UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2056 WESTINGS AVENUE, SUITE 400
NAPERVILLE, IL 60563-2657

November 24, 2025

EAF-RIII-2025-0123
EN 57577
EN 57503
NMED No. 250099 (Closed)
NMED No. 250037 (Closed)

Mark Podgorski
Vice President, Hospital Operations
Goshen Health
200 High Park Ave.
Goshen, IN 46526

SUBJECT: NOTICE OF VIOLATION; NRC REACTIVE INSPECTION REPORT NO. 03014254/2025001 (DRSS) – GOSHEN HEALTH

Dear Mark Podgorski:

This letter refers to the inspection started remotely on February 5, 2025, with onsite inspection conducted on February 28, 2025, at your Goshen, Indiana, facility, with continued in-office review through July 7, 2025. The purpose of the inspection was to review the circumstances surrounding two broken iodine-125 sealed sources that were reported to the U.S. Nuclear Regulatory Commission (NRC) on January 22, 2025, and February 28, 2025, and to ensure that activities were being performed in accordance with NRC requirements. The purpose of the in-office review was to review information that was made available after the onsite inspection. During the inspection, three apparent violations of NRC requirements were identified. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with your staff on July 7, 2025. Inspection Report No. 03014254/2025001 (DRSS) was issued on July 24, 2025, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML25189A268. ADAMS is accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated August 20, 2025, (ML25245A142) you provided a response to the apparent violations.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report dated August 20, 2025, the NRC has determined that three violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding them are described in detail in the subject inspection report. One of these violations involved two instances where you failed to report to the NRC the failure of the titanium encapsulation of two different iodine-125 (I-125) radioactive seed localization (RSL) sealed sources within 24 hours after the discovery of the event as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 30.50(b)(2). The

failure to report events to the NRC is of significant regulatory concern because it impedes the NRCs ability to respond to radiological events and track and trend issues of radiological significance. In your response dated August 20, 2025, you stated that the decision to not perform the notification was based on previous advice given by the NRC. A review of the applicable records and a discussion with the inspectors concluded that the NRC inspectors did not make or communicate to you a reportability determination related to 10 CFR 30.50(b)(2) after the event in 2022 or during the inspection in 2023. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $9,000 is considered for a Severity Level III violation. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

Because your facility has not been the subject of escalated enforcement actions within the last two years or 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. During the inspection, to restore compliance with the reporting requirement, you reported the two events on January 22, 2025, and February 28, 2025. In your response dated August 20, 2025, you stated that to avoid further violations, you had decided to discontinue the radioactive seed localization program at your facility and that termination of this program would occur as of August 28, 2025.

Therefore, to encourage prompt identification and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Acting Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

Two other violations are also cited in the enclosed Notice and were determined to be Severity Level IV. These violations involved the failure to conduct your program in accordance with the statements, representations, and procedures contained in your license renewal applications when you (1) failed to follow procedural requirements following removal of seeds from patients and (2) failed to maintain records of surveys of patients following seed removal. These violations were also evaluated in accordance with the NRC Enforcement Policy and are cited in the Notice because they were identified by the inspector.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance will be achieved is already adequately addressed on the docket in Inspection Report No. 03014254/2025001 (DRSS) and your letter dated August 20, 2025. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its 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 in the NRC's ADAMS, accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, any response you provide 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, 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 withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (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). The NRC also includes significant enforcement actions on its website at (http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/).

If you have any questions concerning this matter, please contact Diana Betancourt-Roldan, Enforcement and Investigations Officer, at 630-810-4373.

Sincerely,

Signed by Giessner, Jack
on 11/24/25

John B. Giessner
Regional Administrator

Docket No. 030-14254
License No. 13-18845-01

Enclosure: Notice of Violation

cc (w/encl): J. Lowden, Radiation Safety Officer (RSO)
State of Indiana

Letter to M. Podgorski from J. Giessner dated November 24, 2025.

SUBJECT: NOTICE OF VIOLATION; NRC REACTIVE INSPECTION REPORT NO. 03014254/2025001 (DRSS) – GOSHEN HEALTH

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OFFICE	RIII-EICS		RIII-DRSS		RIII-DRSS		OE	
NAME	JDraper:bw		REdwards		JHeck		LSreenivas for JPeralta	
DATE	9/22/2025		9/23/2025		9/23/2025		9/30/2025	
OFFICE	RIII-EICS		RIII-ORA					
NAME	DBetancourt-Roldan		JGiessner					
DATE	11/24/2025		10/24/2025					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Goshen Health
Goshen, Indiana
EAF-RIII-2025-0123

Docket No. 030-14254
License No. 13-18845-01

During an NRC inspection started remotely on February 5, 2025, with onsite inspection conducted on February 28, 2025, and continued in-office review through July 7, 2025, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. Title 10 of the *Code of Federal Regulations* (CFR) 30.50(b)(2) requires that each licensee shall notify the NRC within 24 hours after the discovery of an event in which equipment is disabled or fails to function as designed when: (i) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident; (ii) The equipment is required to be available and operable when it is disabled or fails to function; and (iii) No redundant equipment is available and operable to perform the required safety function.

   Title 10 CFR 30.50(c)(1) requires, in part, that licensees make reports required by paragraph (b) of this section by telephone to the NRC Operations Center.

   Contrary to the above, on May 17, 2022, and January 15, 2025, the licensee failed to notify the NRC Operations Center by telephone within 24 hours after the discovery of an event in which equipment failed to function as designed when: (i) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident; (ii) The equipment is required to be available and operable when it is disabled or fails to function; and (iii) No redundant equipment is available and operable to perform the required safety function. Specifically, after the titanium encapsulation of two iodine-125 sealed sources failed on May 16, 2022, and January 14, 2025, the licensee failed to notify the NRC Operations Center by telephone within 24 hours as notifications were not made until February 28, 2025, and January 22, 2025, respectively.

   This is a Severity Level III violation (Section 6.9).

B. License Condition 14 of License No. 13-18845-01, Amendment 70, dated November 26, 2024, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the letter dated September 30, 2021.

   Licensee procedure titled “I-125 Seeds” included in the letter dated September 30, 2021, states, in part, that: (1) the histology technologist will contact Nuclear Medicine for transportation of the seed to Nuclear Medicine; (2) all breast tissue must be scanned with the survey meter located at the grossing station prior to the recorder technician receiving the tissue; and (3) Nuclear Medicine will check daily for outstanding seeds.

Contrary to the above, on January 10, 2025, the licensee failed to conduct its program in accordance with the statements, representations, and procedures contained in the letter dated September 30, 2021. Specifically, (1) the histology technologist failed to contact Nuclear Medicine for transportation of the seed to Nuclear Medicine; (2) all breast tissue was not scanned with the survey meter located at the grossing station prior to the recorder technician receiving the tissue; and (3) Nuclear Medicine failed to check daily for outstanding seeds.

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

C. License Condition 14 of License No. 13-18845-01, Amendment 70, dated November 26, 2024, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the letter dated September 30, 2021.

Item 3.d in the letter dated September 30, 2021, states, in part, that the licensee will meet the requirements in 10 CFR 35.404 and 10 CFR 35.2404.

Title 10 CFR 35.404(b) states, in part, immediately after removing the last temporary implant source from a patient, the licensee shall make a survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed.

Title 10 CFR 35.2404 states, in part, a licensee shall maintain a record of the surveys required by 10 CFR 35.404 for 3 years.

Contrary to the above, prior to February 28, 2025, the licensee failed to conduct its program in accordance with the statements, representations, and procedures contained in the letter dated September 30, 2021. Specifically, the licensee failed to maintain records of surveys of patients with a radiation detection survey instrument to confirm that all sources have been removed immediately after removing the last temporary implant source from the patients.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03014254/2025001 (DRSS) and the letter from Licensee dated August 20, 2025. However, the Licensee is required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect the Licensee’s corrective actions or position. In that case, or if the Licensee chooses to respond, the Licensee should clearly mark its response as a "Reply to a Notice of Violation, (EAF-RIII-2025-0123)," 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, Region III, 2056 Westings Avenue, Suite 400, Naperville, IL 60563 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If the Licensee chooses to respond, the response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

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

Dated this 24 day of November 2025.