

June 26, 2012

Mr. David Brill M.D., Radiation Safety Officer
Cardiology Consultants of East Michigan
1031 Suncrest Drive
Lapeer, MI 48446

SUBJECT: NRC ROUTINE INSPECTION REPORT 03037297/12-001(DNMS) AND NOTICE
OF VIOLATION – CARDIOLOGY CONSULTANTS OF EAST MICHIGAN

Dear Dr. Brill:

On May 1, 2012, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Lapeer, MI facility, with continuing in-office review through May 29, 2012. 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 the review of additional information, and the circumstances and significance involved with the violation. An exit meeting was held between Mr. Bill Lin of my staff and Mr. David Simmonds of your staff by telephone on May 30, 2012.

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, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation concerned the failure to follow the procedure for the safe use of unsealed materials, as required by License Condition 16.A of NRC Materials License 21-32624-01. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation in the Notice because the inspector identified the violation.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. 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>. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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, its enclosure, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the

NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. 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 without redaction.

Please feel free to contact Mr. Bill Lin of my staff if you have any questions regarding this inspection. Mr. Lin can be reached at 630-829-9829.

Sincerely,

/RA/

Hironori Peterson, Acting Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-37297
License No. 21-32624-01

Enclosure:
Notice of Violation

cc w/encl: David Simmonds, Chief
Nuclear Medical Technologist
State of Michigan

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Notice of Violation

cc w/encl: David Simmonds, Chief
Nuclear Medical Technologist
State of Michigan

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NOTICE OF VIOLATION

Cardiology Consultants of East Michigan
Lapeer, MI

Docket No. 030-37297
License No. 21-32624-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on May 1, 2012, with continuing in-office review through May 29, 2012, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

License Condition 16 A of NRC Materials License 21-32624-01 states that the licensee shall conduct its program in accordance with License Application dated June 8, 2006. Section 8.24 Item 10 of License application dated June 8, 2006 states, the licensee have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of Title 10 of the Code of Federal Regulations (CFR) 20.1101 and Title 10 CFR 20.1301.

Section B2.1.1 (part of the Licensee's procedure for Safe Use of Unsealed Byproduct Material) "Patient Identification" states in part, before an injection of radioactivity is administered, the technologist asks the patient to state his/her name and Date of Birth (DOB). The information given by the patient is compared to the information in the patient's chart. The patient will not be injected if there are discrepancies in information or if the consent form is not signed.

Contrary to the above, on April 10, 2012, the licensee failed to ask the patient to state his/her DOB before the administration of radioactivity; this resulted in the administration of radioactivity to a wrong patient.

This is a Severity Level IV violation (Section 6.3.d.3).

Pursuant to the provisions of CFR 2.201, Cardiology Consultants of East Michigan is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Enclosure

Notice of Violation

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

Dated this 26th day of June 2012.