UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

March 9, 2021

EA-20-141

Matthew Kaufman
Vice President of Operations
The William W. Backus Hospital
326 Washington Street
Norwich, CT 06360

SUBJECT: THE WILLIAM W. BACKUS HOSPITAL NRC INSPECTION REPORT NO. 03001287/2020001 AND APPARENT VIOLATIONS

Dear Mr. Kaufman:

On October 22, 2020, Elizabeth Tindle-Engelmann of this office conducted a routine, announced inspection of your activities performed under your Nuclear Regulatory Commission (NRC) license at your facility in Norwich, Connecticut. The inspection was an examination of your licensed activities as they relate to radiation safety, compliance with the Commission's regulations, and the conditions in your license. In-office review concluded on January 26, 2021. The preliminary inspection findings and circumstances surrounding five apparent violations were discussed with you and your staff during a briefing on October 22, 2020, and during an exit meeting held remotely on January 26, 2021. The discussions included the significance of the issues, your corrective actions, and your preventative actions. The enclosed inspection report presents the findings of this inspection.

Based on the results of this inspection, the NRC determined that four apparent violations of NRC requirements occurred related to the improper disposal of licensed material and one apparent violation of NRC requirements occurred related to the calibration of instrumentation used to measure the activity of unsealed byproduct material. The four related apparent violations are being considered for escalated enforcement action 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.

We noted that you took immediate corrective actions to comply with NRC requirements. However, because these apparent violations involved the release of licensed material, the NRC's enforcement action could include a proposed civil penalty. Section 2.3.4, Civil Penalty, of the 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 normally will impose at least a base civil penalty. Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued at this time. Please be advised that the number and 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.

Before the NRC makes its enforcement decision, we are providing you an opportunity to offer your perspective on this matter and provide any information you believe the NRC should take into consideration. You can elect to provide such information by either: (1) responding to the apparent violations addressed in this inspection report within **30 days** of the date of this letter, (2) requesting a Pre-decisional Enforcement Conference (PEC), or (3) requesting Alternative Dispute Resolution (ADR). Alternately, you may choose to accept the violations as characterized in this letter and its enclosure. Please contact Donna Janda, Chief, Medical and Licensing Assistance Branch, NRC Region I, at 610-337-5371 or donna.janda@nrc.gov within **10 days** of the date of this letter to notify the NRC which of the above options you choose. 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 provide a written response, you should provide the following information for each apparent violation: (1) the reasons for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. You should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalties for the apparent violations. 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.

The written response should be sent to the NRC within **30 days** of the date of this letter. The NRC recognizes that many licensees have been impacted by the public health emergency caused by the Coronavirus Disease 2019 (COVID-19). Consequently, you may request an extension of time to submit the response by contacting Donna Janda, Chief, Medical and Licensing Assistance Branch, NRC Region I, at 610-337-5371 or donna.janda@nrc.gov. An extension request should explain the basis for the request and should specify the amount of additional time being requested. An extension request must be submitted no later than **20 days** from the date of this letter. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. You should clearly mark the response as a “Response to Apparent Violations in NRC Inspection Report No. 03001287/2020001; EA-20-141,” and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, NRC Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406.

If you choose to request a PEC, the meeting will be held within 30 days of the date of this letter; although this timeframe may be extended due to impacts from COVID-19. 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 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. The PEC would be open for public observation, and the NRC would issue a press release to announce the conference time and date.

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 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 http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.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. The ADR mediation session should be held within 45 days of the date of this letter, although this timeframe may be extended due to impacts from COVID-19. The mediation session would be closed to public observation, but the time and date would be publicly announced.

In accordance with 10 CFR 2.390 of the NRC's Rules of Practice, 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 or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

Sincerely,

Blake D. Welling

Digitally signed by Blake D. Welling
Date: 2021.03.09 07:09:57 -05'00'

Blake D. Welling, Director
Division of Nuclear Materials Safety

Enclosures:
1. NRC Inspection Report No. 03001287/2020001
2. NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action"

Docket No. 03001287
License No. 06-11734-02

cc w/Encls: Phillip Kohanski, M.D., RSO

cc w/o Encls: State of Connecticut

SUBJECT: THE WILLIAM W. BACKUS HOSPITAL NRC INSPECTION REPORT NO. 03001287/2020001 DATED MARCH 9, 2021

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DATE	2/24/21	03/09/2021			

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001287/2020001
Docket No.	03001287
License No.	06-11734-02
EA No.	EA-20-141
Licensee:	The William W. Backus Hospital
Address:	326 Washington Street Norwich, CT 06360
Inspection Dates:	October 22, 2020, through January 26, 2021
Exit Meeting	January 26, 2021

Inspector: Elizabeth D. Tindle-Engelmann Digitally signed by Elizabeth D. Tindle-Engelmann Date: 2021.03.08 16:27:57 -05'00'

Elizabeth Tindle-Engelmann date
Health Physicist
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

Approved By: Donna M. Janda Digitally signed by Donna M. Janda Date: 2021.03.08 16:41:50 -05'00'

Donna M. Janda, Chief date
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

The William W. Backus Hospital
NRC Inspection Report No. 03001287/2020001

The NRC conducted a routine, announced inspection to review the organization and scope of activities performed under The William W. Backus Hospital's NRC License No. 06-11734-02. The licensee is a small community hospital authorized for 10 CFR 35.100, 35.200, 35.300, and a Gadolinium-153 source pending disposal. Due to the COVID-19 public health emergency (PHE), the inspection began remotely with a review of records. The onsite inspection was conducted on October 22, 2020 in accordance with NRC Inspection Procedure 87131, "Nuclear Medicine Programs, Written Directive Required," with in office review concluding on January 26, 2021. The performance-based inspection examined activities conducted under the license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of the license. Within these areas, the inspection included a review of the licensee's facilities, direct observations of licensed activities, interviews with personnel, and a review of required records. In addition, the circumstances surrounding the improper disposal of licensed material was examined during this inspection.

During the inspection, five apparent violations of NRC requirements were identified. The first four violations involved the inadvertent transfer of seven radioactive sealed sources to a hazardous waste vendor and are being considered for escalated enforcement. The apparent violations involved the failure to:

1) dispose of licensed material in accordance with 10 CFR 20.2001;
2) label each container of licensed material in accordance with 10 CFR 20.1904;
3) test sealed sources for leakage in accordance with 10 CFR 35.67;
4) implement written waste disposal procedures for licensed material in accordance with License Condition 16 of NRC License Number 06-11734-02; and
5) calibrate instrumentation used for direct measurements of unsealed byproduct material prior to administration to each patient in accordance with 10 CFR 35.60.

The licensee's corrective actions for apparent violations 1 – 4 included hiring a contractor to secure, inventory, survey, and dispose of the sealed sources. The licensee's preventative actions for apparent violations 1 – 4 included: 1) performing a thorough review of all Nuclear Medicine (NM) use and storage areas to ensure all licensed material was identified, documented, and labeled in accordance with NRC requirements; 2) updating written procedures; 3) retraining NM staff on written procedures; and 4) properly disposing of several unused sealed sources after this event to reduce the risk of a recurrent violation. The licensee's corrective actions for apparent violation 5 included completing the calibrations in accordance with 10 CFR 35.60. The licensee's preventative actions for apparent violation 5 was to reassign quarterly audit responsibilities to Hartford HealthCare's Radiation Protection Office.

REPORT DETAILS

1. Organization and Scope of the Program

a. Inspection Scope

The inspector reviewed the organization and scope of activities performed under The William W. Backus Hospital's NRC License No. 06-11734-02. Information was gathered through direct observation of licensed activities, interviews with licensee staff, a review of selected records, and a tour of the facilities.

b. Observations and Findings

The William W. Backus Hospital is an acute care community hospital located in Norwich, Connecticut. The NRC license, issued on September 7, 1984, authorizes the medical use of licensed material under 10 CFR 35.100, 35.200, 35.300, and the storage of a Gadolinium-153 sealed source. The Nuclear Medicine (NM) department sees approximately 12 patients per day for an array of general nuclear medicine and nuclear cardiology studies. The NM department uses primarily unit doses of Technetium-99m that are received from Cardinal Health's Hartford location. The NM department also receives and administers approximately six therapeutic doses of Iodine-131 and Radium-223 on a weekly basis. All therapies are performed on an outpatient basis. The NM department is staffed by five full-time Nuclear Medicine Technologists (NMTs) and consists of two hot labs, one injection area, three imaging cameras, and three treadmills. The primary NM hot lab is in the NM department. All radioactive material is received and assayed prior to administration in the primary hot lab. There is an infrequently used satellite hot lab in the cardiology department. The licensee utilizes a contractor for mobile PET services four days per week.

The Radiation Safety Officer (RSO) is onsite daily and serves as the principal NM Authorized User (AU). The RSO is supported by the director of the Hartford HealthCare Radiation Protection Program as needed for radiation safety matters. The licensee's NM department is responsible for performing dose calibrator quality control testing, sealed source inventory and leak tests, surveys, and coordination of instrument calibration. At the beginning of the inspection period, the licensee utilized a consultant for internal audits and training; however, the licensee began performing these tasks internally through the Hartford HealthCare group. The licensee maintains a Radiation Safety Committee (RSC) that meets quarterly to discuss ALARA matters, incidents, and radiation safety.

2. Review of Licensed Activities

a. Inspection Scope

The inspector performed an announced routine inspection utilizing NRC Inspection Procedure 87131, "Nuclear Medicine Programs, Written Directive Required," to conduct the inspection. Information was gathered through interviews with cognizant personnel,

direct observation of licensed activities, review of records, tour of the facility, and through the performance of independent radiation surveys.

b. Direct Observations, Interviews, and Records Review

The inspector toured the facility and observed the receipt of packages containing radioactive material, the return of packages, performance of dose calibrator quality control testing, explanations of procedures to patients, and preparations/administrations of patient dosages. The technologists were knowledgeable and demonstrated safe handling of radioactive material. The inspector toured the service level of the hospital where the licensee had a portal monitor installed as a final survey for all waste leaving the facility. Any items that exceeded the alarm set point were held for decay in storage in a secure location.

The following records were reviewed: annual program audits, RSC meeting minutes, dose rate surveys, contamination surveys, package receipt and return records, dosimetry reports, radioactive waste disposals, decay in storage, dose calibrator calibrations, survey instrument calibrations, well counter calibrations, sealed source inventory, leak test, and transfer records, radiation safety and DOT/HAZMAT training, a sample of written directives for each type of therapeutic treatment, patient release calculations, and patient release instructions. The inspector found that written directives were correctly documented, patients were given appropriate release instructions, and that the licensee documented the basis for release through patient-specific calculations. During the review of the dose calibrator calibrations, the inspector determined that the licensee did not calibrate the dose calibrator in accordance with nationally recognized standards or the manufacturer's instructions in accordance with 10 CFR 35.60(b). The inspector noted that the linearity test for the dose calibrator was to be performed at quarterly intervals per manufacturer's recommendation or in accordance with the nationally recognized standard IEEE N42.13. Specifically, from September 7, 2017, to May 24, 2018, and September 28, 2018, to January 15, 2019, the licensee did not perform a quarterly linearity test for the dose calibrator with serial number 560260 in accordance with manufacturers recommendation or nationally recognized standards. This is an apparent violation of 10 CFR 35.60(b).

Licensee Reported Improper Disposal of Licensed Material

The inspector reviewed the circumstances, corrective actions, and preventative actions surrounding the improper disposal of seven sealed sources that occurred in May 2020. Out of abundance of caution, the licensee reported the incident to the NRC Region I office on May 14, 2020. Initially, the activity present in the sealed sources was unknown. However, during the event investigation, it was determined that there was no regulatory requirement to report the incident to the NRC based on the low activity of radioactive material present in the sealed sources (i.e., less than the reportable quantity of licensed material).

In the spring of 2020, the NM department began an attempt to clean and organize the NM storage closet. The closet was used for decay in storage of licensed material and storage of unused sealed sources at the facility; additionally, it had become the catch-all

location for storage of damaged lead items that were no longer needed. In an effort to create a functional use of space, the licensee determined that the unused lead should be discarded. As such, the licensee removed a 5-gallon bucket that they believed contained lead pigs, lead markers, and damaged lead aprons. Unbeknownst to the licensee's staff, seven shielded dose calibrator vial sources had been placed at the bottom of the bucket and, over the years, lead items had been placed on top of the shielded sealed sources.

The licensee identified a vendor to handle the disposal of the lead items; however, the vendor was not authorized to receive radioactive material. The licensee surveyed the exterior of the bucket with an ion chamber and performed a wipe test using a well counter; they did not identify any readings above background and did not identify any removable contamination. The licensee did not remove all items from the bucket and, therefore, did not identify that there were sealed sources inside the bucket. On May 5, 2020, the licensee transferred the 5-gallon bucket to a hazardous waste vendor, who then transported the bucket to their facility in Ohio. The shipment was transported as solid hazardous waste Class 9, "Miscellaneous." Upon receipt at the facility, the vendor identified that radioactive material was present in the shipment. The vendor contacted the licensee and the state of Ohio. Subsequently, the licensee contacted the NRC Region I office to report the improper transfer of licensed material. The licensee hired a contractor to secure, inventory, survey, and dispose of the sealed sources. The contractor assessed the situation within one week and all sources were shipped out for disposal through an authorized waste broker within one month. It should be noted that while the sealed sources were out of control of the licensee, they were always shielded, and were in the possession of individuals who were experienced with handling other forms of hazardous material.

Apparent Violations from Improper Disposal

Through a review of this event, four apparent violations of NRC requirements were identified. Each apparent violation is described, as follows:

- On May 5, 2020, the licensee inappropriately transferred seven sealed sources to an unauthorized recipient. This is a violation of 10 CFR 20.2001 which requires, in part, that a licensee dispose of licensed material only by transfer to an authorized recipient provided in § 20.2006 or in the regulations in parts 30, 40, 60, 61, 63, 70, and 72 of this chapter.

- The 5-gallon bucket, the lead shields with sealed sources, and some of the sealed sources were not labeled as radioactive. Consequently, for an undetermined amount of time, the licensee was in violation of 10 CFR 20.1904 which requires, in part, that licensees ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in

the vicinity of the containers, to take precautions to avoid or minimize exposures.

- The licensee was unaware that these sealed sources were at their facility. Through review of sealed source inventory and leak test records, it was determined that the licensee had no record of these sealed sources. This is a violation of 10 CFR 35.67 which requires licensees to test sealed sources for leakage and physically inventory sealed sources on a semi-annual basis.

- As required by their NRC license, the licensee maintains a written procedure titled "Radioactive Waste Disposal". This procedure states, in part, that waste will be surveyed with all shielding removed. When the licensee prepared the lead for shipment, they failed to follow this procedure by not thoroughly examining the contents of the bucket. This is a violation of License Condition 17 of NRC License Number 06-11734-02.

Summary of Corrective Actions for Improper Disposal

Immediate corrective actions included hiring a contractor to assess, secure, inventory, survey, and dispose of the sealed sources. The licensee implemented preventative actions including performing a thorough review of all NM use and storage areas to ensure all licensed material was identified, documented, and labeled in accordance with NRC requirements, updating written procedures, and retraining NM staff on written procedures. Additionally, the licensee properly disposed of several unused sealed sources after this event to reduce the risk of a recurrent violation.

During the onsite inspection on October 22, 2020, the inspector reviewed the thoroughness of the corrective actions and observed the licensee perform a physical inventory of their sealed sources.

Independent Radiation Measurements

The inspector performed independent radiation surveys at the facility. The surveys were conducted in the hot labs, the camera rooms, the injection areas, and the radioactive material storage areas; the survey results were consistent with the licensee's postings, the licensee's results, and applicable regulatory limits.

c. Conclusions

During this inspection, five apparent violations of NRC requirements were identified. Apparent violations A through D below are being considered for escalated enforcement action in accordance with the NRC's Enforcement Policy. The following are the apparent violations:

A. 10 CFR 20.2001(a) requires, in part, that a licensee shall dispose of licensed material only by transfer to an authorized recipient, decay in storage, or by release in effluents within the limits in 10 CFR Part 20.

Contrary to the above, from May 5, 2020, through June 12, 2020, the licensee failed to dispose of licensed material only by transfer to an authorized recipient, decay in storage, or by release in effluents within the limits of 10 CFR Part 20. Specifically, on May 5, 2020, the licensee inadvertently transferred seven sealed sources containing an aggregate activity of 114.4 microcuries to an unauthorized recipient. The sources were properly transferred for disposal on June 12, 2020.

B. 10 CFR 20.1904(a) requires, in part, that a licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the amount of radioactivity, the date for which the activity is estimated, radiation levels) to permit individuals handling or using the containers, to take precautions to avoid or minimize exposures.

   Contrary to the above, for an undetermined period of time prior to May 5, 2020, the licensee did not ensure that each container of licensed material bore a durable, clearly visible label bearing the radiation symbol and the words "CAUTION - RADIOACTIVE MATERIAL" or "DANGER – RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the amount of radioactivity, the date for which the activity is estimated, radiation levels) to permit individuals handling or using the containers, to take precautions to avoid or minimize exposures. Specifically, the licensee failed to label seven sealed sources and a 5-gallon bucket containing the licensed material, while the sources were in their possession.

C. 10 CFR 35.67(b)(2) requires, in part, that a licensee in possession of a sealed source shall test the source for leakage at intervals not to exceed 6 months. 10 CFR 35.67(a) requires, in part, that a licensee in possession of sealed sources shall conduct a semi-annual physical inventory of all such sources in its possession.

   Contrary to the above, prior to May 5, 2020, the licensee did not test the sealed sources in its possession for leakage at intervals not to exceed 6 months and did not conduct a semi-annual physical inventory of all such sources in its possession. Specifically, the licensee had seven sealed sources that had not been inventoried or leak tested.

D. License Condition 17 of License Number 06-11734-02 requires, in part, that the licensee conduct their program in accordance with the statements, representations and procedures contained in the application date July 17, 2013 (ADAMS Accession No.: ML13225A250). The application dated July 17, 2013, states, in part, that the licensee has developed and will implement and maintain written waste disposal procedures for licensed material. The licensee created a written procedure entitled "Radioactive Waste Disposal," which states, in part, that waste will be surveyed with all shielding removed and is to be surveyed in the containers used for disposal.

Contrary to the above, on May 5, 2020, the licensee did not survey waste with all shielding removed. Specifically, the licensee surveyed seven sealed sources inside of lead shields and released the sources as non-radioactive for lead recycling.

E. 10 CFR 35.60(a) requires that for direct measurements performed in accordance with 10 CFR 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject. 10 CFR 35.60(b) requires that the licensee calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

Contrary to the above, from September 7, 2017, to May 24, 2018, and September 28, 2018, to January 15, 2019, the licensee did not calibrate the instrumentation required in 10 CFR 35.60(a) in accordance with nationally recognized standards or the manufacturer's instructions as required by 10 CFR 35.60(b). Specifically, the licensee did not perform a quarterly linearity test during these time frames.

3. Exit Meeting

On October 22, 2020, the inspector conducted an onsite inspection debrief with the licensee. The inspection findings, apparent violations, and enforcement process were discussed. The licensee acknowledged the inspection findings. On January 26, 2021, the inspector conducted a virtual exit meeting with the licensee. The licensee acknowledged the inspection findings and confirmed the NRC's understanding of their corrective and preventative actions.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Individual(s) present at virtual entrance meeting
+ Individual(s) present for onsite inspection debrief on October 22, 2020
^ Individual(s) present for virtual exit meeting on January 26, 2021

+^ Tasnuba Hoque, Regional Supervisor- Nuclear Medicine
+^ Bette Blankenship, Director, HHC Radiation Protection Program
#+^ Phillip Kohanski, M.D., RSO
+^ Richard Maskowsky, Regional Director of Radiology
+^ Matthew Kaufman, VP of Operations

INSPECTION PROCEDURES USED

IP 87131, Nuclear Medicine Programs, Written Directive Required

LIST OF NRC SURVEY INSTRUMENT USED

Ludlum Model 2401-P, serial number 285217 (calibration exp. date: September 30, 2021)

LIST OF ACRONYMS USED

ALARA: As Low As Reasonably Achievable
AU: Authorized User
CFR: Code of Federal Regulations
NM: Nuclear Medicine
NMT: Nuclear Medicine Technologist
NRC: Nuclear Regulatory Commission
PET: Position Emission Tomography
RSC: Radiation Safety Committee
RSO: Radiation Safety Officer
SLIV: Severity Level IV

NOTE: The following information is an updated excerpt from NRC Information Notice 96-28 issued in 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 nor 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 an 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?

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

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