



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

November 21, 2023

EA-23-062

Mohammad (Owais) Rafique  
Vice President of Specialty Services  
United Hospital Center  
327 Medical Park Drive  
Bridgeport, WV 26330

**SUBJECT: NOTICE OF VIOLATION – UNITED HOSPITAL CENTER, NRC INSPECTION  
REPORT NO. 030-03375/2023-001**

Dear Mohammad Rafique:

This letter refers to the announced reactive inspection of the United Hospital Center (UHC) conducted by the U.S. Nuclear Regulatory Commission (NRC) on April 20, 2023, and an announced routine inspection performed at the same facility on May 15-16, 2023. Both inspections continued with in-office review through June 27, 2023. The reactive inspection was to evaluate UHC's response to an event that occurred on April 19, 2023 (EN 56477), involving the failure to retract the source for a high dose rate remote afterloader (HDR).

The inspections consisted of a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with UHC personnel. Based on the results of the inspections, the NRC identified three apparent violations (AVs) of NRC requirements. These AVs involved apparent failures to: (1) implement written emergency procedures; (2) wear dosimetry to monitor personnel exposure during routine operations and emergency response; and (3) adequately secure a package containing licensed material from unauthorized access and removal. The NRC discussed the AVs with you during a telephonic exit meeting on July 10, 2023. The AVs were described in the NRC inspection report enclosed with a letter dated August 9, 2023 (ML23184A132).<sup>1</sup>

In the letter transmitting the inspection report, we informed you that the AVs were being considered for escalated enforcement action and provided you the opportunity to address the AVs by either attending a pre-decisional enforcement conference (PEC) or requesting Alternative Dispute Resolution. On October 11, 2023, a PEC was conducted with members of your staff in the NRC's Region I office and over Microsoft Teams to discuss the AVs, their significance, their root causes, and your corrective actions. A summary of the PEC and the corrective actions described by UHC at the conference is included as Enclosure 1 to this letter.

---

<sup>1</sup> Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

Based on the information developed during the inspection and the information that you provided during the conference, the NRC determined that violations of NRC requirements occurred. These violations are cited in the Notice of Violation (Notice), provided as Enclosure 2, and the circumstances surrounding them are described in detail in the subject inspection report.

The first violation involved UHC's failure to implement written procedures for responding to an abnormal situation when the operator was unable to place the HDR source in the shielded position during the April 19, 2023, event. Namely, the licensee failed to follow specific steps to operate emergency equipment (such as pressing a red emergency button on the control console) and did not then wait a specific period of time prior to entering the treatment room. The licensee subsequently failed to pull an unlock key in the access panel of the device to allow the manual retraction of the HDR source.

The NRC staff considered that this violation was the result of a failure to follow emergency procedures during an actual event, inhibiting the licensee's immediate efforts to prevent or mitigate potential significant exposure to staff and the patient. Although none of these individuals received occupational exposure that exceeded any NRC regulatory limits, they received more exposure than they would have otherwise experienced if the procedure had been appropriately implemented. Therefore, the violation has been categorized in accordance with the NRC's Enforcement Policy as a Severity Level III (SL III) violation.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$8,750 is considered for a SL III violation involving a medical licensee. Because UHC has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC staff determined that UHC took prompt and comprehensive corrective actions, and credit is, therefore, warranted. Specifically, UHC is increasing emergency response training for staff involved in HDR procedures from once per year to three times per year and is improving the training by including practical demonstrations of dealing with unexpected errors on the HDR screen and discussing relevant operating experience. The training will be conducted by the HDR vendor and audited by UHC staff to provide additional oversight, identify any potential improvements and to ensure that staff are receiving the training both when onboarding and on an ongoing basis. Additionally, UHC instituted a stop-work expectation, such that, should conditions change during an HDR procedure, the staff will stop and evaluate the deviation and, with management (and, if appropriate, manufacturer) input, determine if they should proceed or terminate the procedure. Following the event, UHC temporarily suspended all HDR operations and will not resume them before documenting the above corrective actions in procedures and providing the staff the revised training.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, after consultation with the Director, Office of Enforcement, I have been authorized not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this SL III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The second violation involved the failure by UHC's Authorized User (AU) to wear their assigned dosimetry on April 19, 2023, both at the initiation of treatment and during the event response. The NRC staff considered that, as a result of this violation, the licensee was unable to monitor

the AU's radiation exposure when the AU entered a high radiation area created by the unshielded HDR source. However, the NRC staff evaluated the AU's historical exposure records and, considering the limited exposures from the AU's routine duties and the estimated exposure from the AU's response to the event, determined there was very low potential for the AU to have received an unmonitored exposure in excess of the regulatory limits. Therefore, the violation has been categorized in accordance with the NRC's Enforcement Policy as a SL IV violation. The violation is cited in the enclosed Notice because it was identified by the NRC.

The third violation involved UHC staff inadvertently storing a package of approximately 107 millicuries of palladium-103 brachytherapy seeds in a utility room for a period of less than five hours on June 1, 2023. The NRC staff considered that the room was accessible by hospital employees who did not have authorization to access radioactive materials and, therefore, the material was not secured from unauthorized access and potential removal. However, the NRC staff considered that the room was locked and not accessible by non-hospital staff and that there is no indication unauthorized access to the material occurred. Further, all hospital staff had received hazardous material training and, as such, would have recognized the package labeling indicating the presence of radioactive material, and had a basic understanding of the radiation hazard. As a result, the potential for unauthorized access and removal, or exposure above the public limits, was very low. Therefore, the violation has been categorized in accordance with the NRC's Enforcement Policy as a SL IV violation. The violation is cited in the enclosed Notice because it was identified by the NRC.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in NRC Inspection Report No. 030-03375/2023-001 and in Enclosure 1 to this letter. 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 "Agency Rules of Practice and Procedure," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, if you choose to provide one, 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, 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 information, 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).

The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

M. Rafique

4

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

Sincerely,

Raymond K. Lorson  
Regional Administrator

Enclosures:

1. Summary of October 11, 2023, Pre-Decisional Enforcement Conference and Description of Corrective Actions
2. Notice of Violation

Docket No. 030-03375  
License No. 47-01458-01

SUBJECT: NOTICE OF VIOLATION – UNITED HOSPITAL CENTER, NRC INSPECTION  
 REPORT NO. 030-03375/2023-001: NOVEMBER 21, 2023

**DISTRIBUTION w/encl:**

SECY	RIDSSECYMAILCENTER
OEMAIL	
OEWEB	
D Dorman, EDO	RIDSEDOMAILCENTER
C Haney, DEDM	
T Herrera, OEDO	
D Pelton, OE	RIDSOEMAILCENTER
J Peralta, OE	
N Hasan, OE	
P Snyder, OE	
J Lubinski, NMSS	RIDSNMSSOD RESOURCE
R Lewis, NMSS	
K Williams, NMSS	
M Burgess, NMSS	
Enforcement Coordinators	
RII, RIII, RIV (M Kowal; D Betancourt-Roldan; J Groom)	
B Clark, OGC	RIDSOGCMAILCENTER
P Moulding, OGC	
L Baer, OGC	
H Harrington, OPA	RIDSOPAMAILCENTER
R Feitel, OIG	RIDSOIGMAILCENTER
D D'Abate, OCFO	RIDSOCFOMAILCENTER
P Krohn, DRSS, RI	R1DRSSMAILRESOURCE
J Quichocho, DRSS, RI	
J Zimmerman, DRSS, RI	
A DeFrancisco, DRSS, RI	
J vonEhr, DRSS, RI	
J Pfingsten, DRSS, RI	
E Spangler, DRSS, RI	
D Screnci, PAO-RI / N Sheehan, PAO-RI	
M Ford, SAO-RI / F Gaskins, SAO-RI	
B Klukan, ORA, RI	
J Nick, ORA, RI	

**ADAMS Document Accession NO.: ML23324A330**

DOCUMENT NAME: S:\Enf-all\Enforcement\Proposed-Actions\Region1\UHC NOV-III EA-23-062.docx

<input checked="" type="checkbox"/> SUNSI Review/MMM		<input checked="" type="checkbox"/> Non-Sensitive <input type="checkbox"/> Sensitive			<input checked="" type="checkbox"/> Publicly Available <input type="checkbox"/> Non-Publicly Available	
OFFICE	RI/ORA	RI/DRSS	RI/ORA	RI/ORA	OE	NMSS
	M McLaughlin	A DeFrancisco	B Klukan	J Nick	P Snyder	M Burgess
DATE	10/24/23	10/31/23	10/31/23	11/01/23	11/16/23	11/16/23
OFFICE					RI/DRSS	RI/ORA
NAME					P Krohn	D Collins
DATE					11/16/23	11/21/23

OFFICIAL RECORD COPY

## ENCLOSURE 1

### SUMMARY OF OCTOBER 11, 2023, PRE-DECISIONAL ENFORCEMENT CONFERENCE AND DESCRIPTION OF CORRECTIVE ACTIONS

On August 9, 2023, the NRC issued United Hospital Center (UHC) a pre-decisional enforcement conference (PEC) letter with an inspection report that described three apparent violations (AVs) of NRC requirements. Two of the AVs were identified during a reactive NRC inspection initiated on April 20, 2023, in response to an April 19, 2023, event (EN 56477) involving the failure to retract the source for a high dose rate remote afterloader (HDR). Specifically, these AVs involved apparent failures to: (AV1) implement written emergency procedures required by UHC's NRC license and (AV2) wear dosimetry during routine operations and emergency response as required by 10 CFR 20.1502(a)(4). The third AV was identified during a routine NRC inspection conducted on May 15-16, 2023. Specifically, AV3 involved the failure to adequately secure a radioactive source from unauthorized access and removal as required by 10 CFR 20.1801.

In the PEC letter, the NRC staff informed the licensee that the AVs were being considered for escalated enforcement action and offered the licensee the choice of requesting a PEC or Alternative Dispute Resolution. The licensee elected to attend a PEC and the conference was conducted on October 11, 2023, at the NRC's Region I office and online using Microsoft Teams.

The licensee's representatives did not contest any of the AVs. They explained that AV1 and AV2 occurred as a result of human performance failures. The licensee's representatives described that their corrective actions were developed with the intention of improving their staff's "muscle memory" of the proper precautions to take during normal operations and actions to implement during off-normal situations.

Specifically, UHC is increasing emergency response training for staff involved in HDR procedures from once per year to three times per year and is improving the training by including practical demonstrations of dealing with unexpected errors on the HDR screen and discussing relevant operating experience. The training will be provided by the HDR vendor and audited UHC staff to provide oversight, identify any potential improvements and to ensure that staff are receiving the training both when onboarding and on an ongoing basis. Additionally, UHC instituted a stop-work expectation, such that, should conditions change during an HDR procedure, the staff will stop and evaluate the deviation and, with management (and, if appropriate, manufacturer) input, determine if they should proceed or terminate the procedure. Following the event, UHC temporarily suspended all HDR operations and will not resume them before documenting the above corrective actions in procedures and providing the staff the revised training.

In addition to the above, the UHC representatives described that they had provided feedback to the HDR vendor about the control screen display, which was described as not user-friendly or intuitive when there are multiple errors.

Regarding AV2, the licensee is instituting a "timeout" practice prior to every HDR procedure to, in part, verify staff are wearing their assigned dosimetry before continuing the procedure. The UHC representatives stated that the timeout process will be audited to ensure it is being performed for 100% of HDR procedures. The licensee will also stage instant-read dosimetry for staff to use in addition to their normal dosimetry in the event of an emergency. The licensee is

including the use of instant-read dosimetry in the emergency procedure and in the hands-on training described above, to ensure staff proficiency.

Regarding AV3, the licensee performed additional training for loading dock personnel on recognizing radioactive material packages. This revised training will be performed annually and with each new hire. The revised training includes review of the procedure for receipt of radioactive packages, which requires the personnel to contact specific staff at the hospital to retrieve the material. The previous procedure specified that the Radiation Safety Officer, Authorized Medical Physicist, or nuclear medicine department should be called. UHC revised the procedure to include a phone number for radiology, which is always staffed, in the event the none of the other contacts are available. The licensee also posted signs in the loading dock with the radioactive package symbols, to ensure staff can identify them. In addition, the licensee is instituting the practice of notifying the loading dock personnel when an incoming radioactive material package is expected to arrive.

The PEC attendance list and the NRC's PEC presentation are attached to this summary.

Attachments:

1. Attendance List
2. NRC Presentation

Attachment 1 - Attendance List

**NRC**

Region I:

Paul Krohn, Director, Division of Radiological Safety & Security (DRSS)  
Brett Klukan, Regional Counsel, Office of the Regional Administrator (ORA)  
Anne DeFrancisco, Chief, Medical and Licensing Assistance Branch (MLAB), DRSS  
Jason vonEhr, Senior Health Physicist, MLAB, DRSS  
Jonathan Pfingsten, Senior Health Physicist, MLAB, DRSS  
Joseph Nick, Team Lead, Enforcement, Allegations & State Liaison (EAGL), ORA  
Marjorie McLaughlin, Senior Enforcement Specialist, EAGL, ORA

Office of Enforcement:

Pete Snyder, Enforcement Specialist

Office of Nuclear Materials Safety and Safeguards:

Michele Burgess, Senior Enforcement Specialist

**United Hospital Center**

Owais Rafique, Assistant Vice President Specialty Clinics and Cancer Services  
John Fernandez, Vice President Operations  
C. Kelly Stoneberg, Radiation Safety Officer  
David Clump, M.D., Physician, Authorized User  
Yin Huang, Authorized Medical Physicist  
Meredith Williams, Director Cancer Services



Attachment 2 – NRC Presentation



**PRE-DECISIONAL  
ENFORCEMENT  
CONFERENCE**

**OCTOBER 11, 2023**

**1:00 P.M.**

# LOGISTICS

## Public Meeting that will be transcribed

- Recording feature of TEAMS
- Transcript will be non-public, but available through FOIA

## Please turn on camera when speaking

- State name and affiliation prior to speaking
- When not speaking, turn off camera and mute microphone

# AGENDA

Opening Remarks & Introductions

NRC

Licensee Opening Remarks

UHC

Overview of Enforcement Process

NRC

Summary of Apparent Violations

NRC

Licensee Presentation

UHC

NRC Caucus

NRC

Closing PEC Remarks

NRC/UHC

Public Questions and Comments

Public

# NRC OPENING REMARKS

- Today's conference is to discuss 3 apparent violations (AVs) of NRC requirements.
- The AVs involve failures by UHC staff to:
  - implement written emergency procedures;
  - wear dosimetry during routine operations and emergency response;
  - adequately secure a radioactive source from unauthorized access and removal.

# NRC OPENING REMARKS

- Please Note:

- The NRC has not made a final enforcement decision on this matter.
- This conference is your opportunity to provide us information you want the NRC to consider in making a final decision.

A decorative graphic on the left side of the slide, consisting of a network of white lines and circles on a blue background, resembling a circuit board or data flow diagram. The lines are vertical and horizontal, with some diagonal connections, and the circles are of varying sizes, some acting as nodes or junctions.

# INTRODUCTIONS



# UNITED HOSPITAL CENTER OPENING REMARKS



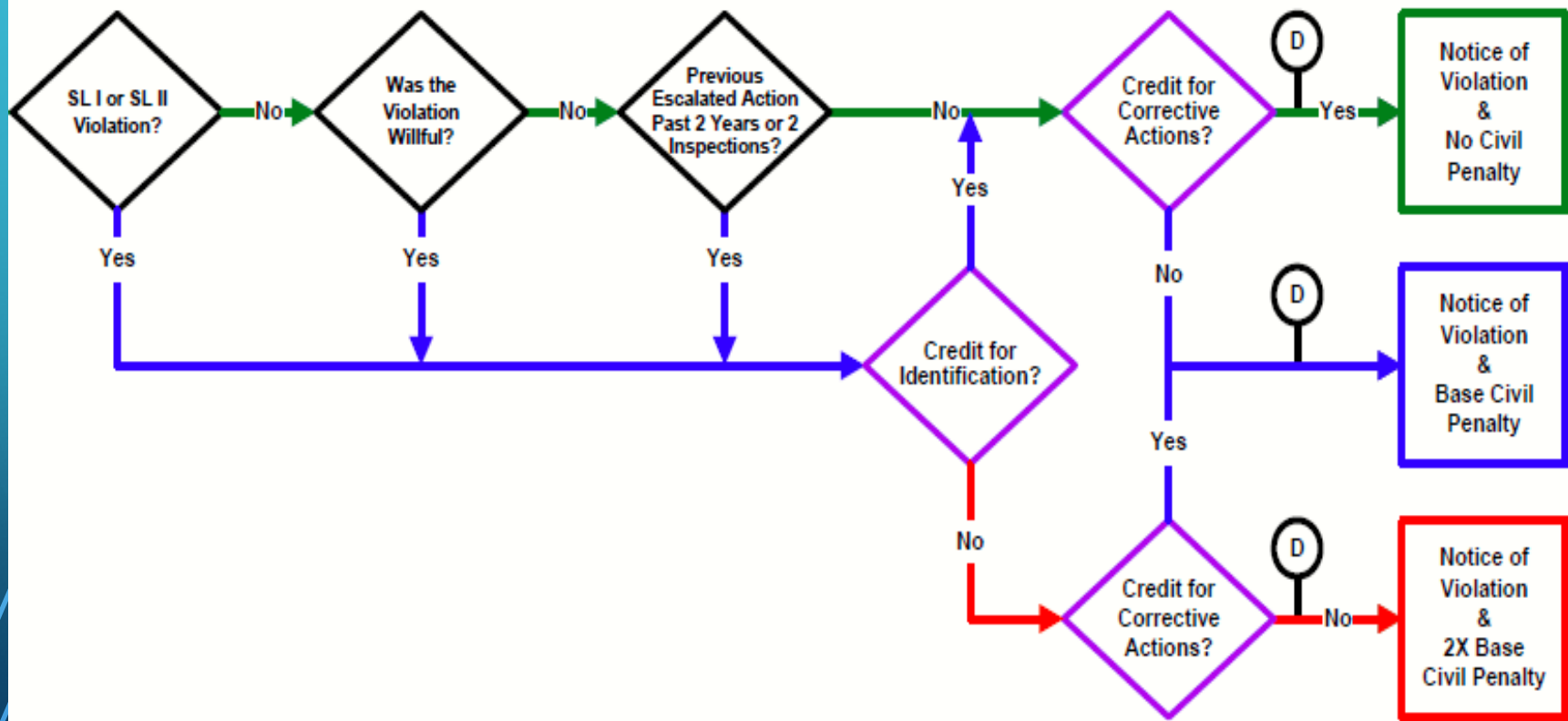
# ESCALATED ENFORCEMENT PROCESS

- NRC Enforcement Policy available at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>
- The significance of violations is assessed based on consideration of the following factors:
  - Actual Consequences
  - Potential Consequences
  - Impact to the Regulatory Process
  - Willfulness

# ESCALATED ENFORCEMENT PROCESS

- From this assessment, a violation is categorized using Severity Levels (SL).
  - SL I is the most significant and SL IV is the least.
  - SL I, SL II, and SL III violations are considered for escalated enforcement action (i.e., a monetary fine) in accordance with our Civil Penalty Assessment Process.

# CIVIL PENALTY ASSESSMENT PROCESS



# ENFORCEMENT PROCESS – ROLE OF PEC

- Following this PEC, the NRC will issue the final enforcement outcome.
- A PEC is not a forum for negotiating the enforcement action. It is an opportunity for you to present additional information you want the NRC to consider.
- The NRC staff's final position will not be communicated today. The NRC staff will consider the information you present, in conjunction with the information from the inspection, to reach a final decision.

# SUMMARY OF APPARENT VIOLATIONS

- A reactive inspection was performed on April 20, 2023, in response to UHC's April 19, 2023, notification regarding an HDR source that had failed to return to its shielded position and a resultant medical event and estimated staff overexposures.
- A routine inspection was subsequently performed on May 15-16, 2023
- Three AVs were identified:
  - Two as a result of the reactive inspection (AV 1 & AV 2).
  - One as a result of the routine inspection (AV 3).

# APPARENT VIOLATION NO. 1 (REACTIVE)

10 CFR 35.610(a)(4) requires, in part, that the licensee implement written procedures for responding to an abnormal situation when the operator is unable to place the [HDR] source in the shielded position.

The licensee's written procedures required, in part, that in the event the [HDR] console indicates that the source has not returned to its safe position at the end of treatment, or the beam-on radiation monitor displays its flashing alarm light, the operator will execute the following emergency procedures:

*Step 1: the Authorized Medical Physicist (AMP) will press one of the RED EMERGENCY BUTTONS and wait 5 seconds. If radiation is still present in the room, GO TO STEP 2.*

*Step 2, the AMP will enter the room and attempt to manually retract the source as follows:*

- *OPEN the access panel.*
- *PULL the unlock key.*
- *Insert finger in recessed indentation and ROTATE the wheel in direction of arrows.*

Contrary to the above, on April 19, 2023, the licensee failed to implement written procedures for responding to an abnormal situation when the operator was unable to place the [HDR] source in the shielded position. Specifically, the licensee failed to: (1) ensure the red emergency button was pressed and 5 seconds elapsed prior to entering the room when either: (a) the console indicates that the source has not returned to its safe position at the end of treatment; or (b) the beam-on radiation monitor displays its flashing alarm light indicating that the source has not returned to its safe position, and both (a) and (b) were true during the beginning of the event on April 19, 2023; and (2) pull the unlock key to allow a manual retraction of a stuck HDR source.

# APPARENT VIOLATION NO. 2 (REACTIVE)

10 CFR 20.1502(a)(4) requires that each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part, and as a minimum 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 individuals entering a high or very high radiation area.

10 CFR 20.1003 defines a “high radiation area” as an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

Contrary to the above, on April 19, 2023, the licensee failed to monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee for individuals entering a high or very high radiation area. Specifically, an Authorized User was not wearing their assigned dosimeter during the treatment leading up to and including the emergency response associated with an event on April 19, 2023, and the circumstances of the emergency response included radiation exposures of up to approximately 33 rem/hour at 30

# APPARENT VIOLATION NO. 3 (ROUTINE)

10 CFR 20.1801 states that the licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on June 1, 2021, the licensee failed to secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas. Specifically, the licensee stored a package containing approximately 107 mCi of palladium-103 brachytherapy seeds in a clean utility room. The radioactive materials were accessible by hospital employees who did not have authorization to access radioactive materials.



A decorative graphic on the left side of the slide, consisting of a network of light blue lines and circles that resemble a circuit board or a data network. The lines are vertical and horizontal, with some diagonal connections, and the circles are small and white with blue outlines.

# UNITED HOSPITAL CENTER PRESENTATION



# BREAK / NRC CAUCUS

A decorative graphic on the left side of the slide, consisting of white lines and circles on a blue background, resembling a circuit board or data flow diagram. The lines are vertical and horizontal, with some branching out to small circles.

# NRC QUESTIONS

The background is a dark teal gradient. In the corners, there are decorative white line-art elements resembling circuit traces or fiber optic paths, with small circles at the end of the lines.

# CLOSING REMARKS

PRIOR TO PUBLIC COMMENT PERIOD



# PUBLIC QUESTIONS & ANSWERS

- TEAMS participants, please raise your hand.
- Phone participants, please press \*5 to raise your hand and \*6 to mute/unmute.

## ENCLOSURE 2

### NOTICE OF VIOLATION

United Hospital Center  
Bridgeport, West Virginia

Docket No.: 030-03375  
License No.: 47-01458-01  
EA-23-062

During a reactive NRC inspection conducted on April 20, 2023, and a routine inspection conducted on May 15-16, 2023, both with in-office review through June 27, 2023, and for which an exit meeting was conducted on June 27, 2023, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

#### I. ESCALATED VIOLATION

10 CFR 35.610(a)(4) requires, in part, that the licensee implement written procedures for responding to an abnormal situation when the operator is unable to place the high dose rate remote after loader (HDR) source in the shielded position.

The licensee's written procedures required, in part, that in the event the HDR console indicates that the source has not returned to its safe position at the end of treatment, or the beam-on radiation monitor displays its flashing alarm light, the operator will execute the following emergency procedures:

Step 1: the Authorized Medical Physicist (AMP) will press one of the RED EMERGENCY BUTTONS and wait 5 seconds. If radiation is still present in the room, GO TO STEP 2.

Step 2, the AMP will enter the room and attempt to manually retract the source as follows:

- OPEN the access panel.
- PULL the unlock key.
- Insert finger in recessed indentation and ROTATE the wheel in direction of arrows.

Contrary to the above, on April 19, 2023, United Hospital Center failed to implement written procedures for responding to an abnormal situation when the operator was unable to place the HDR source in the shielded position. Specifically, United Hospital Center failed to: (1) ensure the red emergency button was pressed and 5 seconds elapsed prior to entering the room when the console indicated that the source had not returned to its safe position at the end of treatment and the beam-on radiation monitor displayed its flashing alarm light indicating that the source had not returned to its safe position; and (2) pull the unlock key to allow a manual retraction of the stuck HDR source.

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

#### II. NON-ESCALATED VIOLATIONS

- A. 10 CFR 20.1502(a)(4), in part, requires that each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part, and as a minimum each licensee shall monitor occupational exposure to radiation from licensed radiation sources under the control of

the licensee and shall supply and require the use of individual monitoring devices by individuals entering a high or very high radiation area.

10 CFR 20.1003 defines a "high radiation area" as an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

Contrary to the above, on April 19, 2023, United Hospital Center failed to monitor occupational exposure to radiation from licensed radiation sources under the control of the licensee for individuals entering a high or very high radiation area. Specifically, an Authorized User was not wearing their assigned dosimeter during a treatment, leading up to and including the emergency response associated with an event on April 19, 2023, and the circumstances of the emergency response exceeded 33.2 rem/hour at 30 centimeters.

This is a Severity Level IV Violation (NRC Enforcement Policy Section 6.3).

- B. 10 CFR 20.1801 states that the licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on June 1, 2021, United Hospital Center did not secure from unauthorized removal or access licensed materials that were stored in a controlled or unrestricted area. Specifically, the licensee stored a package containing approximately 107 mCi of palladium-103 brachytherapy seeds in a clean utility room. The materials were accessible by hospital employees who did not have authorization to access radioactive materials.

This is a Severity Level IV Violation (NRC Enforcement Policy Section 6.7).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 030-03375/2023001 and in Enclosure 1 to the letter transmitting this Notice of Violation (Notice). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, (EA-23-062)," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region I, 475 Allendale Rd. Suite 102, King of Prussia, PA 19406-1415 within 30 days of the date of the letter transmitting this Notice.

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.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible,

the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

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

Dated this 21<sup>th</sup> day of November, 2023.