



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

September 9, 2025

EN57720 / NMED 250269

Dr. David J. Smith, Acting Director, DHA
Acting Principal Deputy Assistant
Secretary of Defense for Health Affairs
Defense Health Agency
7700 Arlington Boulevard, Suite #5101
Falls Church, VA 22042-5101

**SUBJECT: DEFENSE HEALTH AGENCY - NRC INSPECTION REPORT 030-39046/2025-007
AND NOTICE OF VIOLATION**

Dear Dr. David Smith:

This letter refers to the announced reactive inspection conducted from June 10, 2025, with in-office review through August 19, 2025. The purpose of the inspection was to examine a reported medical event which occurred on May 16, 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 and source manufacturer. A final exit briefing was conducted by telephone on August 21, 2025, and included COL Ricardo Reyes, Ph.D., your Radiation Safety Officer, as well as other Defense Health Agency representatives.

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 Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC. The violations involved the failures to: (1) provide a timely report to the NRC following identification of a medical event in accordance with 10 CFR 35.3045(c); (2) retain copies of written directives in accordance with 10 CFR 35.2040; and (3) implement procedures that provide high confidence to determine if a medical event has occurred in accordance with 10 CFR 35.41(a). These violations are documented in the publicly available Notice (Enclosure 1).

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 will be (was) achieved 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 Jason vonEhr of my staff at (610) 337-5256 or via electronic mail at Jason.vonEhr@nrc.gov.

Thank you for your cooperation.

Sincerely,

Farrah Gaskins, Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

Docket No. 030-39046
License No. 45-35423-01

Enclosures:

1. Notice of Violation
2. NRC Inspection Report 030-039046/2025-007

cc w/ enclosures
COL Ricardo Reyes, Ph.D., Radiation Safety Officer

SUBJECT: DEFENSE HEALTH AGENCY - NRC INSPECTION REPORT
030-39046/2025-007 AND NOTICE OF VIOLATION
DATED SEPTEMBER 9, 2025

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NOTICE OF VIOLATION

Defense Health Agency
Falls Church, VA

Docket No. 030-39046
License No. 45-35423-01

During an NRC inspection conducted on June 10, 2025, three violations of NRC requirements were 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 by telephone the NRC Operations Center no later than the next calendar day after discovery of a medical event.

Contrary to the above, on May 17 through 19, 2025, the licensee failed to notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a medical event. Specifically, the licensee discovered a medical event on Friday, May 16, 2025, and did not notify the NRC Operations Center or other NRC points-of-contact until Monday, May 19, 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)).

- B. 10 CFR 35.2040 requires that the licensee retains a copy of each written directive as required by 10 CFR 35.40 for 3 years.

Contrary to the above, for an unknown period prior to June 10, 2025, the licensee failed to retain a copy of each written directive as required by 10 CFR 35.40. Specifically, the licensee had an authorized user complete the written directive prior to administration but disposed of this original copy between this approval by the authorized user and the completion of the procedure and post-procedure documentation, whereupon the written directive and post-procedure documentation was re-printed and re-approved/signed by the authorized user in its entirety.

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

- C. 10 CFR 35.41(a) requires, in part, for any administration requiring a written directive, that the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

10 CFR 35.41(b) requires, in part, that, at a minimum, the procedures required by 10 CFR 35.41(a) must address the determination if a medical event, as defined in 10 CFR 35.3045, has occurred.

Defense Health Agency Procedures Manual (Number 6055.01, dated September 8, 2023) "*Notifications and Reports for Radiation Safety Unusual Occurrences*," developed and maintained pursuant to 10 CFR 35.41. This procedure requires, in part that: (1) "*when unclear about reporting requirements or whether to consider an event a UO [unusual occurrence], facility staff must contact the DHA Radiation Safety Office to determine what reporting requirements exist;*" (2) to "*make initial notifications to the DHA Radiation Safety Office as soon as practicable to allow for consideration of external reporting requirements and associated data collection;*" and (3) in accordance with Appendix 1 of the procedure "*Notifications and Reports for Events Reportable to the*

NRC, FDA, or TJC”, for immediate notification to the DHA [Radiation Safety Office] in the event of a medical event as defined by the NRC’s 10 CFR 35.3045.

Contrary to the above, on May 16, 2025, DHA Walter Reed National Military Medical Center failed to implement Defense Health Agency Procedures Manual (Number 6055.01, dated September 8, 2023) to provide notice to the Defense Health Agency Radiation Safety Office. Specifically, the DHA Walter Reed National Military Medical Center had sufficient information on May 16, 2025, to reasonably conclude that the above-quoted procedure required immediate communication or notice to the DHA Radiation Safety Staff and failed to provide this communication and thus provide the opportunity for the Defense Health Agency as a whole to provide adequate notice to the NRC as required by 10 CFR 35.3045(c).

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

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 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 9th day of September 2025

**U.S. NUCLEAR REGULATORY COMMISSION
REGION I**

Docket: 030-39046

License: 45-35423-01

Report: 2025-007

Licensee: Defense Health Agency

Location Inspected: Walter Reed National Military Medical Center, 8901 Wisconsin Avenue, Bethesda, Maryland, 20889-5600

Inspection Dates: June 10, 2025, with in-office review through August 19, 2025

Inspectors: Jason vonEhr, Senior Health Physicist
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Kelli Trotter, Health Physicist
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Approved By: Farrah Gaskins, Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Attachment: Supplementary Information

EXECUTIVE SUMMARY

Defense Health Agency Walter Reed National Military Medical Center NRC Inspection Report 030-39046/2025-007

A reactive inspection was performed of the Defense Health Agency (DHA) at the Walter Reed National Military Medical Center (WRNMMC) starting on June 10, 2025, with in-office review through August 19, 2025. The purpose of the inspection was to examine a reported medical event which occurred on May 16, 2025, involving an yttrium-90 microsphere administration and resulting in an underdose to the patient. Within the scope of the inspection, the inspection reviewed DHA'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 conditions of the DHA license.

Program Overview

DHA is authorized by NRC License No. 45-35423-01 as a medical broad scope license to use a wide variety of byproduct material, both sealed and unsealed, for medical use, both diagnostic and therapeutic, as well as research, development, and other uses under Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30 and 35. These authorizations are performed at 34 facilities across the United States and its territories as of Amendment No. 14 of the NRC license. WRNMMC was authorized under DHA Permit Authorization No. 101-NH (Amendment No. 21, approved December 14, 2023) for the use of yttrium-90 microspheres under 10 CFR 35.1000, among other authorizations unrelated to the medical event on May 16, 2025.

Inspection Findings

Based on the results of the inspection, three violations of NRC requirements were identified. These violations involved failures to: (1) provide a timely report to the NRC following identification of a medical event in accordance with 10 CFR 35.3045(c); (2) retain copies of written directives in accordance with 10 CFR 35.2040; and (3) implement procedures that provide high confidence to determine if a medical event has occurred in accordance with 10 CFR 35.41(a). These noncompliance's were identified as Severity Level IV violations.

Corrective Actions

The licensee authorized user team committed to a cessation in the use of the specific microcatheter make and brand associated with the treatment and event on May 16, 2025, as the microcatheter was identified as having weaknesses and vulnerabilities associated with the specific aspects of the treatment on May 16, 2025. In addition, DHA and WRNMMC committed to procedure revisions and training for each of the departments involved in the microsphere treatments as well as greater radiation safety team oversight of potential events.

REPORT DETAILS

1. Program Overview

DHA is authorized by NRC License No. 45-35423-01 as a medical broad scope license to use a wide variety of byproduct material, both sealed and unsealed, for medical use, both diagnostic and therapeutic, as well as research, development, and other uses under 10 CFR Parts 30 and 35. These authorizations are performed at 34 facilities across the United States and its territories as of Amendment No. 14 of the NRC license. WRNMMC was authorized under DHA Permit Authorization No. 101-NH (Amendment No. 21, approved December 14, 2023) for the use of yttrium-90 TheraSphere glass microspheres under 10 CFR 35.1000, among other authorizations unrelated to the medical event on May 16, 2025.

2. Observations and Findings

2.1. Inspection Scope

The purpose of the inspection was to examine a reported medical event which occurred on May 16, 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 8.10¹. Within the scope of the inspection, the inspection reviewed WRNMMC's licensed activities conducted under the DHA license as they relate to this medical event, to confirm compliance with the NRC rules, regulations, and with the conditions of the DHA 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 and source manufacturer.

2.2. Timeline of the Medical Event

On May 16, 2025, WRNMMC prepared to perform a treatment on a patient involving yttrium-90 Theraspheres. The treatment was to be split into two parts to treat two separate volumes of the patient's liver, with two separate vials and doses of yttrium-90 microspheres delivered to WRNMMC on May 11, 2025. These two treatments were each provided with a written directive pursuant to 10 CFR 35.40. It was noted by the inspectors that this was WRNMMC's first yttrium-90 Therasphere treatment – although the facility had extensive experience with the Sirtex Medical yttrium-90 SIR-Spheres resin microspheres.

The first portion of the patient's treatment was planned to treat 569 cubic centimeters of the liver, with a desired dose of 410 Gray and total planned activity of 143.4 millicuries of yttrium-90. The second portion of the treatment was planned to treat a much smaller 27 cubic centimeters of the liver, with a desired dose of 1,350 Gray and total planned activity of 22.1 millicuries of yttrium-90. On the morning of the administrations, the WRNMMC Authorized Nuclear Pharmacist (ANP) measured the two yttrium-90 doses as 139.2 millicuries and 23.1 millicuries, representing 98.4 percent and 104.5 percent, respectively, of the desired activities, both within the tolerances established by the

¹ Management Directive 8.10 is publicly available at: <https://www.nrc.gov/reading-rm/doc-collections/management-directives/volumes/vol-8.html>

NRC (10 CFR 35.63(d)) as well as internally by DHA and WRNMMC.

On or about 10:14 am on May 16, 2025, the first of the two administrations was initiated. The dose was delivered and the two physicians (interventional radiologists, and authorized users (AUs) approved under the DHA medical broad scope and identified on the DHA/WRNMMC radioactive materials permit) reported smooth delivery without incident. The materials associated with the first treatment (e.g., vial, tubing, et cetera) were gathered into a container for later evaluation of the delivered activity.

Regarding the second treatment, the same two AUs reported challenges with the patient's vasculature, specifically a hard 'turn' in the patient's vasculature that the more-routinely used microcatheter struggled to follow. As a result, the AUs, in consultation with the manufacturer's consultant (who was on-site for this procedure), utilized a different microcatheter than the first treatment in order to address this challenge. While the first treatment utilized a Terumo Interventional Systems Progreat microcatheter, the second treatment utilized the Boston Scientific Direxion™ 0.021-inch microcatheter.

The AUs were able to place the microcatheter and initiated the second treatment at or about 12:14 pm on May 16, 2025. The AUs, upon commencing delivery, immediately noticed a marked increased resistance when delivering saline through the microsphere delivery system. Typically, the AUs' practice and Boston Scientific's recommendation was for the delivery of three 20-cubic centimeter saline syringes over the course of about 3 minutes to achieve adequate delivery of the suspended yttrium-90 microspheres. In this treatment, with troubleshooting and in consultation with the Boston Scientific representative, five 20-cubic centimeter saline syringes were used in the delivery. The AUs noted leaking of the saline from the overpressure that was being experienced (note: this leaking was not from the radioactive side of the delivery system, and therefore not a contamination concern).

Troubleshooting between the AUs and the Boston Scientific representative was initiated. This troubleshooting included verifying and checking the delivery system connections, confirmation that there were no kinks in the delivery lines, agitation of the lines to dislodge any potential microsphere clumps, and agitation of the vial to ensure suspension of the microspheres. The hub of the delivery microcatheter was examined and it was noted by the AUs that the outer sheath had separated, and a kink was present at this point, but no leakage was noted. The AUs attempted to correct the microcatheter's kink without success. Following these actions, the decision was made by the AUs to end the procedure.

With the termination of the procedure, the AUs noted that the dosimeter placed at the delivery system indicated little to no difference in radiation levels from the start of the procedure, suggesting little to no yttrium-90 had been successfully administered to the patient. A SPECT-CT scan confirmed that there did not appear to be any radioactivity delivered to tissues outside the target volume. Therefore, it was concluded that most or all of the radioactivity from the second treatment remained in the vial.

Following the termination of the second procedure, the materials of the second procedure were assembled for evaluation of the delivered dose. These materials, as well as the residual materials from the first procedure, were brought to the WRNMMC radiopharmacy area where they were surveyed and compared to the initial survey readings. The first procedure's assembled materials were surveyed at or about 1:16 pm

on May 16, 2025, which resulted in a calculated delivered activity of 134.8 millicuries, or approximately 95.3 percent of the desired activity. The second procedure's assembled materials were surveyed at or about 1:20 pm on May 16, 2025. The initial calculation included in error where the survey time was recorded as 1:20 pm on May 19, 2025 (the following Monday), which resulted in a significant decrease in the decay-corrected pre-treatment net survey result. This error caused the initial evaluation to suggest no activity (zero percent) was delivered to the patient. The inspectors noted that the treatment record actually would have concluded that a *negative* activity was delivered to the patient, as the post-treatment survey result (0.873 millirem per hour) would be subtracted from the decay-corrected pre-treatment net survey result (calculated, in error, as 0.452 millirem per hour), however, the manufacturer's electronic written directive form would not allow a result less than zero to be displayed in this particular field, as it would not be physically possible to achieve a negative delivery of activity.

The ANP completed the two TheraSphere planning sheets (which also served as the WRNMMC written directive pursuant to 10 CFR 35.40), one for each treatment, with the post-treatment survey and delivered activity information. These records were brought to the principal AU for review and signature on Friday afternoon. The principal AU reviewed and signed the written directive that same day and believed that a medical event had clearly occurred.

The completed and AU-signed planning sheets were returned to the Radiation Safety team, including the Associate Radiation Safety Officer (ARSO), on Monday, May 19, 2025. At or around 4:09 pm, Monday, May 19, 2025, the ARSO for WRNMMC notified DHA headquarters of the medical event. At or about 5:17 pm on May 19, 2025, DHA notified NRC Headquarters Operations Center and provided a written follow-up via email at 7:20 pm that same day.

The above-described error in the post-treatment survey and dose delivery calculation was identified by the WRNMMC ANP on Tuesday following the procedure (May 20, 2025). The ANP notified the ARSO that same day and provided a corrected copy of the TheraSphere planning sheet. This updated the recorded date for the post-treatment assay to be 1:20 pm on May 16 rather than 1:20 pm on May 19. With this correction, the decay-corrected pre-treatment net survey result changed from 0.452 millirem per hour to 0.984 millirem per hour, which in turn resulted in a calculated delivered activity of 2.5 millicuries, or approximately 11.5 percent of the desired activity. Note that this correction did not change the conclusion regarding the medical event reporting criteria.

2.3. Reportability and Timeliness

Consistent with DHA's reporting to the NRC Headquarters Operations Center, the second treatment is treated separately for reporting criteria from the first treatment. As a result, the 11.5 percent delivery of activity compared to the desired activity and therefore the corresponding target dose (1,350 Gray), constituted a medical event under 10 CFR 35.3045(a)(1)(i)(A). This reporting criteria involves incidents where: (1) the event was not caused by patient intervention; (2) involved the administration of byproduct material and did not involve permanent implant brachytherapy; (3) a dose that differed from the prescribed dose by more than 0.5 Seivert (50 rem) to an organ; and (4) the total dose delivered differs from the prescribed dosage by 20 percent or more.

The NRC, through its inspection, concluded that: (1) WRNMMC did not assert through any documentation nor interviews that patient intervention was a factor in the incident; (2) the administration, involving yttrium-90 microspheres, constituted the administration of byproduct material and did not constitute permanent implant brachytherapy under 10 CFR 35.400; (3) the dose delivered differed by more than 0.5 Seivert (50 rem) to an organ, as the dose differed by approximately 1,194 Gray, which is far in excess of 0.5 Seivert when considering the biological effect of the yttrium-90's radiation profile; and (4) the total dose differed by more than 20 percent, as the delivered dose differed by 88.5 percent from the intended dose.

As a facility authorized under the DHA license, the overall licensee was required to notify the NRC through the NRC Headquarters Operations Center no later than the next calendar day following discovery of the event. The NRC, through its inspection, concluded that WRNMMC "discovered" the event no later than 1:20 pm on May 16, 2025, as a result of the conclusion of the post-treatment survey and resulting calculation of the delivered activity. Although this post-treatment calculation was initially flawed, as already discussed above, both the original calculation and revised calculation had sufficient information to conclude a medical event had occurred. Thus, the requirement would have been to notify the NRC, consistent with 10 CFR 35.3045(c), no later than Saturday, May 17, 2025. WRNMMC did not notify DHA Headquarters staff, including the DHA Radiation Safety Officer (RSO), until Monday, May 19, 2025. Following this internal notification, DHA notified the NRC that same day. This was identified as a violation of 10 CFR 35.3045(c). Consistent with the NRC Enforcement Policy, Section 6.9.d(7), this violation was categorized as a Severity Level IV violation as a result of the report both being late (rather than a failure to make a notification at all) as well as its lack of material impact on the NRC's regulatory response.

DHA prepared and transmitted a written report to the NRC on May 30, 2025, describing its preliminary results into its investigation of the event. The licensee's report was deemed timely against the 15-day requirement in 10 CFR 35.3045(d), which would have a deadline of Monday, June 2, 2025 (15 days following the event falling on Saturday, May 31, 2025, which would be automatically extended to June 2, 2025, consistent with 10 CFR 2.813(a)). The NRC's review of the May 30, 2025, submission included feedback on May 31, 2025, to DHA regarding unredacted information with the patient's name and other identifying information (called out in 10 CFR 35.3045(d)(2) to-be-excluded). Patient identifying information was redacted and re-submitted on Monday, June 2, 2025 (ADAMS Accession No. [ML25191A209](#)). In conclusion, the licensee was determined to be in compliance with 10 CFR 35.3045(d).

The principal AU discussed the treatment with the patient on May 16, 2025, following the procedure (within 24 hours), as documented in a summary email to the WRNMMC ARSO on Tuesday, May 20, 2025. In addition, the principal AU spoke with the referring physician team at the Washington VA [Veterans Affairs] Medical Center on May 16, 2025 (also within 24 hours). Both of these notifications were required and made consistent with the timeliness requirements of 10 CFR 35.3045(e).

The AU later provided a written report to the referring physician team at the prompting of the NRC inspectors, as the earlier communications had been limited to verbal communications. While the written report was not provided within 15 days following the event as required by 10 CFR 35.3045(g)(2), the lack of immediate or anticipated harm to the patient, in combination with the verbal communications given to the referring

physician team, resulted in this noncompliance being concluded as a minor violation.

2.4. Licensee and Manufacturer Follow-up to the Medical Event

The licensee engaged with the manufacturer to provide the underlying delivery system and associated equipment for evaluation and analysis. This would occur following an initial period to allow the residual radioactive material to decay. Furthermore, the licensee communicated that the two involved AUs verbally committed to not use the subject microcatheter (Boston Scientific Direxion 0.021-inch) for future yttrium-90 TheraSphere treatments.

Following receipt of the subject materials and equipment, the manufacturer, Boston Scientific, performed an analysis and provided its resulting observations and conclusions to the NRC, and communicated that the report could be retained as a publicly available document. Following continued communications with the NRC, Boston Scientific indicated that its investigation report would not be ready in time for the transmission of this inspection report. To the extent that the Boston Scientific investigation report, upon receipt and review by the NRC, modifies or changes any NRC observations, findings, or conclusions, the NRC staff will generate additional documentation.

2.5. NRC Observations and Findings

The NRC inspectors performed interviews and reviewed records, procedures, and policies related to the performance of yttrium-90 Therasphere program. The inspectors' review focused on following the yttrium-90 doses on the day of May 16, 2025, as well as a wider review of the licensee's newly established Therasphere program, training associated with the shift from the Sir-Sphere program, and other components, such as the Radiation Safety group's support of the activity. Interviews were conducted with the ANP, health physicists, nuclear medicine technologists, and AUs.

Over the course of the inspection, the inspectors constructed a timeline as described in Section 2.2 above and identified further observations and findings related to the licensee's policies, procedures, and implementation of its program.

During the review of the licensee's two written directives associated with the subject treatment on May 16, 2025, the inspectors identified that the written directives presented were not dated by the AU pursuant to 10 CFR 35.40(a). In interviewing the staff involved, the inspectors learned that a written directive (the top of the TheraSphere planning sheet) was signed by the AU prior to the administration, but the electronic nature of the sheet means that further edits to the record must be completed within the electronic environment. The licensee did not retain the original hard copy signed written directive and instead retained only the final version of the TheraSphere planning sheet, following the delivered activity determination, which was re-distributed for re-signature. It was not clear that the original written directive was being dated by the AU at the time of the signature as required by 10 CFR 35.40(a), and other signatures by the AUs suggested this was likely not the case. However, the licensee's failure to retain a copy of the original signed copy prevented a reasonable conclusion by the inspectors. The licensee was required to retain a copy of the written directive for three years, consistent with 10 CFR 35.2040. The licensee's failure to retain the original signed copy of the written directive was determined to be a Severity Level IV violation of this requirement as it prevented the inspectors from evaluating the original signatures and approvals.

The inspectors reviewed the licensee's policies and procedures, particularly with a focus on the apparent timeliness concern regarding the reporting of the medical event (described above in Section 2.3). Several procedures were proximate to or addressed the yttrium-90 program, however at WRNMMC these documents were department-specific, as four groups had a role in the implementation of the treatment. WRNMMC maintained policies and procedures separate from and in addition to the procedures developed and distributed by DHA headquarters. Regarding the post-administration process, including identification of a medical event, WRNMMC Nuclear Medicine Standard Operating Procedure NM-931 "*Y-90 TheraSphere Therapy and Scan*" required only for the implementing staff to "*document residual and dose administered.*" The Radiation Safety procedure "*Therapy and Diagnostic Patient Procedures*" under Section 6 describes the procedures for yttrium-90 Microsphere therapy and did not identify any post-procedure review to identify medical events. The Interventional Radiology Protocol for yttrium-90 TheraSphere radioembolization did not include any post-procedure medical event evaluation. The nuclear pharmacy standard operation procedure 15.17b "*Y-90 TheraSphere Dose Preparation Procedure*" included, under Section 5 "*Calculation of Dose Delivered,*" a requirement that if the delivery is outside of a 10 percent variance for the implementing staff to immediately notify the ARSO. While the NRC regulatory requirement for medical events has additional criteria (See Section 2.3 of this report, above), this element of the nuclear pharmacy procedure at least appears to have been accomplished, in practice, by the immediate presence of the ARSO when the post-treatment activity delivered dose determination was made, as a result the ANP believed this notification was effectively accomplished.

As an institution, WRNMMC maintained Administrative Instruction 6050.02, which required certain actions and assigned certain responsibilities with respect to the medical event identification and reporting. For example, under Enclosure 2 "*Responsibilities*" Item 3 "*ARSO,*" Subitem U requires the ARSO to "*report Incidents and Unusual Occurrences to DHA RSO [in accordance with] reference (q) [Defense Health Agency Nuclear Regulatory License No 45-35423-01].*"

Applicable to all of DHA's subject facilities, DHA maintained a Procedure Manual titled "*Notifications and Reports for Radiation Safety Unusual Occurrences*" dated September 8, 2023. Under Item 6 of the Procedure, and further described in Enclosure 2 Item 5, ARSOs are directed to report [unusual occurrences] directly to the DHA Radiation Safety Office in accordance with the procedures outlined in Enclosure 3, to be knowledgeable of applicable external reporting requirements, and to ensure timely reports to the DHA Radiation Safety Office. Enclosure 3, Item 1.b directs the implementing staff to contact the DHA Radiation Safety Office when unclear about the reporting requirements or whether to consider an event an unusual occurrence. Appendix 1 to Enclosure 3 described the final criteria of the NRC's medical event criteria, as prescribed in 10 CFR 35.3045(a) and (b), though it was noted that no mention was made regarding the voidance permitted in cases of patient intervention. This Appendix further required immediate notification to the DHA's Radiation Safety Office.

The inspectors concluded that, through the DHA Procedure Manual, the licensee developed a procedure that adequately addressed the identification of medical events (10 CFR 35.41(b)(5)). However, through interviews and the unfolding of events at WRNMMC on May 16, 2025, it was clear to the inspectors that the staff at WRNMMC

were not familiar with nor implementing the DHA Procedure Manual described above. This failure appears to have directly contributed to the failure to initiate reporting within the DHA organization in a timely manner. While DHA's headquarters staff-initiated reporting to the NRC in a timely manner once notified by WRNMMC of the incident, as it was immediately recognized as a medical event, the requirement in 10 CFR 35.3045(c) is applied against the licensee as a whole, rather than against individual portions of the organization (e.g., DHA headquarters versus WRNMMC). The failure of WRNMMC to be familiar with and therefore implement the DHA Procedure Manual as described above was identified as a Severity Level IV failure to implement the DHA Procedure Manual identified above in accordance with 10 CFR 35.41(a).

2.6. Conclusion

The NRC's reactive inspection associated with the review of a medical event that occurred on May 16, 2025, at WRNMMC and DHA's compliance with its NRC license and regulatory requirements identified two violations associated with the failures to: (1) provide a timely report to the NRC following identification of a medical event in accordance with 10 CFR 35.3045(c); (2) retain copies of written directives in accordance with 10 CFR 35.2040; and (3) implement procedures that provide high confidence to determine if a medical event has occurred in accordance with 10 CFR 35.41(a). These noncompliances were identified as Severity Level IV violations.

3. **Corrective Actions**

The licensee prepared its initial corrective actions and communicated these to the NRC as part of their 15-day report following the medical event on May 16, 2025, consistent with 10 CFR 35.3045(d)(1)(vi). These actions included: (1) investigation into the physical delivery device by the manufacturer, Boston Scientific, as described above in Section 2.4 of this report, (2) investigation by the WRNMMC team to integrate lessons learned into the treatment protocol, including updates to the safety and setup checklists and additional troubleshooting steps; (3) a verbal commitment by the treatment team to not use the specific microcatheter device for future microsphere treatments based on the potential weaknesses or vulnerabilities encountered with the device. As described in Section 2.3 of this report, the licensee's 15-day report can be found at ADAMS Accession No. [ML25191A209](#).

Following the NRC on-site inspection, DHA and WRNMMC communicated additional actions being taken or that had already been taken by the facility to ensure the NRC's preliminary findings and the medical event's root causes were addressed. These actions included: (1) a firm commitment regarding the exclusion of the specific microcatheter device for future microsphere treatments; (2) modifications to the documentation, processing, and completion of written directives relative to the performance of the microsphere treatment, such as chain-of-custody concerns, validation of AU endorsement of the written directive, clarifying existing procedures for medical event assessment determination and internal DHA reporting, and performance of refresher training that emphasizes medical event determination and reporting responsibilities for all parties supporting microsphere treatments; and (3) modification of existing procedures for the nuclear pharmacy and other supporting services to create additional safeguards to address written directive weaknesses or issues identified during the inspection. These corrective actions were submitted via email in an unsigned document on August 18, 2025 (ADAMS Accession No. [ML25251A071](#)).

Collectively, the NRC acknowledges these corrective actions as reasonably addressing the identified findings and the underlying direct/contributing causes to those findings.

4. Exit Meeting Summary

The licensee acknowledged the observations and preliminary findings presented by the NRC following the onsite inspection on June 10, 2025, and committed to formulating a corrective action plan. The NRC conducted a final exit briefing via teleconference on August 21, 2025, with DHA representatives, including COL Ricardo Reyes, Ph.D., Radiation Safety Officer, and representatives of WRNMMC. The licensee again acknowledged the findings presented and did not dispute any of the facts presented at the time of the final exit meeting.

SUPPLEMENTARY INFORMATION

LIST OF PERSONS CONTACTED

Captain Melissa C. Austin, WRNMMC, Director
Colonel Ricardo Reyes, Ph.D., DHA, RSO
Nsikak Okosi, WRNMMC, ARSO
Crystal Green, Ph.D., W WRNMMC, Radiation Safety
Xinlian Chen, Pharm D, BCNP, WRNMMC, ANP
Alan Drooz, M.D., WRNMMC, Interventional Radiologist and Authorized User
Major Clayton Brittingham, M.D., WRNMMC, Interventional Radiologist and Authorized User
Stephen Seaman, Boston Scientific Therasphere Consultant

INSPECTION PROCEDURES USED

87103 - Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-39046/2025-007-01	VIO	10 CFR 35.3045(c) – failure to notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a medical event.
030-39046/2025-007-02	VIO	10 CFR 35.2040 – failure to retain written directives.
030-39046/2025-007-03	VIO	10 CFR 35.41(a) – failure to implement written procedures to provide high confidence that, in part, determine if a medical event, as defined in 10 CFR 35.3045, had occurred.

Closed

None

Discussed

030-39046/2025-007-04		10 CFR 35.40(a) – Inconclusive observation regarding whether the licensee’s written directives were dated by the authorized user, prior to the administration, as a result of the licensee’s failure to retain the original copy of the written directive.
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LIST OF ACRONYMS AND ABBREVIATIONS USED

ADAMS	Agencywide Documents Access and Management System
ANP	Authorized Nuclear Pharmacist
ARSO	Associated Radiation Safety Officer
AU	Authorized User
CFR	<i>Code of Federal Regulations</i>
DHA	Defense Health Agency
NRC	Nuclear Regulatory Commission
RSO	Radiation Safety Officer
WRNMMC	Walter Reed National Military Medical Center