



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

June 14, 2018

EA-18-049

Ms. Tina Wood
Chief Operating Officer
VHS Harper-Hutzel Hospital, Inc.
3990 John R Street
Detroit, MI 48201

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03002045/2018001 (DNMS) AND
NOTICE OF VIOLATION – VHS HARPER-HUTZEL HOSPITAL, INC.

Dear Ms. Wood:

On March 20, 2018, through March 22, 2018, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility in Detroit, Michigan, with continued in-office review through May 18, 2018. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of security-related information not available during the onsite inspection. The enclosed inspection report (Enclosure 2) and its non-public Security Addendum (Enclosure 3) present the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, two apparent violations of NRC requirements were identified and are 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 <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violations were of a security-related nature. Details of the apparent violations, as well as the corrective actions that have since been taken to restore compliance with regulatory requirements, are discussed in Enclosure 3. In addition, the inspector identified four Severity Level IV violations of NRC requirements occurred. These violations were also evaluated in accordance with the NRC Enforcement Policy.

Enclosures 1 and 3 contain Sensitive
Unclassified Non-Safeguards Information.
When separated from Enclosures 1 and 3,
this transmittal letter is decontrolled.

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Because the NRC has not made a final determination in the matter of the two apparent violations, the NRC is not issuing a Notice of Violation for these inspection findings at this time. Ms. Deborah A. Piskura of my staff discussed the circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action with you and members of your staff on May 18, 2018.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond in writing to the apparent violations addressed in this inspection report within 30 days of the date of this letter; (2) request a Predecisional Enforcement Conference (PEC); or (3) request Alternate Dispute Resolution (ADR). **Please contact Aaron T. McCraw, Chief of the Materials Inspection Branch, at 630-829-9650 or aaron.mccraw@nrc.gov within ten days of the date of this letter to notify the NRC of your intended response.**

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violations in Inspection Report No. 03002045/2018001(DNMS); EA-18-049," and should include, for the apparent violations: (1) the reason for the apparent violations, or, if contested, the basis for disputing the apparent violations; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance was or will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. In addition, if you choose to provide a written response, please mark your entire response, "Security-Related Information – Withhold from Public Disclosure under Title 10 of the *Code of Federal Regulations* (CFR) 2.390." In accordance with 10 CFR 2.390(b)(ii), the NRC is waiving the affidavit requirements for your response to this letter. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Your response should be sent to the NRC's Document Control Desk, Washington, DC 20555-0001, with a copy mailed to the NRC Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532, within 30 days of the date of this letter. If an adequate response is not received within the time specified or 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, it will afford you the opportunity to provide your perspective on the apparent violations and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the PEC may include the following: 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 to be taken. If a PEC is held, the NRC will issue a press release to announce the time and date of the PEC. The PEC will be closed to public observation due to the security-related nature of the findings.

In lieu of a PEC, you may also request Alternative Dispute Resolution (ADR) with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a third party neutral. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the

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“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 <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. Please contact 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.

Please be advised that the number and characterization of the apparent violations described in the enclosed inspection report 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.

The four Severity Level IV violations of NRC requirements that were identified were also evaluated in accordance with the NRC Enforcement Policy. The violations are also of a security-related nature. The violations are cited in the enclosed, non-public Notice of Violation (Notice) (Enclosure 1) and the circumstances surrounding them are described in detail in Enclosure 3. The violations are being cited in the Notice because the inspector identified the violations.

You are required to respond to the Severity Level IV violations and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements. Because the violations are of a security-related nature, please mark the top of each page of your response “Security-Related Information – Withhold Under 10 CFR 2.390.”

Collectively the apparent violations and the other security-related violations are of concern to the NRC because these violations indicate a lack of adequate oversight of your security program. We attributed the root causes of the violations and apparent violations to a non-unified approach to the implementation of the security program and a lack of awareness of all applicable security requirements. No individual provided expertise or served as the responsible lead for the security program; portions of the security program were managed by three individuals. While the individuals performed the tasks under their responsibilities, they were not fully knowledgeable of the specific security requirements for their respective duties. Effective management of the security program is vital to a licensee's achieving safe and compliant operations. Because these violations indicate a lack of adequate oversight of your security program, you are requested in your response to describe: (1) how you plan to improve the management oversight of your security program; (2) how you plan to monitor the effectiveness of your actions to improve the management oversight of your security program; and (3) why you believe your corrective actions for these violations will be successful in preventing similar violations in the future.

In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's “Rules of Practice,” a copy of this letter and Enclosure 2 will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. However, Enclosures 1 and 3 and any written

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response you provide will not be made available electronically for public inspection because of the security-related information that is or would be contained in each.

Please feel free to contact Ms. Piskura of my staff if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

/RA/

John B. Giessner, Director
Division of Nuclear Materials Safety

Docket No. 030-02045
License No. 21-04127-02

Enclosures:

1. Notice of Violation (non-public)
2. IR 03002045/2018001(DNMS) (public)
3. Security Addendum (non-public)

cc w/encls: Dr. Richard Joyrich, RSO
cc w/encl 2: State of Michigan

~~OFFICIAL USE ONLY – SECURITY-RELATED INFORMATION~~

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Letter to Tina Wood from John Giessner, dated June 14, 2018

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03002045/2018001 (DNMS) AND
NOTICE OF VIOLATION – VHS HARPER-HUTZEL HOSPITAL, INC.

DISTRIBUTION w/encls:

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OFFICE	RIII-DNMS		RIII-DNMS		RIII-EICS		RIII	
NAME	DPiskura:ps		AMcCraw		RSkokowski KLambert for		JGiessner	
DATE	6/6/2018		6/6/2018		6/14/2018		6/14/2018	

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**U.S. Nuclear Regulatory Commission
Region III**

Docket No. 030-02045

License No. 21-04127-02

Report No. 03002045/2018001(DNMS)

EA No. EA-18-049

Licensee: VHS Harper-Hutzel Hospital, Inc.

Facility: 3990 John R Street
Detroit, MI 48201

Inspection Dates: March 20, 2018 - March 22, 2018, with
continued in-office review through May 18, 2018

Exit Meeting Date: May 18, 2018

Inspector: Deborah A. Piskura, Senior Health Physicist

Approved By: Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Enclosures 1 and 3 contain Sensitive
Unclassified Non-Safeguards Information.
When separated from Enclosures 1 and 3,
this transmittal letter is decontrolled.

Enclosure 2

EXECUTIVE SUMMARY

**VHS Harper-Hutzel Hospital, Inc.
NRC Inspection Report 03002045/2018001(DNMS)**

The U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection of VHS Harper-Hutzel Hospital, Inc. (the licensee) on March 20 through 22, 2018, with continued in-office review through May 18, 2018. The in-office review included an assessment of security-related information unavailable during the onsite inspection.

The inspector identified security-related violations. Details of the security-related violations, as well as the corrective actions that have been taken to restore compliance, are discussed in the non-public Security Addendum to this Inspection Report.

REPORT DETAILS

1 Program Overview and Inspection History

VHS Harper-Hutzel Hospital, Inc. is authorized under NRC Materials License No. 21-04127-02 for materials permitted in Title 10 of the *Code of Federal Regulations* (CFR) Sections 35.100, 35.200, 35.300, 35.500, and 35.1000 limited to yttrium-90 microspheres. The hospital's Medical Director of Nuclear Medicine served as the radiation safety officer (RSO). The licensee's nuclear medicine department was staffed with four technologists who performed approximately 200-250 diagnostic nuclear medicine procedures monthly. The licensee performed a full spectrum of studies and received unit doses of technetium-99m from a licensed radiopharmacy. The hospital administered numerous iodine-131 dosages (capsules only) for whole body followup studies, hyperthyroid, and thyroid cancer treatments; all patients were released in accordance with the criteria specified in 10 CFR 35.75. The department also administered 40-50 yttrium-90 microspheres (TheraSpheres) treatments annually. The licensee is also authorized to possess and use a self-shielded irradiator for the irradiation of blood and blood products.

The last routine inspection was conducted on November 16-17, 2015; no violations of NRC requirements were identified during the inspection. Two security-related violations were identified during the previous routine inspection on June 20, and July 10, 2013. The licensee's corrective actions for the previous security-related violations were reviewed during a special, followup inspection on February 13, 2014.

2 Management Oversight and the Radiation Safety Committee

2.1 Inspection Scope

The inspector reviewed the licensee's management of the radiation safety program and the radiation protection program reviews. The inspector interviewed selected licensee staff, the consultant physicist, and the RSO. The inspector also reviewed selected audit reports for the Year 2016 to the year-to-date 2018 period.

2.2 Observations and Findings

The hospital established a radiation safety committee, which met quarterly to review and approve authorized physician users. The meeting minutes indicated the committee member attendance and the topics. The licensee approved its physician users in accordance with the training and experience criteria listed in 10 CFR Part 35.

The licensee retained the services of a consultant who audited the radiation safety program on a quarterly basis; the last audit was conducted on December 5, 2017, with no findings. The consultant (retired in 2018) presented his audit findings during the radiation safety committee meetings. The RSO reviewed and signed the consultant's audit reports.

2.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspector identified no violations of NRC requirements.

3 Other Areas Inspected

3.1 Inspection Scope

The inspector observed licensed activities, interviewed licensee personnel, and reviewed selected records concerning use and security of licensed materials, and other aspects of the radiation safety program. The inspector observed use of byproduct material, including the administration of several dosages for various nuclear medicine studies. The inspector performed confirmatory surveys in areas of radioactive materials use and in public areas.

3.2 Observations and Findings

The inspector observed that licensee personnel maintained constant surveillance of licensed material. In addition, the nuclear medicine hot lab remained secured. The inspector determined that the consultant provided annual training to all staff working with or in the vicinity of licensed material. Through interviews, the inspector determined that the licensee staff understood security requirements for licensed material.

The inspector observed licensee personnel prepare, assay, and administer several unit dosages for various diagnostic testing procedures. The inspector reviewed written directives for several iodine-131 and yttrium-90 patient treatments. The licensee documented the written directive, the verification of the patient identity, and dosage verification. No medical events were identified.

The inspector examined the sealed sources in the licensee's possession. Each source container was noted to bear a clearly visible label identifying the radionuclides and source activities. The licensee's consultant performed inventories and leak tests of the sealed sources and documented the results in his reports.

The licensee posted caution signs, NRC Form 3, and license documents in accordance with 10 CFR Parts 19 and 20. The hot lab was also posted with emergency/decontamination procedures and an approved dosage chart. During facility tours the inspector noted no evidence of eating, drinking, smoking, or cosmetic application in areas where licensed material was used.

The licensee monitored radiation exposure to nuclear medicine technologists using whole body and extremity personnel dosimeters provided by an accredited laboratory. The dosimeters were exchanged on a monthly basis. All technologists were advised of their exposure data at least annually. The inspector reviewed a sampling of dosimetry reports and determined that all monitoring results were below Part 20 occupational exposure limits.

The licensee possessed several calibrated survey instruments used by the nuclear medicine staff. Confirmatory surveys indicated radiation levels consistent with licensee survey records and postings.

The inspector also reviewed records of annual radiation safety training, sealed source leak tests, and annual maintenance/service reports for the blood irradiator. All records indicated that the respective items were performed at the required frequencies.

3.3 Conclusions

The inspector determined that the hospital implemented its radiation safety program and conducted licensed activities safely and in accordance with NRC regulatory requirements. No violations of NRC requirements were identified in this program area.

4 **Exit Meeting Summary**

The NRC inspector presented preliminary inspection findings following the onsite inspection on March 22, 2018, and during the telephonic exit meeting on May 18, 2018. Security-related material received during the inspection was returned to the licensee or destroyed. The licensee acknowledged the findings presented.

LIST OF PERSONNEL CONTACTED

*Scott Berkfeth, Safety Director

*Kimberly Ceccanese, MSN, RN, Director, Regulatory Compliance

#*Richard Joyrich, M.D., Director, Nuclear Medicine, Radiation Safety Officer

Laura Luna, M.S., Consultant

#*Tina Wood, Chief Operating Officer

Several nuclear medicine technologists were also contacted during this inspection

#Attended exit meeting on March 22, 2018.

*Participated in final exit teleconference on May 18, 2018

INSPECTION PROCEDURES USED

IP 87130, Nuclear Medicine Programs, Written Directive Not Required

IP 87131, Nuclear Medicine Programs, Written Directive Required

IP 87132, Brachytherapy Programs