



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

November 10, 2022

IA-22-023

Dr. Nathan Hatfield
HOME ADDRESS DELETED
UNDER 10 CFR 2.390

SUBJECT: NOTICE OF VIOLATION (NRC INVESTIGATION REPORT NO. 1-2021-015)

Dear Dr. Nathan Hatfield:

This letter refers to the investigation completed on December 22, 2021, by the U.S Nuclear Regulatory Commission (NRC) Office of Investigations (OI) regarding your activities at Cabell Huntington Hospital (CHH). The investigation was conducted, in part, to determine whether you, an interventional radiologist and authorized user of Yttrium-90 (Y-90) at the CHH, deliberately failed to wear dosimetry during Y-90 procedures at CHH facilities.

In a letter dated June 22, 2022, (ML22173A061),¹ the NRC described the apparent violation to you and informed you that the NRC was considering issuing an escalated enforcement action for the activities mentioned above. A factual summary of the OI investigation was included with that letter. In the letter, we offered you the opportunity to address the apparent violations by either attending a pre-decisional enforcement conference (PEC) or to provide a written response before we made our final enforcement decision. In a letter dated August 9, 2022 (non-public due to the inclusion of personal privacy information), you provided a written response, in which you explained why the violation occurred and why you did not consider your actions to have been deliberate.

Based on the information developed during the OI investigation, and the information you provided in your written response, the NRC has determined that a deliberate violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) (Enclosure 1).

¹ Designation in parentheses refers to an Agencywide Documents Access and Management System (ADAMS) accession number. Unless otherwise noted, documents referenced in this letter are publicly available using the accession number in ADAMS.

NOTICE OF VIOLATION

Nathan Hatfield
[HOME ADDRESS DELETED
UNDER 10 CFR 2.390]

IA-22-023

During an NRC investigation conducted between June 21, 2021, and December 21, 2021, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 30.10(a)(1) states, in part, that any employee of a licensee may not engage in deliberate misconduct that causes a licensee to be in violation of any NRC rule or regulation.

10 C.F.R. § 30.10(c)(1) defines deliberate misconduct, in part, as an intentional act or omission that a person knows would cause a licensee to be in violation of any rule, regulation, or order.

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, during the period of time between May 2018, to May 2021, you, as an Interventional Radiologist and authorized user for Yttrium-90 at CHH facilities, deliberately failed to wear dosimetry during Y-90 procedures. Your actions caused the licensee to be in violation of 10 CFR 20.1502(a)(1).

This is a Severity Level III violation (Enforcement Policy Sections 6.3).

You are not required to respond to the Notice unless you contest the violation. Should you contest the violation, a response is required within 30 days of the date of this letter, addressing the specific basis for disputing the violation. This response should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Regional Administrator, NRC Region I, 475 Allendale Road, Suite 102, King of Prussia, PA 19406, and marked Open by Addressee Only – Response to a Notice of Violation; (IA-22-023). If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's Agency-wide Document 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 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

Enclosure

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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

This letter will be maintained by the Office of Enforcement in an NRC Privacy Act system of records, NRC-3, "Enforcement Actions Against Individuals." This system, which is not publicly accessible, includes all records pertaining to individuals who are being, or have been considered, for enforcement action, whether such action was taken or not. Detailed information about this system of records, including the NRC-3 system notice, can be accessed from the NRC Web site at <http://www.nrc.gov/reading-rm/foia/privacy-systems.html>.

Dated this 10th day of November 2022.



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
475 ALLENDALE RD, STE 102
KING OF PRUSSIA, PA 19406-1415

November 10, 2022

EA-22-003
NMED NO. 210483 (closed)

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

SUBJECT: CONFIRMATORY ORDER RELATED TO NRC INSPECTION REPORT
NO. 03003370/2021001 AND NRC OFFICE OF INVESTIGATIONS REPORT
NO. 1-2021-015

Dear Tim Martin:

The enclosed Confirmatory Order is being issued to Cabell Huntington Hospital (CHH) as a result of a successful Alternative Dispute Resolution (ADR) mediation session. The commitments in the Confirmatory Order were made by you as part of a settlement agreement with the U.S. Nuclear Regulatory Commission (NRC). The mediation was related to apparent violations of NRC requirements identified in Inspection Report No. 03003370/2021001 and NRC Office of Investigations (OI) Report No. 1-2021-015 and described in an NRC letter dated June 22, 2022 (ML22173A063).¹ The inspection report and a factual summary of the OI investigation were provided as enclosures to the June 22nd letter.

The inspection report documented the results of a routine radiation safety inspection conducted in May 2021, 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 report documented the results of further NRC inspection activities associated with one reportable event (a CHH report to the NRC on October 23, 2021, of an overexposure to an authorized user of Yttrium-90) and one incident (receipt of licensed material at an unauthorized location on November 8, 2021) that occurred after the routine inspection. The purpose of the OI investigation was to determine whether willfulness was associated with apparent failures of authorized users to wear dosimetry during Y-90 administrations at CHH facilities. The investigation concluded that for periods of time between May 2018, to May 2021, an authorized user deliberately failed to wear dosimetry during Y-90 procedures. A final enforcement action to the individual will be handled separately.

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Unless otherwise noted, documents referenced in this letter are publicly-available using the accession number in ADAMS.

In the June 22, 2022, letter, the NRC informed CHH that 14 apparent violations were identified, of which 11 were being considered for escalated enforcement action, including a civil penalty, in accordance with the NRC Enforcement Policy. The letter also stated that one of the apparent violations being considered for escalated enforcement was determined to be willful. In the letter, the NRC provided CHH the option of participating in a pre-decisional enforcement conference or requesting ADR mediation with the NRC in an attempt to resolve the issues. In response to the NRC's letter, CHH requested ADR. An ADR mediation session was consequently held on August 24, 2022, and a preliminary settlement agreement was reached. As evidenced by the signed "Consent and Hearing Waiver Form" (Enclosure 2), dated November 7, 2022, you have agreed to issuance of the Confirmatory Order (Enclosure 1). The Confirmatory Order confirms the commitments made as part of the preliminary settlement agreement with the agreed-upon modifications.

Pursuant to Section 223 of the Atomic Energy Act of 1954, as amended, any person who willfully violates, attempts to violate, or conspires to violate, any provision of this Confirmatory Order shall be subject to criminal prosecution, as set forth in that section. Violation of this Confirmatory Order may also subject the person to civil monetary penalties.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, along with its enclosures, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, if you choose to respond to this letter, should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

Sincerely,

Digitally signed
by Raymond K.
Lorson
Date: 2022.11.10
12:48:45 -05'00'
Raymond K. Lorson
Deputy Regional Administrator

Enclosures:

1. Confirmatory Order
2. Consent and Hearing Waiver Form

Docket No. 030-03370

License No. 47-00404-02

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

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of:

)	
)	Docket No. 03003370
CABELL HUNTINGTON HOSPITAL)	
)	License No. 47-00404-02
)	
)	EA-22-003

**CONFIRMATORY ORDER MODIFYING LICENSE
(EFFECTIVE UPON ISSUANCE)**

I

Cabell Huntington Hospital (CHH) is the holder of byproduct materials License No. 47-00404-02 issued by the U.S. Nuclear Regulatory Commission (NRC or Commission) pursuant to Part 35 of *Title 10 of the Code of Federal Regulations* (10 CFR), “Medical Use of Byproduct Material.” The license authorizes the use of byproduct materials by CHH, in accordance with conditions specified therein. CHH has multiple medical facilities in West Virginia and is authorized to possess and use byproduct material for diagnostic and therapeutic medical uses.

This Confirmatory Order is the result of an agreement reached during an Alternative Dispute Resolution (ADR) mediation session conducted on August 24, 2022.

II

On June 22, 2022, the NRC issued Inspection Report No. 03003370/2021001 to CHH. The report documented the results of a routine inspection in May 2021, that reviewed the activities performed under the NRC license held by CHH to ensure that activities were performed in accordance with NRC requirements and with the conditions of the license. The

inspection report also documented the results of additional NRC inspection activities associated with a CHH report to the NRC on October 23, 2021, concerning an overexposure to an authorized user (AU) of Yttrium-90 (Y-90), and an incident on November 8, 2021, involving the receipt of licensed material at an unauthorized location.

In addition to the inspection, on June 21, 2021, the NRC's Office of Investigations (OI) opened an investigation (OI Case No. 1-2021-015) to determine whether interventional radiologists (IRs) who were authorized users of Y-90 at CHH deliberately failed to wear their supplied dosimetry when administering Y-90 and whether the Radiation Safety Officer (RSO) deliberately failed to require interventional radiologists to wear their dosimetry during Y-90 procedures.

Based on the results of the inspection and investigation, the NRC identified 14 apparent violations, of which 11 were considered for escalated enforcement action. One of the apparent violations being considered for escalated enforcement was determined to be willful. This violation involved CHH's failure to monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee, as required by 10 CFR 20.1502(a)(1), and the apparent willful failure to wear dosimetry by an authorized user of Y-90. Although the violation was determined to be willful, it did not adversely impact patient safety. The other 10 violations considered for escalated enforcement involved CHH's failure to:

- (1) 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;
- (2) provide the RSO with sufficient management prerogative to identify radiation safety problems and stop unsafe operations;
- (3) 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; (4) 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; (5) 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; (6) control the occupational dose to individual adults to an annual dose limit of 5 rem total effective dose equivalent; (7) control the occupational dose to the lens of the eye of individual adults to an annual dose limit of 15 rem dose equivalent; (8) confine possession and use of byproduct materials to the locations and purposes authorized by its license; (9) control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage; and (10) comply with the applicable requirements of the Department of Transportation regulations appropriate to the mode of transport. By letter dated June 22, 2022, the NRC notified CHH of the results of the inspection and OI investigation and offered CHH the opportunity to (1) attend a predecisional enforcement conference or (2) participate in an ADR mediation session, in an effort to resolve these concerns.

In response to the NRC's letter, CHH requested the use of the NRC's ADR process. On August 24, 2022, the NRC and CHH met in an ADR session mediated by a professional mediator, arranged through Cornell University's Institute on Conflict Resolution. The ADR process is one in which a neutral mediator, with no decision-making authority, assists the parties in reaching an agreement on resolving any differences regarding the dispute. This confirmatory order is issued pursuant to the agreement reached during the ADR process.

III

During the ADR mediation session, CHH and the NRC reached a preliminary settlement agreement. The elements of that agreement are set forth below:

Whereas the NRC acknowledges that CHH has taken several corrective actions in response to the violations so as to preclude the occurrence of similar violations in the future. These corrective actions were documented in Inspection Report 03003370/2021001 dated June 22, 2022. In addition to actions described in the report, CHH created and filled a full-time Assistant Radiation Safety Officer position to assist in the implementation of its Radiation Protection Program, in addition to other actions that were described at the ADR session conducted on August 24, 2022.

Select corrective actions [already completed and described during the ADR session] are described below:

1. CHH 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. CHH has also instituted an ALARA [as low as reasonably achievable] review process for unused or unusually low dosimetry results.
2. CHH developed and assigned an electronic training module to the [IR AUs] that provides instruction on the proper use of dosimetry.

3. One [AU] that had exceeded occupational dose limits in calendar year (CY) 2021 was not permitted to work with licensed material for the remainder of CY 2021.
4. CHH provided in-person instruction to supply chain and security staff instructing them to not transport radioactive material to or from CHH facilities.
5. CHH has created an electronic learning module that will be assigned to all staff and will communicate that radioactive material is not to be transported to or from CHH facilities by staff.
6. CHH revised its policy titled "Ordering and Receiving Radioactive Material" to include additional communication information and cautions. Additionally, the policy has been revised to include a system for ordering Ir-192 sources.
7. CHH revised its policy titled "Safely Opening Radioactive Material Packages" to include [receipt of] Ir-192 sources.
8. CHH created a policy regarding the shipping and receiving of Ir-192 sources.
9. CHH restructured its Radiation Safety Committee such that it is now a single committee with oversight of all authorized locations of use.

Therefore, the parties agree to the following terms and conditions:

I. Terms and Conditions to be taken by CHH:

A. Development of a Resource Plan

1. CHH shall review the Radiation Protection Program oversight functions of the RSO and develop a resource plan to ensure compliance with NRC requirements. CHH shall review the applicable guidance in NUREG-1556, "Consolidated Guidance About Materials Licenses," to determine the activities required to be performed by the RSO and to evaluate the resources needed to ensure those activities are adequately completed.

Within 30 days of the effective date of the confirmatory order, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator, along with a copy of the resource plan. The resource plan shall include the individuals' names, qualifications, and time commitment. The reporting structure of the qualified individuals must be documented in the resource plan. The resource plan shall be maintained and made available for NRC inspection for a period of three years after the date of submission of the resource plan to the NRC.

Beginning one year after the date of submission of the resource plan to the NRC, CHH shall review annually and document planned versus actual resources expended by December 31, 2023, and December 31, 2024. The results of these reviews shall be made available for NRC inspection for a period of three years after the date of submission of the resource plan to the NRC.

B. Radiation Safety Committee Charter Development and Implementation

1. CHH shall develop and, after receipt of NRC approval, implement a Radiation Safety Committee (RSC) charter. The charter shall include clearly defined RSC's membership with documented roles and responsibilities for each member, including deliverables and accountability expectations. The charter shall also identify a CHH senior manager to serve as the chairman of the RSC, a reporting structure of the RSC, and applicable training requirements for all RSC members on the roles and responsibilities of their positions within the RSC.

Within 180 days of the effective date of the confirmatory order, CHH shall inform the NRC that CHH has developed an RSC charter by sending a letter to the Region I Administrator and submitting the RSC charter and associated member training materials for NRC review and approval (prior to initial implementation). CHH will notify the NRC in writing of any changes to the RSC charter for a period of up to three years from the date of the receipt of NRC approval of the RSC charter.

2. CHH shall maintain copies of RSC member training materials for a period of 3 years after a training has been conducted for review during NRC inspection. Records of training participation shall include the individual's name, title, and date of training; these records shall also be maintained by CHH and made available during NRC inspection for 3 years after the associated training has been conducted.

C. Third Party Audit

1. Within 360 days of the effective date of the confirmatory order, CHH shall have one or more independent third-party national consulting firms complete [an audit] of CHH's radiation protection program. The audit shall focus on identifying issues and providing recommendations to the licensee. The audit shall include, at a minimum, the following elements:
 - a. The authority and oversight of the consultant RSO and the adequacy of the RSO contract.
 - b. The process and procedures for ordering and receiving various types of radioactive material, including the different methods for purchasing and receiving radioactive material, and how communication impacts this process.
 - c. The occupational monitoring program, to include an assessment of the adequacy of procedures, dosimetry selection, and program implementation.
 - d. CHH's nuclear safety culture relative to the NRC's safety culture policy statement (<https://www.nrc.gov/about-nrc/safety-culture/sc-policy-statement.html>) or equivalent. Specifically, the audit shall identify organizational opportunities to improve nuclear safety culture. This would include training for applicable radiation safety staff and the need for workshops for CHH leadership, as appropriate.

2. CHH shall submit the name and qualifications of the third-party consultant(s) for NRC approval within 90 days of the effective date of the confirmatory order.

3. Within 45 days of completing the third-party audit pursuant to Section I.C.1, CHH shall inform the NRC that the third-party audit is complete by sending a letter to the Region I Administrator. CHH shall maintain and make the results of the audit, including any non-compliances identified, recommendations, and any corrective actions taken or not taken (and why such action was not taken) as a result of the audit, and a copy of the planned actions available for review during NRC inspection for a period of 3 years from the date of NRC notification pursuant to Section I.C.3.

D. Program Assessment

1. Within 180 days of the effective date of the confirmatory order, CHH shall complete a review of the radiation protection program. Specifically, CHH shall analyze, as part of this review, what actions would be needed for it to shift to performance-based oversight of radiation protection, with clear expectations for continuous improvement. The review shall address, at a minimum, whether the following actions would be warranted to implement a performance-based approach: unannounced area audits, process audits, walk downs by management, 1:1 meetings when new managers become responsible for elements of the radiation protection program, processes for determining how to handle areas of non-compliance, and ALARA investigations of abnormal dosimetry results. At a minimum, the radiation protection program shall include documentation of the responsible individual(s), assessment objectives, minimum criteria to consider an assessment complete, frequency of each assessment, action to be taken when findings occur, management and RSC notification of assessment findings.

2. Within 90 days of completing the review pursuant to Section I.D.1, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator, with a written copy of CHH's radiation protection policies and procedures, specifying any revisions made in response to the review conducted pursuant to Section I.D.1. Any policies, findings, and related documentation shall be maintained and made available for NRC inspection for a period 3 years following completion of this action.

E. Training Program

Within 270 days of the effective date of the confirmatory order, CHH shall complete a review of its current radiation protection training program and revise it consistent with the guidance provided in NUREG-1556. Specifically, the review shall assess the sufficiency of training, shall be informed by the results of any periodic assessments of the radiation protection program, and shall establish record-keeping requirements.

1. Within 30 days of completing the review, CHH shall inform the NRC of the completion of the review by sending a letter to the Region I Administrator documenting any planned changes to its training program. The letter shall include a description of the standards used to inform the scope and conduct of the review. CHH shall maintain and make its radiation protection training program, along with associated radiation protection training materials, available to the NRC for inspection for a period of three years after notification to the NRC of the completion of the review.

F. External Communication

1. Within 720 days of the effective date of the confirmatory order, CHH shall have conducted the following communications of the importance of ALARA practices with applicable industry clinicians/physician related organizations. Specifically:
 - a. CHH shall have attempted at least three times to provide a presentation to a national organization that has a membership comprised of physician authorized users of byproduct material. The presentation shall include a description of the reported exposure received by an AU at CHH including the practice used (i.e., hand in the beam), magnitude of exposure, lessons learned, the importance of adherence to NRC requirements for occupational monitoring, and related corrective actions undertaken by CHH. Within 30 days of completing the presentation, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the presentation materials available to the NRC for three years after the presentation for review during NRC inspection. Presentation materials shall consist of a slide show, at a minimum. If the presentation has not been accepted after three submission attempts by CHH to different national organizations, then CHH shall notify the NRC by sending a letter to the Region I Administrator, including with the letter the rejected presentation proposals, as well as intended presentation materials.
 - b. CHH shall have attempted at least three times to publish a paper in a journal that has a readership comprised of physician authorized users of byproduct material. The paper shall include a description of the reported exposure received by an AU

at CHH including the practice used (i.e., hand in the beam), magnitude of exposure, lessons learned, the importance of adherence to NRC requirements for occupational monitoring, and related corrective actions undertaken by CHH. Within 30 days of submitting the paper, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the paper available to the NRC for three years after the paper is submitted for review during NRC inspection. If the paper has not been accepted for publication after three submission attempts have been made by CHH to different journals, then CHH shall notify the NRC by sending a letter to the Region I Administrator, all with copies of all versions of the paper tendered for publication.

2. As specified below, CHH shall discuss the issues it encountered related to the maintenance of its radiation protection program:
 - a. Within 720 days of the effective date of the confirmatory order, CHH shall have attempted at least three times to provide a presentation describing the issues related to the maintenance of its radiation protection program, resolution of the issues, and the path to compliance to a national organization that has a membership comprised of health physics and radiation professionals. Within 30 days of completing this presentation, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the presentation materials available to the NRC for three years after the presentation for review during NRC inspection. Presentation materials shall consist of a slide show, at a minimum. If the presentation has not been accepted after three submission attempts by CHH to different national organizations, then CHH shall

notify the NRC by sending a letter to the Region I Administrator, including with the letter the rejected presentation proposals, as well as intended presentation materials.

- b. Within 720 days of the effective date of the confirmatory order, CHH shall have attempted at least three times to have a paper published by a national journal that has a readership comprised of health physics and radiation professionals related to the issues related to the maintenance of its radiation protection program, resolution of the issues, and the path to compliance. Within 30 days of a paper submission attempt, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the paper available to the NRC for three years after the paper is submitted for review during NRC inspection. If the paper has not been accepted for publication after three submission attempts have been made by CHH to different journals, then CHH shall notify the NRC by sending a letter to the Region I Administrator, along with copies of all versions of the paper tendered for publication.

II. Terms and Conditions to be taken by NRC:

1. The NRC agrees not to issue a civil penalty and does not intend to take further action for the violations described in inspection report 03003370/2021001.
2. The NRC agrees to not issue a separate Notice of Violation in addition to the confirmatory order but, rather, to describe the violations in the body of the confirmatory order instead. The description will include that one of the violations

involved the deliberate actions of a non-employee authorized user for failure to wear required occupational dose monitoring devices and that this violation did not impact patient care.

3. For the NRC's future civil penalty assessment purposes as discussed in the NRC Enforcement Policy, the NRC agrees that the issuance of this Confirmatory Order will be considered as escalated enforcement.
4. The NRC will issue a press release to coincide with the issuance of the confirmatory order.
5. In the event of the transfer of the license of Cabell Huntington Hospital to another entity, the terms and conditions set forth hereunder shall continue to apply to the Cabell Huntington Hospital and accordingly survive any transfer of ownership or license.

On November 7, 2022, CHH consented to issuing this Confirmatory Order with the commitments, as described in Section V below. CHH further agrees that this Confirmatory Order is to be effective upon issuance, the agreement memorialized in this Confirmatory Order settles the matter between the parties, and that CHH has waived its right to a hearing.

IV

Because CHH has agreed to take additional actions to address NRC concerns, as set forth in Section III above, the NRC has concluded that its concerns can be resolved through issuance of this Confirmatory Order.

The NRC finds that CHH's actions completed, as described in Section III above, combined with the commitments as set forth in Section V, are acceptable and necessary; the NRC concludes that with these commitments in place the public health and safety will be reasonably assured. In view of the foregoing, the NRC has determined that public health and safety require that CHH's commitments be confirmed by this Confirmatory Order. Based on the above and CHH's consent, this Confirmatory Order is effective upon issuance.

V

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part 30, IT IS HEREBY ORDERED, EFFECTIVE UPON ISSUANCE, THAT LICENSE NO. 47-00404-02 IS MODIFIED AS FOLLOWS:

A. Development of a Resource Plan

1. CHH shall review the Radiation Protection Program oversight functions of the RSO and develop a resource plan to ensure compliance with NRC requirements. CHH shall review the applicable guidance in NUREG-1556 to determine the activities required to be performed by the RSO and to evaluate the resources needed to ensure those activities are adequately completed.

Within 30 days of the effective date of the Confirmatory Order, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator, along with a copy of the resource plan. The resource plan shall include the individuals' names, qualifications, and time commitment. The reporting structure of the qualified individuals must be documented in the resource plan. The resource plan shall be maintained and made available for NRC inspection for a period of three years after the date of submission of the resource plan to the NRC.

Beginning one year after the date of submission of the resource plan to the NRC, CHH shall review planned versus actual resources expended during calendar year 2023 and document the findings of the review by December 31, 2023. CHH shall perform a similar review for calendar year 2024 and document the findings by December 31, 2024. The results of these reviews shall be made available for NRC inspection for a period of three years after the date of submission of the resource plan to the NRC.

B. Radiation Safety Committee (RSC) Charter Development and Implementation

1. CHH shall develop and, after receipt of NRC approval (as described below), implement an RSC charter. The charter shall include clearly defined RSC's membership with documented roles and responsibilities for each member, including deliverables and accountability expectations. The charter shall also identify a CHH senior manager to serve as the chairman of the RSC, a reporting structure of the RSC, and applicable training requirements for all RSC members on the roles and responsibilities of their positions within the RSC.

Within 180 days of the effective date of the Confirmatory Order, CHH shall inform the NRC that CHH has developed an RSC charter by sending a letter to the Region I Administrator and submitting the RSC charter and associated member training materials for NRC review and approval (prior to initial implementation). CHH will notify the NRC in writing of any changes to the RSC charter for a period of up to three years from the date of the receipt of NRC approval of the RSC charter.

2. CHH shall maintain copies of RSC member training materials for a period of 3 years after a training has been conducted for review during NRC inspection. Records of training participation shall include the individual's name, title, and date of training; these records shall also be maintained by CHH and made available during NRC inspection for 3 years after the associated training has been conducted.

C. Third Party Audit

1. **Within 360 days of the effective date of the Confirmatory Order**, CHH shall engage at least one independent third-party national consulting firm to complete an audit of CHH's radiation protection program. The audit shall focus on identifying issues and providing recommendations to the licensee. The audit shall include, at a minimum, the following elements:
 - a. The authority and oversight of the consultant RSO and the adequacy of the RSO contract.
 - b. The process and procedures for ordering and receiving various types of radioactive material, including the different methods for purchasing and receiving radioactive material, and how communication impacts this process.

- c. The occupational monitoring program, to include an assessment of the adequacy of procedures, dosimetry selection, and program implementation.
 - d. CHH's nuclear safety culture relative to the NRC's safety culture policy statements <https://www.nrc.gov/about-nrc/safety-culture/sc-policy-statement.html> or equivalent. Specifically, the audit shall identify organizational opportunities to improve nuclear safety culture. This would include training for applicable radiation safety staff and the need for workshops for CHH leadership, as appropriate.
2. CHH shall submit the name and qualifications of the third-party consultant(s) for NRC approval **within 90 days of the effective date of the Confirmatory Order.**
3. **Within 45 days of completing the third-party audit pursuant to Section V.C.1,** CHH shall inform the NRC that the third-party audit is complete by sending a letter to the Region I Administrator. CHH shall maintain and make the results of the audit, including any findings identified, recommendations, and any corrective actions taken or not taken (and why such action was not taken) as a result of the audit, and a copy of the planned actions, available for review during NRC inspection for a period of 3 years from the date of NRC notification pursuant to Section V.C.3.

D. Program Assessment

1. **Within 180 days of the effective date of the Confirmatory Order**, CHH shall complete an assessment of its radiation protection program. Specifically, CHH shall analyze, as part of this assessment, what actions would be needed for it to shift to performance-based oversight of radiation protection, with clear expectations for continuous improvement. The assessment shall address, at a minimum, whether the following actions would be warranted to implement a performance-based approach: unannounced area audits, process audits, walk downs by management, one-on-one meetings when new managers become responsible for elements of the radiation protection program, processes for determining how to handle areas of non-compliance, and ALARA investigations of abnormal dosimetry results. At a minimum, the radiation protection program policies and procedures for conducting periodic evaluations shall be updated and shall include documentation of the responsible individual(s), evaluation objectives, minimum criteria to consider an evaluation complete, frequency of each evaluation, action to be taken when findings occur, and management and RSC notification of evaluation findings.

2. **Within 90 days of completing the assessment pursuant to Section V.D.1**, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator, with a written copy of CHH's radiation protection policies and procedures, specifying any revisions made in response to the assessment conducted pursuant to Section V.D.1. Any policies, findings, and related documentation shall be maintained and made available for NRC inspection for a period 3 years following completion of this action.

E. Training Program

1. **Within 270 days of the effective date of the Confirmatory Order**, CHH shall complete a review of its current radiation protection training program and revise it consistent with the guidance provided in NUREG-1556. Specifically, the review shall assess the sufficiency of training, shall be informed by the results of any periodic assessments of the radiation protection program, and shall establish record-keeping requirements.
2. **Within 30 days of completing the review pursuant to Section V.E.1**, CHH shall inform the NRC of the completion of the review by sending a letter to the Region I Administrator documenting any planned changes to its training program. The letter shall include a description of the standards used to inform the scope and conduct of the review. CHH shall maintain and make its radiation protection training program, along with associated radiation protection training materials, available to the NRC for inspection for a period of three years after notification to the NRC of the completion of the review.

F. External Communication

1. **Within 720 days of the effective date of the Confirmatory Order**, CHH shall have conducted the following communications of the importance of ALARA practices with applicable industry clinicians/physician related organizations:

- a. CHH shall have attempted at least three times to provide a presentation to a national organization that has a membership comprised of physician authorized users of byproduct material. The presentation shall include a description of the reported exposure received by an AU at CHH including the practice used (i.e., hand in the beam), magnitude of exposure, lessons learned, the importance of adherence to NRC requirements for occupational monitoring, and related corrective actions undertaken by CHH. **Within 30 days of completing the presentation**, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the presentation materials available to the NRC for review during NRC inspections for three years after the presentation. Presentation materials shall consist of a slide show, at a minimum. If the presentation has not been accepted after three submission attempts by CHH to different national organizations, then CHH shall notify the NRC by sending a letter to the Region I Administrator, including with the letter the rejected presentation proposals, as well as intended presentation materials.

- b. CHH shall have attempted at least three times to publish a paper in a journal that has a readership comprised of physician authorized users of byproduct material. The paper shall include a description of the reported exposure received by an AU at CHH including the practice used (i.e., hand in the beam), magnitude of exposure, lessons learned, the importance of adherence to NRC requirements for occupational monitoring, and related corrective actions undertaken by CHH.

Within 30 days of a paper submission attempt, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the paper available to the NRC for review during NRC inspections for three years after the paper is submitted to the journal for review. If the paper has not been accepted for publication after three submission attempts have been made by CHH to different journals, then CHH shall notify the NRC by sending a letter to the Region I Administrator, all with copies of all versions of the paper tendered for publication.

2. As specified below, CHH shall discuss the issues it encountered related to the maintenance of its radiation protection program.
 - a. **Within 720 days of the effective date of the Confirmatory Order**, CHH shall have attempted at least three times to provide a presentation describing the issues related to the maintenance of its radiation protection program, resolution of the issues, and the path to compliance to a national organization that has a membership comprised of health physics and radiation professionals. **Within 30 days of completing this presentation**, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the presentation materials available to the NRC for three years after the presentation for review during NRC inspection. Presentation materials shall consist of a slide show, at a minimum. If the presentation has not been accepted after three submission attempts by CHH to different national organizations, then CHH shall notify the NRC by sending a letter to the Region I Administrator, including with the letter the rejected presentation proposals, as well as intended

presentation materials.

- b. **Within 720 days of the effective date of the Confirmatory Order**, CHH shall have attempted at least three times to have a paper published by a national journal that has a readership comprised of health physics and radiation professionals related to the issues related to the maintenance of its radiation protection program, resolution of the issues, and the path to compliance. **Within 30 days of a paper submission attempt**, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the paper available to the NRC during NRC inspections for three years after the paper is submitted to the journal for review. If the paper has not been accepted for publication after three submission attempts have been made by CHH to different journals, then CHH shall notify the NRC by sending a letter to the Region I Administrator, along with copies of all versions of the paper tendered for publication.

This agreement is binding upon successors and assignees of CHH. The Regional Administrator, Region I, may relax or rescind, in writing, any of the above conditions upon demonstration by CHH or its successors of good cause.

VI

In accordance with 10 CFR 2.202 and 10 CFR 2.309, any person adversely affected by this Confirmatory Order, other than CHH, may request a hearing within thirty (30) calendar days of the date of issuance of this Confirmatory Order. Where good cause is shown, consideration

will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the “Guidance for Electronic Submissions to the NRC” (ADAMS Accession No. ML13031A056) and on the NRC’s public website at <https://www.nrc.gov/site-help/e-submittals.html>.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at Hearing.Docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals/getting-started.html>. After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at <https://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals.html>, by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9:00 a.m. and 6:00 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their

initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)-(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at <https://adams.nrc.gov/ehd>, unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as previously described, click "cancel" when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

If a person other than CHH requests a hearing, that person shall set forth with particularity the manner in which their interest is adversely affected by this Confirmatory Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an order designating the time and place of any hearings. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 30 days from the date of this Confirmatory Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

FOR THE NUCLEAR REGULATORY COMMISSION

Raymond
K. Lorson


Digitally signed by
Raymond K. Lorson
Date: 2022.11.10
12:49:58 -05'00'

Raymond K. Lorson
Deputy Regional Administrator
NRC Region I

Dated this 10th day of November 2022

CONSENT AND HEARING WAIVER FORM

Cabell Huntington Hospital hereby agrees to comply with the terms and conditions of Confirmatory Order arising out of an alternative dispute resolution process to be issued relating to enforcement action No. **EA-22-003**. The Confirmatory Order will be immediately effective upon its issuance. By signing below, **Cabell Huntington Hospital** consents to the issuance of the referenced Confirmatory Order, effective immediately upon its issuance and, by doing so, agrees to waive the right to request a hearing on all or any part of the Confirmatory Order.



Tim Martin
Chief Operating Officer
Cabell Huntington Hospital

Date

11/7/2022