



Materials Inspection Report

1. Licensee/Location Inspected: VHS Harper-Hutzel Hospital, Inc. 3990 John R Street Detroit, MI 48201 Report Number(s) 2024-001	2. NRC/Regional Office Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. Docket Number(s) 030-02045	4. License Number(s) 21-04127-02	5. Date(s) of Inspection February 8, 2024

LICENSEE:
 The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.
 - A. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
 (Non-cited violation(s) was/were discussed involving the following requirement(s))
 - B. The following violation(s) is/are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
 (Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE AND DATE
LICENSEE'S REPRESENTATIVE		
NRC INSPECTOR	Ryan Craffey	 <small>Digitally signed by Ryan J. Craffey Date: 2024.02.20 08:47:18 -06'00'</small>
BRANCH CHIEF	Rhex Edwards	 <small>Digitally signed by RHEX EDWARDS Date: 2024.02.28 08:22:54 -06'00'</small>



Materials Inspection Record

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4. Report Number(s): 2024-001	5. Date(s) of Inspection: February 8, 2024
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6. Inspector(s): Ryan Craffey	7. Program Code(s): 02240	8. Priority: 2	9. Inspection Guidance Used: IP 87130
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10. Licensee Contact Name(s): Joel Rogers, MS - RSO	11. Licensee E-mail Address: jrogers@landauermp.com	12. Licensee Telephone Number(s): 313-573-0490
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13. Inspection Type: <input type="checkbox"/> Initial <input type="checkbox"/> Routine <input checked="" type="checkbox"/> Non-Routine <input type="checkbox"/> Announced <input checked="" type="checkbox"/> Unannounced	14. Locations Inspected: <input type="checkbox"/> Hybrid <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote	15. Next Inspection Date (MM/DD/YYYY): 05/16/2025 <input type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input checked="" type="checkbox"/> No change
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16. Location(s) Inspected List:
3990 John R Street, Detroit, MI

17. Scope and Observations:
VHS Harper-Hutzel Hospital is a teaching hospital affiliated with Wayne State School of Medicine in midtown Detroit, Michigan. The hospital is authorized to use byproduct material for diagnostic and therapeutic nuclear medicine, for Y-90 microsphere administrations, and for use in a blood irradiator. The scope of this inspection was limited to an evaluation of corrective actions taken in response to a SLIII violation of 10 CFR 35.41(a)(2) for implementing procedures which did not provide high confidence that all Y-90 microspheres treatments were in accordance with written directives.

The inspector visited the hospital in Detroit and confirmed that the licensee had obtained a new low-range ionization chamber for pre- and post-treatment measurements as described in its written response dated May 19, 2023. The instrument was calibrated, operable, and sufficiently sensitive to provide high confidence in determining whether microsphere administrations were in accordance with the written directive. Background readings (4-5 uR/hr) were now negligible compared to pre-treatment readings (1+ mR/hr), and all involved staff were familiar with the new instrument and how to use it. The inspector also confirmed that the licensee had implemented a revised written directive template and treatment checklist as described in its written response. The inspector reviewed a selection of records for treatments performed in 2022 and 2023 and confirmed that the licensee had used the revised template and checklist for each treatment to adequately address whether a medical event had occurred (none had).

No additional examples of this violation were identified, and all corrective actions appeared adequate and effective. Therefore, this violation is closed. No other violations were identified as a result of this inspection.

The SLIV violations from 2021 and 2023 remain open for evaluation during a future routine inspection.

Signature and Date - Branch Chief



Digitally signed by RHEX EDWARDS
Date: 2024.02.28 08:22:32 -06'00'