



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

June 1, 2021

EA-20-141

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

SUBJECT: NOTICE OF VIOLATION, EXERCISE OF DISCRETION, AND PROPOSED IMPOSITION OF CIVIL PENALTY \$3,750 – THE WILLIAM W. BACKUS HOSPITAL, NRC INSPECTION REPORT NO. 03001287/2020001

Dear Mr. Kaufman:

This letter refers to an inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) on October 22, 2020, with continued in-office review through January 26, 2021, at the William W. Backus Hospital facility in Norwich, Connecticut (Licensee). The purpose of the inspection was to examine the William W. Backus Hospital's licensed activities as they relate to radiation safety, compliance with the Commission's regulations, and the conditions in the license. Based on the results of the inspection, the NRC identified five apparent violations (AVs) of NRC requirements. The NRC discussed the AVs with you during a telephonic exit meeting on January 26, 2021. The AVs were described in the NRC inspection report sent to the Licensee with a letter dated March 9, 2021 (ML21069A055)¹.

Four of the AVs were related to an event that occurred on May 5, 2020, involving the inadvertent shipment of licensed material to an unauthorized recipient. Specifically, on May 5, 2020, Licensee staff removed a 5-gallon bucket that they believed only contained lead pigs, lead markers, and damaged lead aprons. The Licensee staff performed radiation and contamination surveys of the exterior of the bucket, but did not remove the items within and, therefore, failed to identify that seven shielded sealed sources had been placed at the bottom of the bucket. The Licensee staff shipped the bucket to a hazardous waste facility that was authorized to dispose of the lead items but was not authorized to possess radioactive material. The waste facility staff identified the presence of the radioactive sources and notified the Licensee. The Licensee staff hired a contractor to secure, inventory, and survey the radioactive sealed sources at the waste facility until they were properly transferred for disposal. The fifth AV was related to the calibration of instrumentation used to measure the activity of unsealed byproduct material.

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

In the March 9, 2021, letter transmitting the inspection report, we informed the Licensee that four of the AVs (those related to the unauthorized disposal event) were being considered for escalated enforcement action, including a civil penalty. In the letter, we provided the Licensee the opportunity to address the AVs identified in the report by either attending a pre-decisional enforcement conference (PEC), engaging the NRC in Alternative Dispute Resolution (ADR) mediation, or providing a written response before we made our final enforcement decision.

In a letter dated April 8, 2021 (ML21103A408; non-public), Ms. Jacqueline Hoell and Mr. Matthew Kaufman of the Licensee's organization provided a response to the AVs and described the actions taken and planned by the William W. Backus Hospital to address these issues, as further described below. In the letter, Ms. Hoell and Mr. Kaufman also stated that the William W. Backus Hospital did not contest any of the violations.

Based on the information developed during the inspection and the information provided in the William W. Backus Hospital's April 8, 2021, response, the NRC has determined that the violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) and the circumstances surrounding them were described in detail in the subject inspection report.

As described above, the first four violations are related to the inadvertent shipment of licensed material by the William W. Backus Hospital to an unauthorized recipient. These violations involved the failure by the Licensee to: (1) dispose of the sources in accordance with 10 CFR 20.2001 when they transferred the sources to an unauthorized recipient; (2) ensure that each source contained a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" in accordance with 10 CFR 20.1904; (3) test the sources for leakage and perform a physical inventory at the required interval in accordance with 10 CFR 35.67; and (4) implement written waste disposal procedures for licensed material as required by license condition 17.

The NRC considers the violations above to be significant because they involved the improper disposal of radioactive material to a facility that was not authorized to receive or possess such material. Therefore, these violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III (SL III) problem. The NRC Enforcement Policy can be found on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$7,500 is considered for a SL III problem. Because The William W. Backus Hospital has not been the subject of any escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for corrective action in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC staff determined that credit for corrective action is warranted. Namely, as noted above, the William W. Backus Hospital appropriately responded to the event by effectuating the proper control and disposal of the radioactive materials. Additionally, Licensee staff reviewed all nuclear medicine use and storage areas at the facility to confirm all radioactive material is inventoried and that all containers with radioactive materials are appropriately labeled. Furthermore, Licensee staff properly disposed of several unused sealed sources after this event to reduce the risk of future occurrence of a similar violation. The William W. Backus Hospital also instructed its nuclear medicine staff members on the established hospital policy requiring source container labeling and the survey requirements for radioactive materials intended for release (disposal). In

addition, Licensee staff amended the procedure to require a second signature (by a nuclear medicine staff member or the Radiation Safety Officer) to confirm the shipment content and survey results.

Although the NRC staff determined that corrective credit was warranted, the staff noted that in accordance with Section 3.6 of the NRC Enforcement Policy, discretion to apply a civil penalty should be considered for violations involving the loss of control of regulated material. The NRC staff considered that regulated material was transported and controlled by unauthorized members of the public and remained at an unauthorized facility for a period of almost a month before it was properly disposed. The NRC staff also considered that the material was shielded and was controlled from further unauthorized access while awaiting proper disposal. Therefore, to emphasize the importance of control of licensed material, and considering the unique circumstances of this case, I have been authorized, after consultation with the Director, Office of Enforcement, to exercise enforcement discretion and issue the enclosed Notice and Proposed Imposition of Civil Penalty in the amount of \$3,750. In addition, issuance of this Notice constitutes escalated enforcement action that may subject the William W. Backus Hospital to increased inspection effort.

The NRC recognizes that many licensees have been impacted economically by the public health emergency caused by the Coronavirus Disease 2019 (COVID-19). Consequently, as described in the enclosed Notice, the NRC is extending by 30 days the period of time by which the civil penalty must be paid (i.e., extending the deadline from 30 days to 60 days from the date of this Notice), and the NRC would consider a request for additional time, if appropriate. Please refer to the enclosed Notice for further instructions.

The additional violation related to the calibration of instrumentation used to measure the activity of unsealed byproduct material, is documented in the enclosed Notice as a SL IV violation. This violation is cited in the Notice in accordance with Section 2.3.2 of the NRC Enforcement Policy because it was identified by the NRC.

If you disagree with this enforcement sanction, you may deny the violations, as described in the Notice, or you may request alternative dispute resolution (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 (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 ADR program can be found 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's program as a neutral third party. If you are interested in pursuing this issue through the ADR program, please contact: (1) the ICR at (877) 733-9415; and (2) Donna Janda, Chief, Medical and Licensing Assistance Branch at 610-337-5371 **within 10 days** of the date of this letter. You may also contact both ICR and Ms. Janda for additional information. Your submitted signed agreement to mediate using the NRC ADR program will stay the time period for payment of the civil penalties and the required written response, as identified in the enclosed Notice, until the ADR process is completed.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective steps that have been taken and the results achieved; and (3) the corrective steps that will be taken; and (4) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03001287/2020001 and your letter dated April 8, 2021. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, 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 Agency-wide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <https://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

If you have any questions concerning this matter, please contact Donna Janda of my staff at 610-337-5371.

Sincerely,

David C. Lew
Regional Administrator

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254, "Payment Methods"

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

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

SUBJECT: NOTICE OF VIOLATION AND PROPOSED CIVIL PENALTY \$3,750 –
 THE WILLIAM W. BACKUS HOSPITAL, NRC INSPECTION REPORT NO.
 03001287/2020001: DATED June 1, 2021

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ML21102A188

DOCUMENT NAME: [https://usnrc-my.sharepoint.com/personal/mmm3_nrc_gov/Documents/MMM3/Shared Enforcement/Final Actions/Backus Hosp NOV-III-CP EA-20-141.docx](https://usnrc-my.sharepoint.com/personal/mmm3_nrc_gov/Documents/MMM3/Shared%20Enforcement/Final%20Actions/Backus%20Hosp%20NOV-III-CP%20EA-20-141.docx)

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OFFICE	RI/ORA	RI/DRSS	RI/ORA	RI/ORA	OE	NMSS
	M McLaughlin	D Janda (JEN for)	B Klukan via email	R McKinley via email	J Peralta via email	M Burgess via email
DATE	4/12/2021	4/13/2021	4/13/2021	4/13/2021	5/12/21	5/07/21
OFFICE	OGC				RI/DRSS	RA
NAME	L Baer NLO via email				B Welling via email	D Lew/
DATE	5/21/21				5/21/21	6/01/21

ENCLOSURE 1

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

The William W. Backus Hospital
Norwich, Connecticut

Docket No.: 03001287
License No.: 06-11734-02
EA-20-141

During an NRC inspection conducted between October 22, 2020, and January 26, 2021, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

- 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" and 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 while the sources were in their possession. Furthermore, the Licensee failed to label a 5-gallon bucket containing the sealed sources.

- 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(g) 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 No. 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 (ML13225A250; non-public). 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." This procedure 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 lead recycling.

This is a Severity Level III Problem (NRC Enforcement Policy Sections 2.3.4 and 6.3).
Civil Penalty - \$3,750 (EA-20-141)

II. Violation Not Assessed a Civil Penalty

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. Specifically, the Licensee did not perform a linearity test during these time frames.

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

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03001287/2020001 and your letter dated April 8, 2021. However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of the letter transmitting this Notice of Violation. In that case, or if you choose to respond, clearly mark your response as a Reply to a Notice of Violation, and send it to the Director, Office

of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 2100 Renaissance Blvd. Suite 100, King of Prussia, PA 19406, and the Document Control Desk, Washington, DC 20555-0001.

The Licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Within 30 days of the date of this Notice, the Licensee must either confirm to the NRC in writing that it will pay the civil penalty or provide its written answer protesting the civil penalty. However, in the event the Licensee elects to pay the civil penalty, in recognition of the economic impact to licensees by the public health emergency caused by the Coronavirus Disease 2019 (COVID-19), the NRC is extending the period of time by which the civil penalty must be paid from 30 days to 60 days from the date of this Notice. Should the Licensee fail to pay the civil penalty within 60 days of the date of this Notice, the NRC will issue an order imposing the civil penalty.

Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation (EA-20-101)" and may: (1) deny the violation listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty. Separately, the Licensee may request an additional extension of time to pay the civil penalty as a result of impacts to the Licensee from COVID-19. Such an extension request must be in writing and should explain the basis for the request and should specify the amount of additional time being requested. This extension request must be submitted to the NRC no later than 50 days from the date of this Notice (i.e., at least 10 days before the initial 60-day deadline to pay the civil penalty).

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205, should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., Reply to Notice of Violation, Extension of time to pay the civil penalty request, Statement as to payment of civil penalty, or Answer to a Notice of Violation, should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 2100 Renaissance

Blvd. Suite 100, King of Prussia, PA 19406, and the Document Control Center, Washington, DC 20555-0001. Your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agency-wide 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. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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

Dated this 1st day of June, 2021.