

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

October 23, 2024

EA-24-043

Cheryl Ficara, RN, MS HHC Senior Vice President Hartford Hospital 80 Seymour St. Hartford, CT 06106

SUBJECT: HARTFORD HOSPITAL - APPARENT VIOLATION OF NRC REQUIREMENTS – NRC OFFICE OF INVESTIGATIONS REPORT NO. 1-2023-010

Dear Cheryl Ficara:

This letter documents the preliminary results of an investigation conducted by the U.S. Nuclear Regulatory Commission (NRC) Office of Investigations (OI) between April 11, 2023, and April 9, 2024, at Hartford Hospital. The purpose of the investigation was to determine whether a former employee of Hartford Hospital deliberately caused you to maintain a record, required to be retained, that was not complete and accurate in all material respects. A factual summary of OI Investigation Report No. 1-2023-010 is included as Enclosure 1 to this letter.

Based on the results of this investigation, an apparent violation of Title 10 of the *Code of Federal Regulations* (10 CFR) 30.9, "Completeness and accuracy of information," was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <u>http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html</u>.

The apparent violation, which is described in Enclosure 2, involves Hartford Hospital's failure to retain information, required by NRC regulations to be maintained, in a manner complete and accurate in all material respects. Specifically, on or about July 5, 2022, a former Hartford Hospital employee completed sections of a Radioactive Spill Report for a spill of radioactive material that occurred on May 13, 2022, and documented in the Spill Report inaccurate information pertaining to the concentrations or quantities of residual radioactive contamination. The former Hartford Hospital employee documented inaccurate pre- and post-decontamination survey results and failed to document information about the equipment used to measure the contamination levels. 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 characterization of the apparent violation, as well as the number of identified violations, described herein may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

Before the NRC makes its enforcement decision regarding the apparent violation, we are providing you an opportunity to: (1) respond to the apparent violation 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.

C. Ficara

If you choose to provide a written response, it should be clearly marked as a "Response to An Apparent Violation in NRC Investigation Report No. 1-2023-010; EA-24-043" and should include for the apparent violation (AV): (1) the reason for the AV or, if contested, the basis for disputing the AV; (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.

The written response should be sent to the NRC within 30 days of the date of this letter. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Additionally, your response should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy mailed to Paul Krohn, Director, Division of Radiological Safety and Security, NRC Region I, 475 Allendale Road, Suite 102, King of Prussia, PA 19406-1415. If an adequate response is not received within the time specified or if an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the meeting should be held in our office in King of Prussia, PA, within 30 days of the date of this letter. The conference will afford you the opportunity to provide your perspective on this matter, as well as 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 to be discussed during the conference might 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.

You should be aware that the promptness and comprehensiveness of your corrective actions will be considered in assessing any civil penalty for the apparent violation. 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 (Enclosure 3).

In lieu of a PEC, you may also request ADR mediation 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. Mediation is a voluntary, informal process in which a trained neutral individual (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's program can be obtained at https://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact the 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.

A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter. The PEC, if held, would be closed to public observation because the NRC's preliminary findings are based on an NRC OI report that has not been publicly disclosed. An ADR mediation session would also be closed to public observation as the mediation process is confidential. However, the time and date of the PEC or ADR mediation would be publicly announced.

C. Ficara

Please contact Anne DeFrancisco, Chief, Medical Assistance and Licensing Branch, NRC Region I, at 610-337-5078 or <u>Anne.DeFrancisco@nrc.gov</u> 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 if an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room and in the NRC Agency-wide Documents Access and Management System (ADAMS), accessible from the NRC website at https://www.nrc.gov/reading-rm/adams.html.

Please note that final NRC investigation documents, such as the OI report described above, may be made available to the public under the Freedom of Information Act (FOIA), subject to redaction of information appropriate under the FOIA. Requests under the FOIA should be made in accordance with 10 CFR 9.23, "Requests for Records." Additional information is available on the NRC website at http://www.nrc.gov/reading-rm/foia/foia-privacy.html.

If you have any questions concerning this matter, please contact Anne DeFrancisco of my staff at 610-337-5078.

Sincerely,

Paul G. Krohn, Director Division of Radiological Safety and Security

License No. 06-00253-04 Docket No. 030-01239

Enclosures:

- 1. Factual Summary of Investigation 1-2023-010
- 2. Apparent Violation Being Considered for Escalated Enforcement
- 3. NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action"

C. Ficara

SUBJECT: HARTFORD HOSPITAL - APPARENT VIOLATION OF NRC REQUIREMENTS – NRC OFFICE OF INVESTIGATIONS REPORT NO. 1-2023-010 DATED OCTOBER 23, 2024

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ENCLOSURE 1 Factual Summary of NRC Office of Investigations Case No. 1-2023-010

On April 11, 2023, the U.S. Nuclear Regulatory Commission (NRC), Office of Investigations (OI) initiated Investigation No. 1-2023-010 to determine whether on May 13, 2022, a former Hartford Hospital employee failed to follow radioactive material spill procedures required by Hartford Hospital's NRC license in response to a spill of yttrium-90 (Y-90), and falsified records. Specifically, the NRC investigated whether the responsible individual failed to perform adequate contamination surveys following the event and falsified contamination survey results when preparing a spill report approximately two months later. The investigation was completed on April 9, 2024.

Hartford Hospital's spill procedure, "Management of a Spill of Radioactive Material HHC," is required to be implemented in accordance with Condition 17 of the hospital's NRC License. Section 9 addresses procedures for responding to a spill and Section 10 identifies trigger levels used for further surveying. Section 12 requires personnel to "[s]urvey hands, clothing, and shoes for contamination prior to leaving the area with an appropriate survey meter or method, i.e., Geiger counter or swipes (Well Counter)." Section 13 requires personnel to "[t]ake swipes of the entire area, remembering to include floors, equipment, handles, etc." and to "[d]ocument final survey, showing area to be free of contamination and that proper spill procedures were followed." Personnel are specifically instructed to "[k]eep these in your records" and to "[d]ocument everything in the radioactive spill report."

The spill report records used by Hartford Hospital contain two parts: Part 1 documents when, where, and how the spill occurred, who was involved, decontamination efforts and results, type of radioisotopes, instructions for taking surveys, and actions to prevent reoccurrence; Part 2 consists of the Wipe Test Decontamination Form, which is used to record radiation detection devices used, areas with contamination, and pre- and post-decontamination survey results.

The investigation confirmed that, on May 13, 2022, the responsible individual led a test for which preparation began in the Hartford Hospital Nuclear Medicine Department (NMD) Hot Lab, during which a spill of Y-90 occurred. The wrist, clothes, and shoes of the NMD worker assisting with the test preparation were contaminated as were multiple surfaces within the Hot Lab. The shoes of a second NMD worker traversing through the area were also contaminated. The responsible individual's testimony confirmed that the individual performed contamination surveys of the workers and of the Hot Lab floors and affected surfaces. Further, the responsible individual's testimony confirmed that the individual wrote down those survey results and later entered the results into a file on the individual's laptop.

Hartford Hospital documents reviewed during the investigation indicated the Radioactive Spill Report (Part 1) and Wipe Test Decontamination Form (Part 2) were not completed in their entirety and appeared to contain inaccurate information. Information from the investigation identified that, following the event, one of the contaminated workers completed portions of Part 1 of the spill report and emailed the responsible individual on May 17, 2022, May 31, 2022, and on July 5, 2022, identifying that the responsible individual needed to enter missing measurements in the spill report. Subsequently, on or about July 5, 2022, the responsible individual entered the measurements for contaminated clothes and Hot Lab areas and finalized the spill report.

The investigation identified that Part 2 of the finalized spill report was missing required information about the instruments used to perform the surveys and evaluate the wipes (e.g.,

Enclosure 1

equipment, models, serial numbers, calibration dates, etc.), pre- and post-decontamination survey results, and did not include contamination survey results for the floor areas near the spill. The responsible individual testified having "a lot of experience" handling radiological spills and that it was the individual's responsibility to review spill reports. Other Hartford spill reports that were approved and, in some instances, prepared by the individual were found to be complete with information in every field. Testimony identified that the responsible individual used multiple instruments to include an ion chamber, Geiger Muller and Well Counter during your surveys, but the individual was "not sure why" they had not documented all the associated equipment information and survey data. The responsible individual also confirmed understanding that spill reports needed to be filled out completely.

The survey data recorded in Part 1 of the finalized spill report indicated that the pre- and postdecontamination survey levels for all three individuals involved were the same value. Specifically, the surveys for the worker with the contaminated wrist and clothing were documented in Part 1 at background radiation levels, and the responsible individual testified that initial survey readings were "very high." Further, the responsible individual stated that, "I should have put additional comment, you know, that initial reading was not available because of high radiation."

Lastly, the documented contamination survey results in Part 2 of the finalized spill report were atypical of instrumentation readings. The responsible individual initially testified that they, "put it rough as approximate," and that, "maybe sometimes I round up." Later, the individual stated that, "I put exact information," and answered, "Yes," when asked if the information was exactly what you got from the well counter. However, review of the well counter survey history in its device memory did not identify a record of readings or wipe test results during the time period of the spill. Also, the responsible individual stated, "So, that day, I went back in my office around 2:30 and made sure that, you know, [the measurements] are saved [in the computer]." A forensic examination of the laptop was performed and did not find any documents related to the survey results that could verify the well counter readings entered in the spill report.

Based on the evidence gathered during the investigation, the responsible individual appears to have deliberately failed to follow radioactive material spill procedures as required by Hartford Hospital's U.S. Nuclear Regulatory Commission (NRC) License and to have falsified records material to the NRC. The individual's actions appear to have placed Hartford Hospital in violation of its NRC License Condition 17, 10 CFR 30.9, 10 CFR 20.1501, and 10 CFR 20.2103. Specifically,10 CFR 30.9(a) requires that information required by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects. 10 CFR 20.2103, in part, requires licensees to maintain records showing the results of surveys required by 10 CFR 20.1501 for three years post record creation. 10 CFR 20.1501(a)(2)(ii) requires licensees to make surveys that are reasonable under the circumstances to evaluate concentrations or quantities of residual radioactivity.

ENCLOSURE 2 Apparent Violation Being Considered for Escalated Enforcement

10 CFR 30.9(a) requires that information required by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects. 10 CFR 20.2103, in part, requires licensees to maintain records showing the results of surveys required by 10 CFR 20.1501 for three years post record creation. 10 CFR 20.1501(a)(2)(ii) requires licensees to make surveys that are reasonable under the circumstances to evaluate concentrations or quantities of residual radioactivity.

License Condition 17 of License No. 06-00253-04 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the Application dated January 28, 2015 (ML15048A168). The Application dated January 28, 2015, commits the licensee to implement the written procedures it has developed for safe response to spills of licensed material in accordance with 10 CFR 20.1101.

Hartford Hospital's "Management of a Spill of Radioactive Material HHC" procedure dated December 14, 2021, states: "Take swipes of the entire area, remembering to include floors, equipment, handles, etc. Document final survey, showing area to be free of contamination and that proper spill procedures were followed. Keep these in your records, Document everything in the Radioactive Spill Report."

Contrary to the above, as of July 5, 2022, Hartford Hospital maintained information, required by the Commission's regulations to be retained, that was not complete and accurate in all material respects. Specifically, a former licensee employee completed sections of a Radioactive Spill Report for a spill of radioactive material that occurred on May 13, 2022, with inaccurate information pertaining to the concentrations or quantities of residual radioactive contamination. Specifically, the former licensee employee documented inaccurate pre- and post-decontamination survey results and failed to document information about the equipment used to measure the contamination levels. This information is material to the NRC: 1) (as to accurate contamination survey results) to verify that contamination has not been spread to uncontrolled areas; 2) (as to accurate personnel contamination results) to demonstrate that personnel were able to decontaminate to acceptable levels, and 3) (as to survey information, including the instrument used to obtain that information) to allow the NRC to evaluate the sufficiency of the licensee's spill response and to demonstrate that the licensee is managing their program adequately by following its written procedures.

ENCLOSURE 3 NRC Information Notice 96-28

https://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html ADAMS Accession No. ML031060071