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

May 4, 2026

EAF-RI-2026-0026
EN 58119

Nathan Burt, Vice President of Operations
West Virginia University Hospitals, Inc.
P.O. Box 9006
Morgantown, WV 26506-9006

SUBJECT: WEST VIRGINIA UNIVERSITY HOSPITALS, INC., NRC INSPECTION REPORT NO. 030-20233/2026-001

Dear Nathan Burt:

This letter refers to the announced inspection initiated remotely by the Nuclear Regulatory Commission (NRC) on January 20, 2026, and continued onsite from February 9-12, 2026, at your facility in Morgantown, West Virginia. The purpose of the inspection was to examine a reported loss of licensed radioactive material that was discovered by West Virginia University Hospitals, Inc. (WVUH) on January 16, 2026, involving a therapeutic dose of lutetium-177. The inspection consisted of interviews with personnel, as well as a selected examination of procedures and representative records. A final exit meeting was conducted on April 14, 2026, and included you, Steven Root, your Radiation Safety Officer, as well as other WVUH representatives.

Based on the results of this inspection, the NRC identified two apparent violations (AV), one of which is being considered for escalated enforcement action in accordance with the NRC's Enforcement Policy. The current Enforcement Policy is available on the NRC's web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The details of the NRC's observations and findings are documented in the enclosed publicly available inspection report. The AVs involved WVUH's apparent failures regarding: (1) the timely reporting to the NRC following discovery of the missing radioactive material, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2201(a)(1)(i); and (2) the disposal of licensed material only by means permitted by 10 CFR 20.2001(a) (i.e., transfer to an authorized recipient, decay in storage, by release in effluents within the limits in 10 CFR 20.1301, or as otherwise authorized in 10 CFR Part 20).

Since one of the two apparent violations involves improper transfer for disposal of licensed material, the NRC is considering proposing imposition of a civil monetary penalty. Section 2.3.13, "Failure to Control and Loss of NRC-Regulated Material," of the NRC Enforcement Policy states that for violations where a licensee has lost required control of its regulated licensed material for any period of time, the NRC may exercise discretion and impose a civil penalty. The base civil penalty amount, as set out in Section 8.0, "Table of Base Civil Penalties," of the Policy, is based on approximately three times the expected average cost of authorized disposal; however, the NRC may exercise its discretion to mitigate or escalate a civil penalty amount based on the merits of a specific case.

Therefore, you may provide information regarding the actual expected cost of authorized disposal that you believe the NRC should consider in making a final enforcement decision. However, NRC will not normally reduce the civil penalty to an amount below the lowest base civil penalty for such cases (i.e., $9,000).

Before the NRC makes its final enforcement decision, we are providing you with an opportunity to (1) respond to the apparent violations addressed in this inspection report in writing within 30 days of the date of this letter, (2) request a Pre-decisional Enforcement Conference (PEC), or (3) request Alternative Dispute Resolution (ADR) mediation. If a PEC is held, it will be open for public observation, and the NRC will issue a press release to announce the time and date of the conference. If you decide to participate in a PEC or pursue ADR, please contact **Monica Ford at (610) 337-5214 or via email at Monica.Ford@nrc.gov within 10 days of the date of this letter**. A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in NRC Inspection Report 030-20233/2026-001; EAF-RI-2026-0026," and should include: (1) the reason for the AVs, or, if contested, the basis for disputing the AVs; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance was or will be achieved. Your response may reference or include previously docketed correspondence if the correspondence adequately addresses your response. Additionally, your response should be sent to U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy mailed to Marc Ferdas, Acting Director, Division of Radiological Safety & Security, U.S. Nuclear Regulatory Commission Region I, 475 Allendale Road, Suite 102, King of Prussia, PA, 19406, and emailed to R1Enforcement@nrc.gov within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

If you choose to request a PEC, the conference will include an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the PEC may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the AVs. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing for your response.

In lieu of a PEC or written response, you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third-party. The technique that the NRC has decided to employ is mediation: a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be

creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC ADR program can be obtained at https://www.nrc.gov/about-nrc/regulatory/enforcement/adr/post-investigation.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC program as a neutral third party. Please contact ICR at 877-733-9415 within **10 days** of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

Please be advised that the characterization of the apparent violations described in the enclosed inspection report may change as a result of further review. You will be advised by separate correspondence of the results of our deliberations on this matter.

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

If you have any questions related to this matter, please contact Monica Ford or my staff at (610) 337-5143 or Monica.Ford@nrc.gov.

Sincerely,

MARC FERDAS Digitally signed by MARC FERDAS
Date: 2026.05.04 12:33:25 -04'00'

Marc Ferdas, Acting Director
Division of Radiological Safety and Security
Region I

Docket No. 030-20233
License No. 47-23066-02

Enclosure:
1. Inspection Report No. 030-20233/2026-001
2. Excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action"

cc w/Encl:
Steven Root, M.S. Director, Radiation Safety Department and Radiation Safety Officer
Kristen Daft, Associate Radiation Safety Officer
State of West Virginia

SUBJECT: WEST VIRGINIA UNIVERSITY HOSPITALS, INC., NRC INSPECTION REPORT NO. 030-20233/2026-001
DATED MAY 4, 2026

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SCD No. ML26103A047
ADAMS Accession Nos.: Pkg ML26103A038, Ltr ML26103A035
e-Concurrence No.: 20260413-20004

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Docket:	030-20233
License:	47-23066-02
Report:	2026-001
EA No.:	EAF-RI-2026-0026
Licensee:	West Virginia University Hospitals, Inc.
Location Inspected:	J. W. Ruby Memorial Hospital, 1 Medical Center Dr., Morgantown, West Virginia, 26506
Inspection Dates:	Initiated remotely on January 20, 2026, continued onsite February 9-11, 2026, with in-office review through March 23, 2026
Inspectors:	Jason vonEhr, Senior Health Physicist Medical & Licensing Assistance Branch Division of Radiological Safety & Security Candace Krout, Health Physicist Commercial, Industrial, R&D and Academic Branch Division of Radiological Safety & Security
Approved By:	Monica Ford, Acting Chief Medical & Licensing Assistance Branch Division of Radiological Safety & Security
Attachment:	Supplementary Information

EXECUTIVE SUMMARY

West Virginia University Hospitals, Inc.
NRC Inspection Report 030-20233/2026-001

A non-routine inspection was initiated remotely on January 20, 2026, and continued onsite from February 9-12, 2026, at West Virginia University Hospitals, Inc. (WVUH), concurrent to a separate planned inspection activity. The inspection was an examination of a reported loss of licensed radioactive material that was discovered by WVUH on January 16, 2026, as it related to public health and safety, to confirm compliance with the NRC's rules, regulations, and with the conditions of the U.S. Nuclear Regulatory Commission (NRC) license. Within the scope of the inspection, the inspection consisted of interviews with personnel, as well as a selected examination of procedures and representative records.

Program Overview

WVUH is authorized as a medical broad scope by NRC License No. 47-23066-02 to conduct medical diagnosis, therapy, and research in humans, among other NRC-licensed activities, using byproduct material under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30 and Part 35 at its facilities in Morgantown, Ranson, and Fairmont, West Virigina.

Inspection Findings

Through the performance of the NRC inspection, two apparent violations (AV) were identified. The AVs involved WVUH's apparent failure regarding: (1) the timely reporting to the NRC following discovery of the missing radioactive material; and (2) the disposal of licensed material only by means permitted by 10 CFR 20.2001(a) (i.e., transfer to an authorized recipient, decay in storage, by release in effluents within the limits in 10 CFR 20.1301, or as otherwise authorized in 10 CFR Part 20).

Corrective Actions

The licensee submitted a 30-day report dated February 12, 2026, to the NRC outlining their investigation, conclusions, and corrective actions associated with the event (Agencywide Documents Access and Management System (ADAMS) Accession No. ML26055A071[1]). The corrective actions in this letter included revising the package receipt procedure and providing additional training for both nuclear medicine technologists and environmental services staff.

[1] NRC Agencywide Documents Access and Management System (ADAMS) Accession Numbers listed in this letter may be accessible using the hyperlink below with the associated ADAMS Accession Number inserted in place of the "ML" at the end: https://www.nrc.gov/docs/ML

REPORT DETAILS

1. Program Overview

WVUH is authorized as a medical broad scope by NRC License No. 47-23066-02 to conduct medical diagnosis, therapy, and research in humans, among other NRC-licensed activities, using byproduct material under 10 CFR Part 30 and Part 35 at its facilities in Morgantown, Ranson, and Fairmont, West Virigina.

2. Observations and Findings

2.1. Inspection Scope (IP87103)

The announced, non-routine inspection was initiated remotely on January 20, 2026, and continued onsite from February 9-12, 2026. The inspection was performed concurrently with other planned inspection activities by the NRC at WVUH. The scope of this portion of the inspection was an examination of a reported loss of licensed radioactive material that was discovered by WVUH on January 16, 2026, involving a therapeutic dose of lutetium-177, as it related to public health and safety, to confirm compliance with the NRC's rules, regulations, and with the conditions of the NRC license. Within the scope of the inspection, the inspection consisted of interviews with personnel, and a selected examination of procedures and representative records.

2.2. Timeline of Event

WVUH received and checked in a package containing lutetium-177, specifically Lutetium Dotatate Lutathera, to the Nuclear Medicine Department of the J.W. Ruby Memorial Hospital in Morgantown, West Virginia, at 10:45 am on January 15, 2026. The package contained approximately 247 millicuries of lutetium-177 at the time the package was checked in. The package was surveyed using a Ludlum Model 3 survey meter with a background reading at one meter and an on-contact reading of 0.05 millirem/hour. The package was wiped to evaluate any removable contamination, with none detected. The dosage was intended for a patient scheduled for treatment the next day (January 16, 2026).

On January 16, 2026, at approximately 8:45 am, the licensee staff was preparing for the administration for the patient and identified the dosage was not where it is normally stored. Radiation Safety, through the Associate Radiation Safety Officer (ARSO), was nearby to support the administration and therefore immediately aware of the issue. The lead nuclear medicine technologist called the technologist that received the dosage the prior day to understand if the technologist recalled any details about the dosage and where it might be. The licensee began searching for and investigating this as a loss of radioactive material.

The licensee was able to review security camera footage that appeared to show the WVUH environmental services department staff taking the Lutathera transportation box to the trash compactors (Figure 1). WVUH contacted the solid waste vendor, to attempt to recover the material. The waste management company stated that the roll off dumpster had already been through the transfer station and was on its way to the landfill. WVUH requested an opportunity to inspect and survey the waste prior to it going into the landfill but that request was denied.

Figure 1 – Image from WVUH security camera footage showing the licensee's Lutathera transportation packaging being taken out to the loading dock for disposal as non-radioactive, non-hazardous trash.

The packaging around the radioactive material was believed to have been left in-place by the licensee prior to this unintentional disposal. The configuration of the package was such that the lead shield was likely to remain closed and thus to pose only minimal external radiation hazard. This configuration included a heavy-duty adhesive tape holding the two ends of the shielding together as well as a plastic cellophane-like bag surrounding it. This is shown below in Figure 2, a pair of images supplied by WVUH from the next scheduled Lutathera administration.

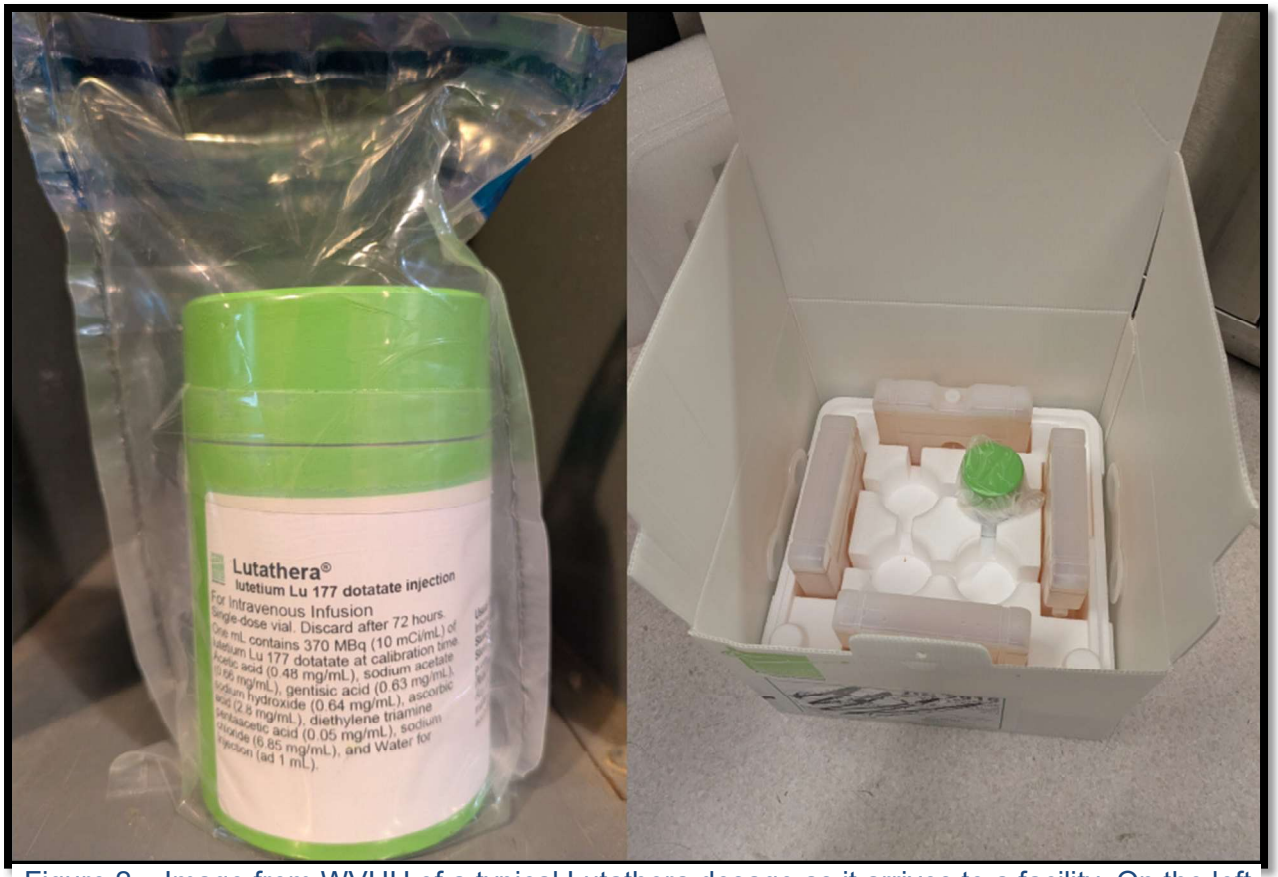

Figure 2 – Image from WVUH of a typical Lutathera dosage as it arrives to a facility. On the left is the green shielded vessel with a heavy-adhesive tape between the top and bottom. On the right is the shipping materials, including heavy ice-packs.

2.3. Reportability and Timeliness

WVUH reported the loss of lutetium-177 on January 16 at 3:38 pm to the NRC's Headquarters Operations Center. The loss of the radioactive material was subject to the reporting requirements in 10 CFR 20.2201(a)(1)(i), which requires immediate reporting to the NRC following the discovery of the loss of radioactive material exceeding 1,000 times the quantity listed in 10 CFR Part 20, Appendix C. At the time of discovery, the lutetium-177 was approximately 225 millicuries, more than 1,000 times the corresponding value of 0.1 millicuries found in Appendix C.

The licensee discovered the loss of the material at approximately 08:45 am on the morning of January 16; however, the licensee did not report the loss to the NRC until 3:38 pm, a difference of approximately seven hours. Pursuant to Regulatory Issue Summary 2005-21 "Clarification of the Reporting Requirements in 10 CFR 20.2201," the NRC's interpretation of "immediate" was clarified to be within four hours after discovery. Consistent with this, an apparent violation of 10 CFR 20.2201(a)(1)(i) was identified concerning the delay in reporting the loss of radioactive material to the NRC.

Following the telephonic notification, the licensee was required to provide a 30-day report, consistent with 10 CFR 20.2201(b). The resultant written report, dated

February 12, 2026, was received by the NRC electronically on February 13, 2026, and was therefore deemed timely. The report included the information required by regulation, with no concerns identified as to the report.

2.4. NRC Observations and Findings

The NRC performed a series of interviews of involved personnel, tours of the involved infrastructure and facilities, and review of pertinent records involved in the receipt and intake of the lutetium-177 dosage on January 15, 2026.

The interviews with WVUH staff provided confirmation of the licensee's described timeline of operations, as well as additional details regarding the handling of the dosage upon receipt and the licensee's extensive investigatory efforts made to recover the dosage. The inspectors interviewed the two technologists, the lead technologist, the molecular imaging supervisor, the ARSO, and the Radiation Safety Officer (RSO), with general agreement regarding the details of the timeline and events leading up to and following discovery. The Radiation Safety staff, including the ARSO and RSO, became quickly involved with investigating the loss of the dosage, including outreach to the hospital's solid waste vendor—who reported no issues or radiation alarms at its facilities—however, the solid waste vendor was unwilling to intervene in its waste processing stream to provide WVUH personnel an opportunity to intercept and potentially recover the radioactive material. Additional details regarding the licensee's interactions with the solid waste vendor are provided in the licensee's 30-day report dated February 12, 2026. The licensee's staff produced written contemporary statements to capture their details and memories of the sequence of events.

The licensee's normal intake procedure required that the radioactive dosage to be surveyed and wiped for determination of contamination. Following these steps, the dosage would be removed from the packaging and placed in a fume hood within the nuclear medicine department's hot lab for storage pending the administration to the patient the next day. Based on the interviews and reviews of related records, it appears that one of the technologists assumed the dosage had been removed from the package and associated shipping material, at which point the package had its trefoil defaced and the package and associated materials set outside the hot lab for pickup by WVU Environmental Services.

The licensee demonstrated with reasonable and adequate radiation instrumentation that the dosage, within the normal packaging, would not have been readily detectable against background radiation levels while in a trash can used for non-radioactive waste, thus removing other opportunities for the licensee's staff to have identified the dosage through other normal mechanisms (e.g., end-of-day surveys). Staff involved were queried for their training, including refresher training, which the licensee provided documentation for. No concerns were identified with regards to the training content or frequency for involved licensee staff.

Radiation portal monitors were installed between the hot lab and the normal waste streams, through which the dosage's package is believed to have been taken. The inspectors concluded through demonstration by the licensee, and through review of other radiation incidents (e.g., patient waste), that the portal monitors were still functional and had a reasonably low trigger level; however, the radiation levels being emitted from the lutetium-177 dosage did not appear to be sufficient to be detected and/or trigger the portal monitors when the dosage's shielding was intact.

Significant radiation exposures to members of the public are highly unlikely given that the dose likely remained within its shielding and that the shielding was in a configuration that would require active intervention by an outside individual and that such intervention was highly unlikely.

2.5. Apparent Violations

Two apparent violations (AVs) were identified associated with the NRC's requirements. The AVs involved WVUH's apparent failures regarding: (1) the timely reporting to the NRC following discovery of the missing radioactive material; and (2) the inappropriate transfer of a dosage of lutetium-177 during its unintended removal and misplacement as the dosage was disposed of via non-hazardous material trash management stream.

Consistent with the above, the two AVs are described below.

1. 10 CFR 20.2201(a)(1)(i) requires that each licensee shall report by telephone immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to 10 CFR Part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas.

   Contrary to the above, on January 16, 2026, the licensee failed to report by telephone immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to Part 20 under such circumstances that it appeared to the licensee that an exposure could result to persons in unrestricted areas. Specifically, the licensee provided its report by telephone approximately seven hours following discovery of the loss of 241.83 mCi of Lu-177 (an aggregate quantity greater than 1,000 times the quantity in Appendix C), a duration of time exceeding what the NRC expects by "immediate" reporting, consistent with Regulatory Issue Summary 2005-21.

2. 10 CFR 20.2001(a) requires, in part, that a licensee shall dispose of licensed material only by permitted means (i.e., transfer to an authorized recipient, decay in storage, by release in effluents within the limits in 10 CFR 20.1301, or as otherwise authorized in 10 CFR Part 20).

   Contrary to the above, on January 15, 2026, the licensee failed to dispose of licensed material by a means permitted by 10 CFR 20.2001(a). Specifically, the licensee inadvertently disposed of a 241.83 mCi dosage of lutetium-177 via ordinary non-hazardous trash processing and therefore failed to utilize an appropriate means of disposal via 10 CFR Part 20, Subpart K.

2.6. Conclusion

The NRC's inspection of WVUH's compliance with NRC license and regulatory requirements identified two AVs associated with WVUH's apparent failure regarding: (1) the timely reporting to the NRC following discovery of the missing radioactive material; and (2) the disposal of licensed material only by means permitted by 10 CFR 20.2001(a) (i.e., transfer to an authorized recipient, decay in storage, by release in effluents within the limits in 10 CFR 20.1301, or as otherwise authorized in 10 CFR Part 20).

3. Corrective Actions

The licensee submitted a 30-day report dated February 12, 2026, to the NRC outlining their investigation, conclusions, and corrective actions associated with the event. The licensee's corrective actions were described in this letter and included modifying the package intake procedure pursuant to 10 CFR 20.1906 to include breaking down the transport packaging (to preclude a dose being left inside), performing a nuclear medicine refresher training on all nuclear medicine policies and procedures for staff, and adding a standing item during monthly staff meetings for a staff-lead effort to review a different, rotating nuclear medicine policy/procedure for ongoing education and training.

4. Exit Meeting Summary

The NRC conducted a final exit meeting via teleconference on April 14, 2026, with WVUH representatives, including: Nathan Burt, Vice President of Operations, Stephen Root, Director, Radiation Safety Department, and other representatives of WVUH. The licensee acknowledged the findings presented and did not dispute any of the facts presented.

SUPPLEMENTARY INFORMATION

LIST OF PERSONS CONTACTED

Nathan Burt, Vice President of Operations
Stephen Root, Director, Radiation Safety Department, Radiation Safety Officer
Kristen Daft, Associate Radiation Safety Officer
Jennifer Pettry, Molecular Imaging Supervisor
Julie Coddington, Lead Nuclear Medicine Technologist

INSPECTION PROCEDURES USED

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

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-20233/2026-001-01	AV	10 CFR 20.2001(a) – apparent failure to dispose of licensed material appropriately.
030-20233/2026-001-02	AV	10 CFR 20.2201(a)(1)(i) – apparent failure to make an immediate report following discovery of lost radioactive material in excess of 1,000 times the associated 10 CFR Part 20 Appendix C value.

Closed

None

Discussed

None

LIST OF ACRONYMS AND ABBREVIATIONS USED

ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
ARSO	Associate Radiation Safety Officer
AV	Apparent Violation
CFR	*Code of Federal Regulations*
NRC	Nuclear Regulatory Commission
PEC	Pre-decisional Enforcement Conference
RSO	Radiation Safety Officer
WVUH	West Virginia University Hospitals, Inc.

NOTE: The following information is an updated excerpt from NRC Information Notice 96-28 issued during 1996.

NRC INFORMATION NOTICE 96-28

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

May 1, 1996

NRC INFORMATION NOTICE 96-28: SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action or written response is required.

Background

On June 30, 1995, NRC revised its Enforcement Policy, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, NRC encourages and expects identification and prompt, comprehensive correction of violations.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section VI.A of the Enforcement Policy. Minor violations are not subject to formal enforcement action. Nevertheless, the root cause(s) of minor violations must be identified and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as required by 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence.

In some cases, such violations are documented on Form 591 (for materials licensees) which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a predecisional enforcement conference may be held to discuss those actions.

The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a predecisional enforcement conference with the licensee and the level of sanction proposed or imposed.

Discussion

Comprehensive corrective action is required for all violations. In most cases, NRC does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation.

It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest, but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation.

Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the particular case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation. Typically, such reviews include:

   Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers. Tours and observations of the area where the violation occurred, particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that may have contributed to the violation as well as those items that may result in future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred. Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its overall objectives and requirements are clearly stated and implemented. Procedures should be

reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the **current** requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to provide a record that can be audited and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

   Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns **and** prevent recurrence of the violation.

   It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, **immediate** corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

In evaluating the root causes of a violation and developing effective corrective action, consider the following:

1. Has management been informed of the violation(s)?

2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?

3. Have precursor events been considered and factored into the corrective actions?

4. In the event of loss of radioactive material, should security of radioactive material be enhanced?

5. Has your staff been adequately trained on the applicable requirements?

6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?

7. Has your staff been notified of the violation and of the applicable corrective action?

8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?

9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?

10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?

11. Is a system in place for keeping abreast of new or modified NRC requirements?

12. Does your staff appreciate the need to consider safety in approaching daily assignments?

13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?

14. Have work hours affected the employees' ability to safely perform the job?

15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?

16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?

17. Has management established a work environment that encourages employees to raise safety and compliance concerns?

18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?

19. Has management communicated its expectations for safety and compliance?

20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?