

August 23, 2013

EA-13-165

Donald C. Cox, Executive Director
Police Authority
VHS Harper–Hutzel Hospital, Inc.
McLaughlin Hall
3740 John R Street
Detroit, MI 48201

SUBJECT: NRC ROUTINE INSPECTION REPORT NO.03002045/2013001(DNMS),
AND NOTICE OF VIOLATION – VHS HARPER–HUTZEL HOSPITAL, INC.

Dear Mr. Cox:

On June 20 and July 10, 2013, with continued in-office review through August 1, 2013, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection of your facility located in Detroit, Michigan. The purpose of the inspection was to determine whether activities authorized under your license were conducted safely and in accordance with NRC requirements. The in-office review included detailed evaluation of information provided during and after the inspection and the overall determination of the circumstances and significance of the issues identified during the inspection. A final exit meeting was held between Mrs. Deborah Piskura of my staff and yourself by telephone on August 1, 2013.

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, one apparent violation was identified and is 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 violation is of a security-related nature. Details about the apparent violation are available in the Inspection Report, enclosed with this letter. Immediate corrective action for the apparent violation has since been taken to restore compliance with NRC requirements. Because the NRC has not made a final

Enclosures 1 and 3 Contain Sensitive Unclassified Non-Safeguards Information. When separated from these enclosures, this transmittal document and Enclosure 2 are decontrolled.

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determination on this matter, the NRC is not issuing a Notice of Violation for these particular inspection findings at this time. The circumstances surrounding the apparent violation, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you at the preliminary debrief on July 10, 2013

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond in writing to the apparent violation addressed in this inspection report within 30 days of the date of this letter; (2) request a Predecisional Enforcement Conference (PEC); or (3) request Alternative Dispute Resolution (ADR). If a PEC is held, the NRC will issue a press release to announce the time and date of the conference; however the PEC will be closed to public observation since security-related information will be discussed and the report has not been made publicly available. Please contact Aaron McCraw at (630) 829-9650 within 10 days of the date of this letter concerning your choice of response.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in Inspection Report No. 03002045/2013001(DNMS); EA-13-165" and should include for each apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (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 violation. 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's website at: <http://www.nrc.gov/reading-rm/docollections/gen-comm/info-notices/1996/in96028.html>. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. 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, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference 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.

In lieu of a PEC, you may also request 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 "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

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agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be obtained at <http://www.nrc.gov/aboutnrc/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.

In addition, please be advised that the number and characterization of 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.

During the inspection, the inspector also determined that one Severity Level IV violation of NRC requirements occurred. This violation was also evaluated in accordance with the NRC Enforcement Policy. This violation is also of a security-related nature. The violation is cited in the enclosed, non-public Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited in the Notice because the inspector identified the violation.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was or will be achieved is already adequately addressed on the docket in Inspection Report No. 03002045/2013001 (DNMS). Therefore, you are not required to respond to this violation unless the description herein 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 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 made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/readingrm/adams.html>. Enclosures 1 and 3 contain security-related information and disclosure to unauthorized individuals could present a security vulnerability; therefore, Enclosures 1 and 3 will not be made available electronically for public inspection.

Because this issue involves security-related information, your response, if you choose to provide one, may not be made available electronically for public inspection in the NRC's Public Document Room or from ADAMS. Please mark the top of each page of your response, "Security-Related Information – Withhold Under 10 CFR 2.390."

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Please feel free to contact Mrs. Piskura if you have any questions concerning this matter. You can reach Mrs. Piskura at (630) 829-9867.

Sincerely,

/RA/

Patrick L. Loudon, Acting Director
Division of Nuclear Materials Safety

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

Enclosures:

1. Notice of Violation (Non-Public)
2. Inspection Report No. 03002045/13001(DNMS) (Publicly Available)
3. Security Addendum to Inspection Report (Non-Public)

cc w/ encls: Susan Adams, MT(ASCP), Manager, Blood Bank

cc w/ encl 2: Valerie Gibson, Chief Operating Officer
Richard Joyrich, M.D., Radiation Safety Officer

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Please feel free to contact Mrs. Piskura if you have any questions concerning this matter. You can reach Mrs. Piskura at (630) 829-9867.

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cc w/ encl 2: Valerie Gibson, Chief Operating Officer
Richard Joyrich, M.D., Radiation Safety Officer

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Letter to Donald C. Cox from Patrick Loudon, dated August 23, 2013

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03002045/2013001 (DNMS) –
VHS HARPER–HUTZEL HOSPITAL, INC.

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

Docket No. 030-02045

License No. 21-04127-02

Report No. 03002045/2013001(DNMS)

EA No. EA-13-165

Licensee: VHS Harper–Hutzel Hospital, Inc.

Facility: 3990 John R Street
Detroit, Michigan

Dates of Inspection: June 20 and July 10, 2013, with
continued in-office review through
August 1, 2013

Exit Meeting: August 1, 2013

Inspector: Deborah A. Piskura, Health Physicist

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

Enclosure 2

EXECUTIVE SUMMARY

**VHS Harper-Hutzel Hospital, Inc.
NRC Inspection Report 03002045/2013001(DNMS)**

This was a routine inspection of VHS Harper–Hutzel Hospital, Inc., in Detroit, Michigan, on June 20 and July 10, 2013, with continued in-office review through August 1, 2013. The VHS Harper-Hutzel Hospital, Inc. is a large medical institution with authorization to use a variety of isotopes for diagnostic and therapeutic patient administrations.

The inspector identified one apparent security-related violation and one Severity IV security-related violation. The facts and circumstances surrounding the apparent violation and the Severity Level IV violation, as well as licensee’s corrective actions to prevent similar violations, are documented in the Security Addendum to this inspection report.

Report Details

1 Program Overview

The VHS Harper-Hutzel Hospital, Inc. (licensee), was authorized to use byproduct material permitted in Title 10 of the *Code of Federal Regulations* (CFR) Sections 35.100, 35.200, 35.300, 35.500, and 35.1000. The licensee employed four full-time technologists who performed approximately 300 diagnostic nuclear procedures per month. The licensee performed a full spectrum of diagnostic studies. The licensee operated a separate nuclear cardiology department within the hospital. The licensee received unit doses from a licensed radiopharmacy. In addition, the licensee maintained an active therapy program which included radioiodine, microspheres, and beta-emitting radiopharmaceuticals. Radioiodine was obtained from the pharmacy in capsule form.

The last routine inspection on August 17-18, 2011, identified no violations of NRC requirements. The previous inspection on February 11-12, 2008, identified one security-related violation; however, the NRC did not pursue enforcement action because the licensee made a good-faith attempt to implement the security requirement and made a commitment to take prompt corrective actions. The application of good faith attempt only applied to the initial inspection and would not apply to future inspections.

2 Radiation Safety Program

2.1 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 the use of byproduct material, including diagnostic and therapeutic patient administrations. The inspector performed confirmatory surveys in areas of radioactive materials use and in public areas.

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 consultant presented his audit findings during the radiation safety committee meetings.

The licensee monitored personnel for radiation dose when they used licensed materials, and no individuals received doses above regulatory limits. Licensee personnel received initial and annual training for the use of materials and demonstrated their knowledge of radiation safety concepts and procedures. 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. Caution signs, NRC Form 3s, and license documents were posted in accordance with

NRC requirements. During facility tours the inspector noted no evidence of eating, drinking, smoking, or cosmetic application in restricted areas. The licensee secured its radioactive materials within the nuclear medicine laboratories.

The inspector observed licensee personnel prepare, assay, and administer several unit dosages for various testing procedures. The inspector also observed the administration of a sodium iodine-131 hyperthyroid treatment. The inspector reviewed the written directive for the procedure and interviewed the physician authorized user who attended the patient with no regulatory issues noted.

2.3 Conclusions

The inspector determined that the hospital effectively 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 area.

3 **Exit Meeting Summary**

The NRC inspector presented preliminary inspection findings following the onsite inspection on July 10, 2013. The licensee did not identify any documents or processes reviewed by the inspector as proprietary. The licensee acknowledged the findings presented. A final telephonic exit meeting was held on August 1, 2013.

PARTIAL LIST OF PERSONNEL CONTACTED

Susan Adams, MT(ASCP), Manager, Blood Bank
Michael Beri, MT(ASCP) STAT Lab Supervisor
Martin H. Bluth, M.D., Ph.D., Associate System Medical Director
Kim Ceccanese, Director, Regulatory Compliance
Donald C. Cox, Executive Director, Police Authority, T&R Officer
Donna Diegel, Officer
James Fieder, MT (ASCP)
Valerie Gibson, Chief Operating Officer
Daniel Herman, Security Supervisor, Central Campus
Lawana Jollivete, Safety Director
Richard Joyrich, M.D., Radiation Safety Officer
Reynaldo A. Magdaleno, Office Coordinator I
Barbara Ann O'Malley, M.D., Director of Clinical Laboratories
Beth Yuskowatz, Employment Specialist

Several nuclear medicine technologists, laboratory medical technologists, and security officers were also contacted