

## UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III 2056 WESTINGS AVENUE, SUITE 400 NAPERVILLE, IL 60563-2657

August 20, 2025

EAF-RIII-2025-0060

Branden Hill System Director of Radiology Services Munson Medical Center 1105 6th Street Traverse City, MI 49684

SUBJECT: NOTICE OF VIOLATION; NRC ROUTINE INSPECTION REPORT NO. 03002074/2023001 (DRSS) – MUNSON MEDICAL CENTER

Dear Branden Hill:

This letter refers to the inspection conducted on November 28, 2023, through November 29, 2023, at your Traverse City and Cadillac, Michigan, facilities with continued in-office review through April 24, 2025. The purpose of the inspection was to review activities performed under your U.S. Nuclear Regulatory Commission (NRC) license to ensure that activities were being performed in accordance with NRC requirements. The purpose of the in-office review was to perform additional review of occupational dose and dosimetry information not available during the onsite inspection. During the inspection, five 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 you during a final exit briefing on April 24, 2025. Inspection Report No. 03002074/2023001 (DRSS) was issued on May 22, 2025, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML25125A107. ADAMS is accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html.

In our May 22, 2025, 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, by providing a written response, or by attending an Alternative Dispute Resolution mediation session before we made our final enforcement decision. In a letter dated June 20, 2025, you provided a written response to the apparent violations. The publicly available portion of this response is in ADAMS at accession number ML25204A031.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report dated June 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. The violations involve the failure to: 1) monitor individuals' exposure to radiation in accordance with Title 10 of the Code of Federal Regulations (10 CFR) 20.1502(a)(1); 2) either maintain documentation justifying not monitoring individuals or monitor them in accordance with License Condition 16.A of NRC License No. 21-08317-01; and 3) ensure, through the Radiation Safety Officer, that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements in accordance with 10 CFR 35.24(b).

The failure to monitor individuals' exposure to radiation and ensure that radiation safety activities are being performed in accordance with requirements is a significant safety concern as it could result in individuals unknowingly receiving exposures in excess of regulatory requirements. Therefore, these violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III problem.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$9,000 is considered for a Severity Level III problem.

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. In your response, you identified the following actions to correct and prevent recurrence of the violations identified above: (1) issuing extremity dosimeters to all authorized users of yttrium-90 (Y-90) microspheres; (2) revising the interventional radiology procedure to require verification of correct dosimetry use; (3) adding a Y-90 authorized user to the Radiation Safety Committee (RSC) and requesting medical physics consultant participation at RSC meetings; and (4) revising procedures to vet all new programs or services that involve licensed radioactive material or unlicensed radiation producing equipment to ensure dosimetry requirements are met. Based on these actions, the NRC determined that credit was warranted for *Corrective Action*.

Therefore, to encourage prompt and comprehensive correction of violations and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the 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 problem constitutes escalated enforcement action that may subject you to increased inspection effort.

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 was achieved is already adequately addressed on the docket in Inspection Report No. 03002074/2023001 (DRSS) and the letter from you dated June 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 <a href="http://www.nrc.gov/reading-rm/adams.html">http://www.nrc.gov/reading-rm/adams.html</a>. If you provide a response, 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

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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 Officer, at 630-810-4373.

Sincerely,

Signed by Giessner, Jack on 08/20/25

John B. Giessner Regional Administrator

Docket No. 030-02074 License No. 21-08317-01

Enclosure: Notice of Violation

cc (w/encl): Joseph R. Wissing, Radiation

Safety Officer

K. LaRaia, VP of Oncology, Women's Health and Professional Services J. Botti, Consulting Physicist, Medical Physics Consulting State of Michigan

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Letter to B. Hill from J. Giessner dated August 20, 2025.

## SUBJECT: NOTICE OF VIOLATION; NRC ROUTINE INSPECTION REPORT NO. 03002074/2023001 (DRSS) – MUNSON MEDICAL CENTER

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## NOTICE OF VIOLATION

Munson Medical Center Traverse City, Michigan Docket No. 030-02074 License No. 21-08317-01 EAF-RIII-2025-0060

During an NRC inspection conducted on November 28, 2023, through November 29, 2023, with continued in-office review through April 24, 2025, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

(1) Title 10 CFR 20.1502(a)(1) requires, in part, that each licensee monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Title 10 CFR 20.1201(a)(2)(ii) requires, in part, that the annual limit to the skin of the extremities is a shallow-dose equivalent of 50 rem (0.5 Sievert).

Contrary to the above, until April 1, 2024, the licensee failed to monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and failed to supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a)(2)(ii). Specifically, three interventional radiologists were not provided extremity dosimetry while working with licensed and unlicensed radiation sources.

(2) License Condition 16.A of NRC License Number 21-08317-01, Amendment 66, required, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the licensee's renewal application dated May 7, 2021.

Section 8.10.2 of the licensee's renewal application dated May 7, 2021, stated, "Either we will maintain for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502 or we will monitor in accordance with the criteria in the section titled, 'Radiation Safety Program-Occupational Dose' in NUREG-1556, Vol. 9, Rev. 3, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Medical Use Licensees."

Contrary to the above, until April 1, 2024, the licensee failed to either maintain documentation demonstrating that unmonitored individuals were not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502 or monitor in accordance with the criteria in NUREG-1556, Vol. 9, Rev. 3. Specifically, the licensee did not maintain documentation demonstrating that interventional radiologists who handled yttrium-90 TheraSpheres™ were not likely to receive a radiation dose in excess of the limits nor did the licensee monitor these individuals' dose to the skin of the extremities.

(3) 10 CFR 35.24(b) requires that a licensee's management appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, is required to ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

Contrary to the above, as of April 24, 2025, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the licensee's procedures and regulatory requirements. Specifically, the licensee failed to:

- Monitor occupational exposure to the skin of the extremities, or maintain documentation demonstrating that radiation doses would not exceed limits, of interventional radiologists who were exposed to radiation from yttrium-90 TheraSphere™ microspheres and x-ray producing fluoroscopy machines in accordance with 10 CFR 20.1502(a)(1) and License Condition 16.A of NRC License Number 21- 08317-01, respectively;
- Evaluate records indicating deep dose equivalent exposures exceeded the annual limit for total effective dose equivalent to determine the cause of the excess dose, or correct the dose record;
- Submit written reports within 30 days after learning of doses that appeared to exceed
  the annual limit for occupational dose to an adult interventional radiologist for
  multiple years in accordance with 10 CFR 2203(a)(2)(i); and
- Periodically evaluate "action levels" for continued appropriateness to ensure compliance with 10 CFR 20.1501 and 1502 in accordance with the licensee's "Radiation Safety Officer Authority, Duties and Responsibilities."

This is a Severity Level III problem (Sections 6.3 and 6.7)

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken 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. 03002074/2023001 (DRSS) and the letter from you dated June 20, 2025. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, (EAF-RIII-2025-0060)," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy mailed to the NRC Region III Office, 2056 Westings Avenue, Suite 400, Naperville, IL 60563 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you choose to respond, your 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 <a href="http://www.nrc.gov/reading-rm/adams.html">http://www.nrc.gov/reading-rm/adams.html</a>. 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, you may be required to post this Notice within two working days of receipt.

Dated this day 20th day of August 2025.