verify the use of dosimeters by all participants. In addition, the licensee engaged in a series of independent audits and spot-checks by radiation support staff to double-check the use of dosimeters in this area. Overall, no regulatory non-compliances were identified.

4.2.3. Review of Violation of 10 CFR 35.24(g)

The third violation associated with this group of violations involved 10 CFR 35.24(g): the licensee's failure to provide the RSO the sufficient authority, organizational freedom, time, resources, and management prerogative as it concerns matters of radiation safety and regulatory compliance. Specifically, CHH senior management failed to involve the RSO in important aspects related to a labor strike, ultimately circumventing the RSO's ability to fulfil the duties and responsibilities of the position by causing an iridium-192 source to be delivered to an unauthorized location in November 2021. While this specific violation dealt with highly situation-specific circumstances, the inspection nonetheless assessed the RSO's position, authority, and interaction with senior CHH management. Management appeared engaged at the RSC and sufficient lines of communication for radiation safety and regulatory compliance appeared to be in place and well-utilized. Since the NRC's 2021 inspection, senior CHH management was particularly involved in and was committed to restoring compliance and building an effective and lasting radiation safety program. Overall, no regulatory non-compliances were identified.

4.2.4. Review of Violation of 10 CFR 19.12(a)

The fourth violation associated with this group of violations involved 10 CFR 19.12(a): the licensee's failure to provide adequate instruction to personnel regarding the NRC regulations and license conditions as they concern the protection of personnel from exposure to radiation and/or radioactive material. The violation concerned five physicians who were AUs on the NRC license and performed licensed activities in the

form of yttrium-90 microspheres and other activities related to interventional radiology. CHH had relied on the physicians' prior experience and education and thus had not provided effective training to the physicians. As a result of the NRC's findings, CHH has incorporated the physicians into mandatory training provided by the radiation support staff, largely in an online format, in order to bridge the physicians' experience and education with facility-specific policies and expectations, in particular towards occupational exposure and the correct use of dosimetry. In the inspectors' interviews with physicians, including an AU involved in the 2021 inspection's findings, the personnel well-understood the expectations and policies of CHH as they concerned radiation exposure, monitoring, and the logistics of dosimetry return and exchange. Overall, no regulatory non-compliances were identified.

4.2.5. Review of Violation of 10 CFR 20.1201(f)

The fifth and final violation associated with this group of violations involved 10 CFR 20.1201(f): the licensee's failure to reduce the dose that personnel may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. In particular, CHH failed to account for occupational exposure received by five physicians, the AUs discussed in Section 4.2.4 of this report, while performing duties involving exposure to radiation at one or more facilities outside of the CHH NRC license.

CHH engaged with the outside facilities and the dosimetry vendor to make use of the vendor's existing multi-facility monitoring program and further engaged with CHH staff to provide the additional information necessary to the dosimetry vendor to support this multi-facility engagement. With regards to NRC-licensed activities and the personnel at CHH who support these activities, only a very small fraction appeared to be engaged in activities outside of CHH that involve occupational exposure to radiation. This limited population was reviewed by the inspectors and dosimetry results appeared to be available and accounted for by CHH. CHH, through its radiation support staff, engaged the outside facilities to participate within the same dosimetry vendor and thus allow a more automated aggregation and sharing of occupational exposure results.

The NRC inspectors provided feedback and best practices for identifying staff or physicians who may be or may in the future begin occupational duties outside of CHH involving exposure to radiation, engaging with the dosimetry vendor(s), and other related matters. Overall, no regulatory non-compliances were identified.

4.3. Group 2: Violations Associated with the Occupational Exposure Limits

The 2021 inspection identified three violations associated with CHH's failure to control occupational exposure to within NRC-established annual limits. These included violations against 10 CFR 20.1201(a)(1)(i), (a)(2)(i), and (a)(2)(ii), for exposures beyond NRC annual limits for the whole body, the lens of the eye, and the skin or extremity respectively.

The three violations described above involved the five AUs discussed above in Section 4.2, each associated with yttrium-90 microsphere procedures and other closely related non-NRC licensed activities (primarily interventional radiology) which are associated with significant exposures to radiation. As already described in Section 4.2

above, CHH has significantly altered its radiation exposure monitoring programs as a result of the NRC's 2021 inspection. The inspectors performed extensive independent reviews of staff and physician dosimetry results, CHH's review of abnormally high or low dosimetry results, as well as missing, unused, or unreturned dosimeters, and finally the oversight by the RSC to these various program areas. No radiation exposures to any staff or physicians involved in NRC-licensed activities were found by the inspectors or the CHH radiation support staff to have exceeded NRC-regulatory requirements. Additional shielding was purchased and provided to the staff and physicians working in the interventional radiology suite to reduce the radiation exposure to personnel from these procedures. Signage and other reminders were provided in the applicable rooms to reduce the chances for accidental exposure to the primary radiation beams used by the machines. Finally, when a physician deems it medically necessary for the physician to have a hand or other body part within the primary radiation beam, the revised program triggers additional radiation safety program oversight and documentation. Overall, no regulatory non-compliances were identified.

4.4. Group 3: Violations Related to the Unauthorized Location

The 2021 inspection identified three violations associated with CHH's failure to confine its possession and use of licensed material to authorized locations and related failures associated with the adequacy of the security of these materials and the transportation related to returning this licensed material to an authorized location. These included violations against 10 CFR 30.34(c), 10 CFR 20.1802, and four examples of failures to comply with 10 CFR 71.5 and the associated U.S. Department of Transportation regulations in Title 49.

The first two of these violations involved the redirection of certain deliveries by senior CHH management to an unauthorized location, which included a shipment of an iridium-192 source, and the inadequate security of this material while at the unauthorized location. During this inspection the inspectors confirmed correct routing of shipments of radioactive material to authorized license locations. These include unsealed byproduct material for nuclear medicine as well as further iridium-192 sources for use in the HDR programs. CHH senior management, RSC members (including representatives of each of the functional areas and facilities), and radiation support staff were knowledgeable of the 2021 finding. Shipments were observed over the course of the NRC's three days onsite in 2023, without any issues concerning the delivery of the material (i.e. to an unauthorized location) nor the security of the material upon delivery. Further shipments were reviewed through interviews and documentation of the deliveries.

Concerning the four examples provided in the violation of 10 CFR 71.5: these examples involved failures related to 49 CFR 172.702, 49 CFR 177.817(a), 49 CFR 172.600(c), and 49 CFR 173.475. These violations involved the failures to: (1) provide adequate hazardous materials transportation training to relevant staff; (2) prepare and provide shipping papers when transporting hazardous materials; (3) provide emergency response information with the shipment; and (4) ensure external radiation and contamination levels were below applicable limits, respectively. Each of these examples of the violation of 10 CFR 71.5 arose as a direct result of the licensee's efforts to return the iridium-192 source from the unauthorized location to the authorized location, and primarily the involvement of inadequately trained and experienced personnel to address the pertinent regulatory requirements.

No further instances of non-compliance were identified by the NRC during the 2023 inspection of CHH with regards to the three violations described above.

4.5. Group 4: Violations that were Not Considered for Escalated Enforcement

The 2021 inspection identified three violations that were not considered for escalated enforcement. These included violations against 10 CFR 35.92(a), a license commitment from License Condition 14, and 10 CFR 35.633. As these violations were not associated with the NRC's Order, the review of these items during the 2023 inspection included the closure of each violation with the basis described below.

4.5.1. Review of Violation of 10 CFR 35.92(a)

The first violation associated with this group of violations involved 10 CFR 35.92(a): the licensee's failure to ensure radioactive material being released through decay-in-storage as non-radioactive waste was indistinguishable from background radiation levels. In particular, yttrium-90 waste was released by CHH on two occasions with radiation survey results of the package distinguishable from background radiation levels. The NRC's 2023 inspection reviewed decay-in-storage processes, documentation, and interviewed staff involved in the implementation of the radioactive waste program as well as radiation support staff who provide auditing and oversight of this process. Staff demonstrated the radiation surveys that would be performed and provided access to the records of waste disposal, a sample of which was reviewed without any instances identified by the NRC of further noncompliance. In review of the licensee's oversight activities, such as spot checks, auditing, and other related activities, no instances of noncompliance were identified by the licensee. Staff across CHH were provided remedial training to remind personnel of the relevant CHH policies and procedures, and the NRC regulations that provides the basis for them. As a result of all the above, this violation is considered closed.

4.5.2. Review of Violation of License Condition 14

The second violation associated with this group of violations involved commitments made by CHH and incorporated into the NRC license via License Condition 14. Specifically, the letters dated January 23, 2013 (for St. Mary's Medical Center, CHH License Condition 14.C) and July 29, 2013 (for Cabell Huntington Hospital, CHH License Condition 14.I), in which CHH committed to the provision of emergency equipment for the HDR, including two pairs of long handled locking forceps, heavy-duty wire cutters, and a tape measure. While it is not recommended by any of the HDR manufacturers to use heavy-duty wire cutters in virtually all foreseeable emergency situations for an HDR, they remain, nonetheless, artifacts of prior commitments on the NRC license.

Regardless, the inspectors reviewed the emergency equipment both at Cabell Huntington Hospital and St. Mary's Medical Center, each of which maintained an HDR. Both facilities had all the required emergency response equipment available within the treatment room and in good working order. No deficiencies or concerns were identified, and as result of the anticipated continued possession of this equipment this violation is considered closed.

4.5.3. Review of Violation of 10 CFR 35.633(a)(2)(i)

The third and final violation associated with this group of violations involved 10 CFR 35.633(a)(2)(i): the licensee's failure to verify the length of the transfer tubes and applicators used with the high dose rate afterloaders as part of the full calibration of the high dose rate afterloader.

In response to the NRC's 2021 inspection finding, the licensee modified its procedures for the performance of full calibrations as they pertain to the verification of transfer tube and applicator length. The inspectors interviewed the relevant radiation support staff and AMPs and reviewed the full calibrations performed in response to 10 CFR 35.633. Documentation was reasonable and complete in each instance, with adequate processes in place to ensure verification of transfer tube and applicator length with each full calibration. No repeated instances were identified of this violation, and revised procedures and policies appeared to provide confidence recurrence of this violation would not occur. As a result, this violation is considered closed.

5. Exit Meeting Summary

The NRC inspectors presented preliminary inspection findings following the onsite inspection on July 20, 2023. The licensee acknowledged the findings presented and committed to formulating a corrective action plan. The NRC conducted a final exit briefing via teleconference with Tim Martin, Chief Operating Officer, Jim Norweck, Radiation Safety Officer, Tina Shoemaker, Assistant Radiation Safety Officer, and representatives of each of the facilities identified on the NRC license on September 7, 2023. The licensee acknowledged the findings presented and did not dispute any of the facts presented.

SUPPLEMENTAL INSPECTION INFORMATION

LIST OF PERSONS CONTACTED

Tim Martin, Chief Operating Officer
Jim Norweck, Radiation Safety Officer
Tina Shoemaker, Assistant Radiation Safety Officer
Nancy Godby, Director of Radiology, Cabell Huntington Hospital
Jeff Adkins, Director of Radiology, St. Mary's Medical Center
Meredith Henderson, Nuclear Medicine Supervisor, Cabell Huntington Hospital
Jill Stevens, Nuclear Medicine Supervisor, St. Mary's Medical Center

INSPECTION PROCEDURES USED

87130 – Nuclear Medicine Programs
87132 – Brachytherapy Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-03370/2023-001-01	VIO	Failure to ensure that dosages were not used when they did not fall within the prescribed dosage range or the dosage differed from the prescribed dosage by more than 20 percent (10 CFR 35.63(d)).

Closed

030-03370/2021-001-01	VIO	Failure to ensure radioactive material being released through decay-in-storage was indistinguishable from background radiation levels (10 CFR 35.92(a)).
030-03370/2021-001-02	VIO	Failure to provide certain emergency equipment for high dose rate afterloaders (License Condition 14.C and 14.I)
030-03370/2021-001-03	VIO	Failure to verify the length of the transfer tube and applicator during a full calibration of a high dose rate afterloader (10 CFR 35.633(a)(2)(i)).

Discussed

030-03370/2021-001-04	VIO	Failure to develop and implement an adequate radiation protection program (10 CFR 20.1101(a)).
030-03370/2021-001-05	VIO	Failure to monitor occupational exposure from licensed and unlicensed sources of radiation under the control of the licensee (10 CFR 20.1502(a)).

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030-03370/2021-001-06	VIO	Failure to provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative as it concerns matters of radiation safety and regulatory compliance (10 CFR 35.24(g)).
030-03370/2021-001-07	VIO	Failure to provide adequate instruction to personnel (10 CFR 19.12(a)).
030-03370/2021-001-08	VIO	Failure to reduce the dose that personnel may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person (10 CFR 20.1201(f)).
030-03370/2021-001-09	VIO	Failure to limit occupational radiation exposure of the whole body to within NRC-established annual limits (10 CFR 20.1201(a)(1)(i)).
030-03370/2021-001-10	VIO	Failure to limit occupational radiation exposure of the lens of the eye to within NRC-established annual limits (10 CFR 20.1201(a)(2)(i)).
030-03370/2021-001-11	VIO	Failure to limit occupational radiation exposure of the skin or extremity to within NRC-established annual limits (10 CFR 20.1201(a)(2)(ii)).
030-03370/2021-001-12	VIO	Failure to limit possession and use of licensed material to authorized locations (10 CFR 30.34(c)).
030-03370/2021-001-13	VIO	Failure to secure material while in storage (10 CFR 20.1802).
030-03370/2021-001-14	VIO	Failure to comply, in four examples, with U.S. Department of Transportation requirements (10 CFR 71.5).

LIST OF ACRONYMS AND ABBREVIATIONS USED

ADAMS	Agencywide Documents Access and Management System
ALARA	As Low As Reasonably Achievable
AU	Authorized User
AMP	Authorized Medical Physicist
CFR	*Code of Federal Regulations*
CHH	Cabell Huntington Hospital
HDR	High Dose Rate Afterloader
NRC	Nuclear Regulatory Commission
PET	Positron Emission Tomography
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
VIO	Violation