UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

February 22, 2022

EN 55635
NMED No. 210533

Mr. Matthew Eastburn
Regional Director, Outpatient Services
Ascension St. Vincent Hospital
2001 W. 86th St.
Indianapolis, IN 46260

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03001579/2021001(DNMS) AND NOTICE OF VIOLATION – ASCENSION ST. VINCENT HOSPITAL

Dear Mr. Eastburn:

On December 17, 2021, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your facility in Anderson, Indiana, with continued in-office review through February 1, 2022. The purpose of the inspection was to review a medical event involving a high dose rate remote afterloader (HDR) that was reported to the NRC on December 9, 2021 (EN 55635). The in-office review included a review of a written report that was submitted on December 23, 2021. Ms. Elizabeth Tindle-Engelmann of my staff conducted a final exit meeting with you and your staff on February 1, 2022, to discuss the inspection findings. This letter presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations concerned the licensee's failure: (1) to implement procedures to provide a high confidence that each administration of radiation for therapy is in accordance with the written directive, as required by Title 10 of the *Code of Federal Regulations* (CFR) 35.41; (2) to provide operational and safety instructions initially and at least annually to individuals who operate the HDR, as required by 10 CFR 35.610; and (3) to perform full calibrations of the HDR in accordance with 10 CFR 35.633. The violations are cited in the enclosed Notice of Violation (Notice). The NRC is citing the violations in the enclosed Notice because the inspector identified them.

The inspector determined that the root causes of the violations were related to a failure to implement procedures and failure to provide adequate instruction to your staff at your facility in Anderson, Indiana. As corrective actions to restore compliance and to prevent recurrence you created a new procedure for time-outs associated with HDR treatments. Additionally, at your Anderson facility, you have decided to cease HDR operations and remove the HDR from that site. Finally, you will review HDR operations at your other facilities to prevent a similar occurrence at those facilities.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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

Please feel free to contact Ms. Tindle-Engelmann of my staff if you have any questions regarding this inspection. She can be reached at 630-829-9681.

Sincerely,

Michael A. Kunowski Signed by Kunowski, Michael on 02/22/22

Michael A. Kunowski, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-01579
License No. 13-00133-02

Enclosure: Notice of Violation

cc w/encl: Edward Wroblewski, Radiation Safety Officer
State of Indiana

Letter to M. Eastburn from M. Kunowski, dated February 22, 2022.

SUBJECT: NRC INSPECTION REPORT NO. 03001579/2021001(DNMS) – ASCENSION ST. VINCENT HOSPITAL

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OFFICE	RIII-DNMS		RIII-DNMS					
NAME	ETindle-Engelmann		MKunowski					
DATE	2/22/2022		2/22/2022					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Ascension St. Vincent Hospital
Indianapolis, IN

License No. 13-00133-02
Docket No. 030-01579

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on December 17, 2021, with continued in-office review through February 1, 2022, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.41(a) states that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

The licensee developed a policy titled “HDR Patient Treatment” on August 11, 2015. The policy states, in part, that the authorized medical physicist shall select the appropriate patient and appropriate plan from the computer library on the treatment console.

The policy also states, in part, that a time-out is conducted by the authorized medical physicist to verify the written directive, prescription, applicator in use, patient’s previous HDR fractions, and current source strength.

Contrary to the above, on December 7, 2021, the licensee did not implement written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee failed to implement their procedure titled “HDR Patient Treatment” when the incorrect patient and incorrect plan was selected from the computer library on the treatment console, and when the authorized medical physicist did not conduct a time-out to verify the written directive, prescription, applicator in use, and current source strength.

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

B. 10 CFR 35.610(d)(2) states, in part, a licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in the operating procedures for the unit.

Contrary to the above, from 2019 to 2021, the licensee did not provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility including instruction in the operating procedures for the unit. Specifically, the licensee did not provide operational and safety instructions, with instruction in the operating procedures for the unit, initially and at least annually to all authorized medical physicists and authorized users who operated the unit at the facility.

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

C. 10 CFR 35.633(a) states, in part, that a licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit before medical use following replacement of the source.

10 CFR 35.633(b) states, in part, that to satisfy the requirements of paragraph (a) of this section full calibration measurements must include determination of length of the source transfer tubes and length of the applicator.

Contrary to the above, prior to December 17, 2021, the licensee was authorized to use a remote afterloader unit for medical use and did not perform full calibration measurements that included determination of length of the source transfer tubes and length of the applicator. Specifically, the licensee failed to determine the length of the source transfer tubes at any frequency. Furthermore, while the licensee measured the diameter of the applicator for each treatment, the licensee failed to determine the length of the applicator as part of their full calibration measurements.

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

Pursuant to the provisions of 10 CFR 2.201, Ascension St. Vincent Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violations, or, if contested, the basis for disputing the violations or their severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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.

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, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated this 22nd day of February 2022.

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-01579
License No.	13-00133-02
Report No.	03001579/2021001(DNMS)
EN No./NMED No.	55635 / 210533
Licensee:	Ascension St. Vincent Hospital
Facility:	2001 W. 86th St. Indianapolis, IN 46260
Inspection Dates:	December 17, 2021 - February 1, 2022
Exit Meeting Date:	February 1, 2022
Inspector:	Elizabeth Tindle-Engelmann, Health Physicist
Approved By:	Michael A. Kunowski, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Ascension St. Vincent Hospital
NRC Inspection Report 03001579/2021001(DNMS)

An announced reactive inspection was conducted on December 17, 2021, with in-office review through February 1, 2022, of Ascension St. Vincent Hospital (Ascension) in Anderson, Indiana. The licensee is a multi-site medical institution with facilities across the State of Indiana. The U.S. Nuclear Regulatory Commission (NRC) License No. 13-00133-02 authorizes Ascension to use byproduct material for various medical applications including medical uses permitted by Title 10 of the Code of Federal Regulations (CFR) 35.600 in High Dose Rate remote afterloaders (HDRs).

The scope of the inspection was limited to a review of the circumstances surrounding a medical event that was reported on December 9, 2021, and the licensed activities associated with the use of HDRs at Ascension's facility in Anderson. The reported medical event involved an individual receiving the incorrect treatment plan during an HDR treatment on December 7, 2021. Specifically, the written directive indicated that the patient was supposed to receive five fractions of 600 rad at the surface of the applicator. However, the patient received four fractions of 600 rad at the surface of the applicator and one fraction of 500 rad at 5 mm from the surface of the applicator. The fraction delivered on December 7, 2021, was, on average, 23% higher at the prescribed treatment location than intended. The licensee determined that the patient received a total of 3030 rad through the course of the treatment, which is 1% higher than the intended dose of 3000 rad. The licensee performed a root cause analysis and submitted a written report to the NRC on December 23, 2021.

During the inspection, the inspector identified three violations of NRC requirements. The violations concerned the licensee's failure: (1) to implement procedures to provide a high confidence that each administration is in accordance with the written directive, as required by 10 CFR 35.41; (2) to provide operational and safety instructions initially and at least annually to individuals who operate the HDR, as required by 10 CFR 35.610; and (3) perform full calibrations of the HDR in accordance with 10 CFR 35.633.

As corrective action for the apparent violations, the licensee planned to: (1) create a new time-out procedure for HDR treatments; (2) cease HDR operations at their Anderson facility and remove the HDR from the site; and (3) review HDR operations at their other facilities to prevent a similar occurrence.

REPORT DETAILS

1 Program Overview and Management Oversight

Ascension St. Vincent Hospital is authorized under NRC Materials License No. 13-00133-02 to use byproduct material for various medical applications in accordance with 10 CFR 35.100, 200, 300, 400, 600, and 1000. Licensed material is authorized to be used at multiple facilities within the State of Indiana. The licensee is authorized for iridium-192 in HDRs for medical use in accordance with 10 CFR 35.600 at facilities located in Anderson, Indianapolis, and Newburgh.

The licensee has a full time Radiation Safety Officer (RSO) that provides radiation safety support and oversight to all of the licensee's facilities. Additionally, the licensee maintains an active Radiation Safety Committee to provide oversight of licensed activities. Medical physics services are provided by a local consulting group.

2 Medical Event and HDR Program

2.1 Inspection Scope

From December 17, 2021, through February 1, 2022, the inspector reviewed the circumstances surrounding a medical event that was reported on December 9, 2021, and other licensed activities associated with the licensee's use of HDRs at their facility in Anderson. The inspection reviewed the following areas: HDR calibrations, HDR spot checks, root cause analysis, select policies and procedures, training, treatment plans, and written directives.

2.2 Medical Event Observations and Findings

Ascension's Anderson facility typically treats three patients per year using HDR brachytherapy, with each patient receiving 3 - 5 fractions over the course of their treatment. Due to the low patient volume, this facility infrequently has multiple patients undergoing treatment at the same time. One full time Authorized Medical Physicist (AMP) is assigned to the Anderson facility.

On November 22, 2021, a written directive was signed by an Authorized User (AU) for Patient B to receive three fractions of 500 rad at a distance of 5 mm from the surface of the applicator for a total dose of 1500 rad. The cylinder diameter was 3 cm and the active length was 4 cm. The three fractions were delivered on November 22, December 3, and December 9, 2021, without incident.

On November 9, 2021, a written directive was signed by an AU for Patient A to receive five fractions of 600 rad at the surface of the applicator for a total dose of 3000 rad. The cylinder diameter was 3 cm and the active length was 4 cm. The first four fractions were delivered on November 10, November 17, November 24, and December 1, 2021, without incident. On December 7, 2021, Patient A was scheduled to receive their fifth HDR fraction. The patient arrived at the facility and was checked in through normal procedures. The patient's identify was confirmed by the nurse in accordance with the licensee's policy titled "Patient Identification for Care, Treatment, and Services." The patient was brought into the HDR treatment room by the nurse. The AU joined the nurse

and the patient for standard pre-treatment consultation. The AU placed the applicator in the patient. Simultaneously, the AMP was preparing for the treatment by selecting the treatment plan on the treatment console and printing the pre-treatment plan. The AMP entered the treatment room to connect the transfer tubes to the HDR unit and to perform a pre-treatment survey. The nurse, AU, and AMP left the treatment room and went to the treatment console. Prior to initiating treatment, the AMP conducted a time-out by stating Patient B's last name, "last fraction," and the active treatment time. The AU acknowledged this information, signed the pre-treatment plan, and the treatment was initiated. Upon completion of the treatment, the AMP surveyed the patient and the treatment room. The applicator was removed and the patient was released.

On December 8, 2021, the billing department contacted the AMP to ask for Patient A's case to be closed since the schedule indicated the last fraction was delivered on December 7, 2021. At that time, the AMP realized that the treatment delivered to Patient A was Patient B's treatment plan. The AMP informed the AU of the error. The AU attempted to contact the referring physician but was unable to inform them of the error until December 9, 2021, due to the referring physician's surgical schedule. The AU was on scheduled vacation from December 10 through December 13, 2021; the AU notified the patient of the error on December 14, 2021. The licensee notified the NRC Operations Center of the event on December 9, 2021. EN Number 55635 and NMED number 210533 were assigned. The licensee submitted a written report on December 23, 2021. The inspector determined that the licensee notification on December 9 and the written report on December 23 met the content and timeliness requirements of 10 CFR 30.3045.

Patient Effect

Patient A was supposed to receive five fractions of 600 rad at the surface of the applicator. However, the patient received four fractions of 600 rad at the surface of the applicator and one fraction of 500 rad at 5 mm from the surface of the applicator. The fraction delivered on December 7, 2021 was, on average, 23% higher than intended at the prescribed treatment location. No single dwell location was more than 30.303% different. The licensee determined that the patient received a total of 3030 rad through the course of the treatment which is 1% higher than the intended dose of 3000 rad. On December 7, 2021 the patient received slightly higher doses to surrounding organs. The patient received 361 rad to the bladder, compared to the intended 350 rad this is 0.62% higher. The patient received 374 rad to the rectum, compared to the intended 325 rad this is 2.97% higher.

The treating physician compared the intended treatment plan and delivered treatment plan. The treating physician determined there was no concern for consequences to surrounding organs, consequences to the patient, or need for further treatment.

There was no impact to Patient B since Patient B received the intended treatment plan. The licensee reviewed all HDR fractions for 2021 and determined this was an isolated event.

Licensee Root Cause Analysis/Corrective Actions

The licensee performed a root cause analysis by evaluating human factors, processes, communication, and the environment. The licensee determined that the failure point was in the implementation of their procedures. Contributing factors were determined to be multitasking which caused distractions for the staff. The licensee implemented interim corrective actions to reduce distractions and provided immediate instruction on time-out procedures. The licensee's long term corrective actions included creating a "HDR Time-Out Procedure" that has three time-outs to provide multiple stop gates. The first time-out occurs between the nurse and the AMP to confirm the patient being treated that day. The second time-out occurs between the nurse, AMP, AU, and patient where the patient confirms their name, date of birth, and fraction. This information is to be compared to the pre-treatment plan. The third time-out occurs between the nurse, AMP, and AU at the treatment console to confirm the pre-treatment plan is the same as the treatment plan on the console. During the inspection exit meeting, the licensee communicated an additional corrective action which includes ceasing HDR operations at their Anderson facility, removing the HDR from the Anderson site, and reviewing HDR operations at their other facilities to prevent similar occurrences at those facilities.

NRC Root Cause Analysis

The inspector determined that the root causes of the violations were related to a failure to implement procedures and failure to provide adequate instruction to staff.

Specifically, in order to provide high confidence that each administration is in accordance with the written directive, the licensee developed a policy titled "HDR Patient Treatment" on August 11, 2015. The policy states, in part, that the AMP shall select the appropriate patient and appropriate plan from the computer library on the treatment console. However, on December 7, 2021, the licensee failed to implement their procedure when the incorrect patient and incorrect plan was selected from the computer library on the treatment console. Furthermore, the policy states, in part, that a time-out is conducted by the AMP to verify the written directive, prescription, applicator in use, patient's previous HDR fractions, and current source strength. However, on December 7, 2021, the licensee failed to implement their procedure when the AMP did not conduct a time-out to verify the written directive, prescription, applicator in use, and current source strength. This is a violation of 10 CFR 35.41(a) which requires licensees to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Based on a review of the licensee's training program, it was determined that the licensee did not provide operational and safety instructions, with instruction in the operating procedures for the unit, at least annually to all AMPs and AUs who operated the unit at the facility. Specifically, from 2019 through 2021 the AU never received operational instruction on the unit and the AMP had not been instructed on the "HDR Patient Treatment" Policy. This is a violation of 10 CFR 35.610(d)(2) which states, in part, a licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in the operating procedures for the unit.

2.3 HDR Program Observations and Findings

The inspector toured the licensee's facilities and determined that the HDR source was kept secure, required postings were present, and required procedures were available. The licensee's staff demonstrated daily spot check procedures and elements from the full calibration measurements. Based on a review of the most recent full calibration records and the demonstration, it was determined that the licensee did not perform full calibration measurements that included the determination of the length of the source transfer tubes and the length of the applicator. This is a violation of 10 CFR 35.633(a) which requires licensees to perform full calibration measurements on each unit before medical use following replacement of the source. The full calibrations must include the determination of the length of the source transfer tubes and the length of the applicator as stated in 10 CFR 35.633(b). It should be noted, that with each treatment, the licensee was measuring the diameter of cylindrical applicators, but they never measured the length of the applicator.

2.4 Conclusions

The inspector reviewed the medical event in accordance with Inspection Procedure 87103 and the HDR program in accordance with Inspection Procedure 87132. The inspector identified three violations of NRC requirements with regard to the licensee's failure to: (1) to implement procedures to provide a high confidence that each administration is in accordance with the written directive, as required by 10 CFR 35.41; (2) to provide operational and safety instructions initially and at least annually to individuals who operate the HDR, as required by 10 CFR 35.610; and (3) perform full calibrations of the HDR in accordance with 10 CFR 35.633.

3 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings during an inspection exit briefing on February 1, 2022. Upon completion of in-office review, a virtual exit meeting was held on February 1, 2022 with the licensee. On both occasions, the licensee acknowledged the findings and committed to implementing commensurate corrective and preventative actions.

LIST OF PERSONNEL CONTACTED

^* Earl Dietrich, Chief Physicist
# Matthew Eastburn, Regional Director, Outpatient Services
^*# Jennifer Lefler, Regional Manager, Quality
^*# Tracy Massey, Nursing Manager
^*# Shane VanDeman, Physicist
^*# Edward Wroblewski, RSO
^*# Alexander Yeh, M.D.

^ Present at entrance meeting on December 17, 2021.
* Present at exit briefing on February 1, 2022.
# Present at virtual exit meeting on February 1, 2022.

INSPECTION PROCEDURES USED

87103: Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
87132: Brachytherapy Programs

LIST OF ACRONYMS AND ABBREVIATIONS USED

AMP:	Authorized Medical Physicist
Ascension:	Ascension St. Vincent Hospital
AU:	Authorized User
CFR:	Code of Federal Regulations
HDR:	High Dose Rate remote afterloader
NRC:	Nuclear Regulatory Commission
RSO:	Radiation Safety Officer