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

May 15, 2026

Steve Kirk, Associate Administrator
Charleston Area Medical Center
P.O. Box 1547
Charleston, WV 25326

SUBJECT: CHARLESTON AREA MEDICAL CENTER – NRC INSPECTION REPORT 030-09164/2025-001 AND NOTICE OF VOLATION

Dear Steve Kirk:

This letter refers to the announced reactive inspection conducted onsite on June 18, 2025, and with continued in-office review through May 7, 2026. The purpose of the inspection was to examine a reported medical event which occurred on April 28, 2025, involving an yttrium-90 microsphere administration which resulted in an underdose to the patient. The NRC determined through internal review that additional follow-up was appropriate, necessary, and consistent with Management Directive 8.10 (available at: https://www.nrc.gov/reading-rm/doc-collections/management-directives/volumes/vol-8.html). Within the scope of the inspection, the inspection reviewed your licensed activities conducted under your license as they relate to this medical event, to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC) rules, regulations, and with the conditions of your license. Specifically, the inspection consisted of interviews with personnel, including the source manufacturer, and a selected examination of procedures and representative records from the licensee. A final exit briefing was conducted by telephone on May 7, 2026, and included Dr. Kim Lowe, Radiation Safety Officer, Tuanya Layton, Medical Imagining Quality Member, and Kathy Newsome, Nuclear Medicine Supervisor. Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC's Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation is cited in the enclosed Notice of Violation (Notice) because the violation was identified by the NRC. The violation involved failure to provide a timely report to the NRC following identification of a medical event in accordance with 10 CFR 35.3045(c). This violation is documented in the publicly available Notice (Enclosure 1).

The NRC has concluded that information regarding: (1) the reason for the violation and (2) the corrective actions that have been taken is already adequately addressed both on the docket and as described in the NRC's inspection report (Enclosure 2). 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, should you choose to provide one, 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 should segregate your response for health and safety matters from security matters, and further should not include any personal privacy, proprietary, or safeguards information so that as much of your response can be made available to the Public without redaction.

If you have any questions regarding this matter, please contact Netra Patel of my staff at (610) 337-5364 or via electronic mail at Netra.Patel@nrc.gov.

Thank you for your cooperation.

Sincerely,

MONICA FORD

Digitally signed by MONICA FORD
Date: 2026.05.15 08:49:45 -04'00'

Monica Ford, Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

Docket No. 030-09164
License No. 47-15473-01

Enclosures:

1. Notice of Violation
2. NRC Inspection Report 030-09164

cc w/ enclosures
Dr. Kim Lowe, Radiation Safety Officer

NOTICE OF VIOLATION

Charleston Area Medical Center
Charleston, WV

Docket No. 030-09164
License No. 47-15473-01

During an NRC inspection conducted on June 18, 2025, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.3045(c) requires that the licensee shall notify the NRC Operations Center by telephone no later than the next calendar day after discovery of a medical event.

   Contrary to the above, on April 28 through May 4, 2025, the licensee failed to notify the NRC Operations Center by telephone no later than the next calendar day after discovery of a medical event. Specifically, the licensee discovered a medical event on Monday, April 28, 2025, and did not notify the NRC Operations Center or other NRC points-of-contact until Sunday, May 4, 2025, beyond the next calendar day from discovery of the medical event.

   This is a Severity Level IV violation (Enforcement Policy Section 6.9.d(7)).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed both on the docket and as described in the NRC's inspection report (Enclosure 2). 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," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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

Your response, should you choose to provide one, will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR and provide the legal basis to support your request for withholding the information from the public.

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

Dated This 15th day of May 2026

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03009164/2025001
Docket No.	03009164
License No.	47-15473-01
Licensee:	Charleston Area Medical Center
Address:	P.O. Box 1547 Charleston, WV 25326-1547
Inspection Dates:	06/18/2025
Exit Meeting	05/07/2026
Inspector:	Netra Patel, Health Physicist Medical and Licensing Assistance Branch Division of Radiological Safety & Security
Approved By:	Monica Ford, Chief Medical and Licensing Assistance Branch Division of Radiological Safety and Security
Attachment:	Supplementary Information

EXECUTIVE SUMMARY

Charleston Area Medical Center
NRC Inspection Report 030-09164/2025-001

A reactive onsite inspection was performed of the Charleston Area Medical Center (CAMC) on June 18, 2025, with continued in-office review through May 07, 2026. The purpose of the inspection was to examine a reported event which occurred on April 28, 2025, involving an yttrium-90 microsphere administration and resulting in an underdose to the patient. Within the scope of the inspection, the inspection reviewed CAMC's licensed activities conducted under its license as they relate to the medical event, to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC) rules, regulations, and with the license conditions of CAMC.

Program Overview

CAMC is authorized by NRC License No. 47-15473-01 as a medical specific license to use a wide variety of sealed and unsealed byproduct material, both sealed and unsealed, for diagnostic and therapeutic uses under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35.

Inspection Findings

Based on the results of the inspections, one violation of NRC requirements was identified. This violation involved failure to provide a timely report to the NRC following identification of a medical event in accordance with 10 CFR 35.3045(c). This noncompliance was identified as Severity Level IV violation.

Corrective Action

The licensee developed initial corrective actions and included them in its 15-day report to the NRC. These actions included planning an investigation of the treatment vials, tubing, microcatheter, and stopcock once the activity has decayed - to analyze the discrepancy. The licensee also provided a written commitment via email on May 5, 2026, to update existing procedures for completing the written directive.

To prevent future recurrence, the licensee committed to eliminating the use of extra stopcocks between the administration tubing and the microcatheter, using single-vial administration for liver sites that are difficult to catheterize, using SIR-Spheres instead of TheraSpheres when appropriate, and having the AU increase the number of flushes per vial during administration. Additionally, the licensee committed to revising its procedure to ensure timely reporting of medical events.

REPORT DETAILS

1. Observations and Findings

1.1 Inspection Scope

The purpose of the inspection was to examine a reported medical event which occurred on April 28, 2025, involving an yttrium-90 microsphere administration which resulted in an underdose to the patient. The NRC determined through internal review that additional follow-up was appropriate, necessary, and consistent with Management Directive 8.10. Within the scope of the inspection, the inspection reviewed CAMC's licensed activities to confirm compliance with the NRC rules, regulations, and with the conditions of the CAMC license. Specifically, the inspection consisted of interviews with personnel, including source manufacturers, and a selected examination of procedures and representative records from the licensee.

1.2 Timeline of the Medical Event

On April 28, 2025, CAMC prepared to administer a treatment involving yttrium-90 TheraSpheres to a patient. The procedure was planned in two stages, targeting separate regions of the liver. Three vials of yttrium-90 microspheres were delivered to CAMC on April 24, 2025. A written directive was prepared in accordance with 10 CFR 35.40.

The first stage was intended to treat segment 6 of the liver with a prescribed dose of 305 Gray and a planned activity of 2.202 GBq of yttrium-90. The second stage targeted the left lobe of the liver using two vials, each delivering an equal dose, with a prescribed dose of 300 Gray and a total planned activity of 3.498 GBq.

The vials received contained activities of 2.202 GBq for segment 6 and two vials of 1.749 GBq each for the left lobe. Administration began at 10:19 AM on April 28, 2025, for segment 6 and was completed without incident. At 10:39 AM, treatment of the left lobe was initiated using a three-way stopcock to allow both doses to be administered in a less invasive manner. No issues were observed. The Authorized User (AU) confirmed that the microcatheter was flushed with saline at the recommended volume and flow rate per manufacturer instructions, and no kinks or obstructions were noted.

At approximately 11:05 AM, post-treatment measurements of all three vials were performed by the Radiation Safety Officer (RSO). These results were entered into the manufacturer's electronic written directive, which indicated that the left lobe received only 71.2% of the intended dose. The records were reviewed and signed by the AU on the same day, without recognizing that a medical event had occurred. The completed directive was then returned to the RSO, who signed it the following day, also without noting the discrepancy.

On May 3, 2025, five days after the treatment, the RSO re-examined the written directive and suspected that a medical event had occurred. The RSO contacted the AU on May 4, 2025, and confirmed that a medical event had taken place. The RSO subsequently reported the medical event to the HOO on the same day.

1.3 Reportability and Timeliness

Consistent with CAMC's protocol, the left lobe was treated separately from segment 6. Following the RSO's post-treatment review, CAMC had sufficient information to conclude that a medical event had occurred and that the criteria in 10 CFR 35.3045(c) were met, requiring notification to the NRC Headquarters Operations Center no later than April 30, 2025. After re-examining the written directive on May 3, 2025, CAMC notified the NRC the next day, May 04, 2025. This was identified as a violation of 10 CFR 35.3045(c). In accordance with the NRC Enforcement Policy, Section 6.9.d(7), this constitutes a Severity Level IV violation. Note that the licensee's notification to the NRC was late, rather than a failure to notify. CAMC submitted a written report to the NRC on May 19, 2025, describing its preliminary investigation of the event.

1.4 Licensee and Manufacture Follow-up to the Medical Event

The licensee coordinated with the manufacturer to assess the delivery system, associated equipment, and related performance analysis. The assessment was conducted only after allowing adequate decay time for residual radioactive material. In addition, the AU informed the RSO and the committee that, for future yttrium90 procedures, a three way stopcock should not be used and the microcatheter should be flushed at least five times.

1.5 NRC Observations and Findings

The NRC inspector was onsite on June 18, 2025, and conducted interviews and reviewed records, procedures, and policies related to the yttrium-90 TheraSphere program. The inspector also examined the yttrium-90 delivery system and associated equipment used on the day of the treatment. Interviews were conducted with the RSO, manufacturer's representative, and the Quality Manager. On May 14, 2025, an interview was conducted with the RSO, and AU via teams.

During the review of the licensee's written directive associated with the April 28, 2025, treatment, it was determined that after the post-treatment survey was performed, the RSO completed the written directive and forwarded it to the AU for review and signature. At this point, the licensee had sufficient information to determine whether a medical event had occurred, but the discrepancy was unnoticed. The written directive was then signed by the RSO the following morning; however, the discrepancy still went unnoticed. It was not until

the RSO revisited the written directive several days later that the dose deviation was identified as a medical event. Once the medical event was recognized, the requirements of 10 CFR 35.3045(c) were followed.

1.6 Conclusion

The NRC's reactive inspection, conducted in response to a medical event that occurred on April 28, 2025, evaluated the facility's compliance with its NRC license and regulatory requirements. The inspection identified one violation: failure to provide a timely report to the NRC after identifying a medical event, as required by 10 CFR 35.3045(c). This noncompliance was identified as a Severity Level IV violation.

2. Corrective Actions

The licensee prepared its corrective actions and communicated these to the NRC as part of their 15-day report following the medical event reported on May 4, 2025, consistent with 10 CFR 35.3045(d)(1)(vi). In the written report CAMC committed to investigate the treatment vials, tubing, microcatheter, and stopcock once the activity has decayed to analyze the discrepancy, and additionally the CAMC team provided a written commitment on May 5, 2026, to update existing procedures for completing the written directive immediately after the treatment. CAMC further committed to (1) not using an additional stopcock of any kind between the administration tubing and the microcatheter; (2) prioritizing single-vial administration when catheterization of the target liver segment was expected to be difficult, which could require rescheduling the patient or using SirSpheres instead of TheraSpheres; (3) increasing the number of flushes per vial during administration to a minimum of five; (4) revising its procedure to ensure timely identification and reporting of medical events. The licensee's 15-day report can be found at ADAMS Accession No.ML25272A107 and corrective action can be found at ADAMS Accession No. ML26127A420.

Collectively, the NRC acknowledges that these corrective actions adequately address the identified finding as well as the associated direct and contributing causes.

3. Exit Meeting

The licensee acknowledged the observations and preliminary findings presented by the NRC following the onsite inspection on June 18, 2025. The NRC conducted the final exit briefing via a Teams meeting on May 07, 2026, with the RSO, Nuclear Medicine Supervisor, and Medical Imaging Quality Manager in attendance.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Kim Lowe, PharmD, BCNP, Radiation Safety Officer
Tuanya A. Layton, RBA, CNMT, Medical Imaging Quality Manager
Amy Deipolyi, MD, Authorized User

INSPECTION PROCEDURES USED

IP 87103 – Inspection of Material Licenses Involved in an Incident or Bankruptcy Filing

LIST OF NRC SURVEY INSTRUMENT USED

Ludlum 2401-P, SN 352329 Cal Date March 05, 2025

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

03009164/2025001 – 10 CFR 35.3045(c) – failure to notify by telephone the NRC Operation Center no later than the next calendar day after discovery of a medical event.

Closed

None

Discussed

None

LIST OF ACRONYMS USED

RSO: Radiation Safety Officer
ARSO: Assistant Radiation Safety Officer
CAMC: Charleston Area Medical Center
CFR: Code of Federal Regulation
AU: Authorized User
NRC: Nuclear Regulatory Commission