



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

February 2, 2017

EA-16-214
EN 51888
NMED No. 160158 (Closed)

Mr. Larry Genzink
Director, Radiology Services
Spectrum Health Hospitals
100 Michigan Street NE
Grand Rapids, MI 49503

SUBJECT: NOTICE OF VIOLATION – SPECTRUM HEALTH HOSPITALS;
NRC REACTIVE INSPECTION REPORT NO. 03001989/2016001(DNMS)

Dear Mr. Genzink:

This refers to the U.S. Nuclear Regulatory Commission (NRC) reactive inspection conducted on May 3, 2016, at your Grand Rapids, Michigan facility, with continued in-office review through August 25, 2016. The purpose of the inspection was to review the circumstances, root and contributing causes, and corrective actions for a medical event that you reported to the NRC on April 27, 2016. During the inspection, an apparent violation of NRC requirements was identified. The significance of the issue and the need for lasting and effective corrective actions was discussed with members of your staff during the telephonic exit meeting that was held on October 18, 2016. Details regarding the apparent violation were provided in NRC Inspection Report No. 03001989/2016001(DNMS) dated November 1, 2016. The inspection report is available electronically in the NRC's Agencywide Documents Access Management System (ADAMS) at accession number ML16306A207.

In the 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 or by providing a written response before we made our final enforcement decision. In a letter dated December 12, 2016, you provided a response to the apparent violation.

Based on the information developed during the inspection and your response to the inspection report dated, December 12, 2016, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation involved the failure to implement written procedures which provided high confidence that an administration of yttrium-90 microspheres was in accordance with the written directive, as required by Title 10 *Code of Federal Regulations* (CFR) Section 35.41(a)(2). Specifically, the authorized user did not properly implement the licensee's written procedure with regard to verification of catheter position prior to administration.

The root cause of the violation was human error. Specifically, the authorized user failed to implement the step related to verification of catheter position. This violation is of concern to the NRC because of the consequences to patients, as in this case, that led to a medical event, as defined in 10 CFR 35.2. Therefore, this violation is categorized in accordance with the NRC Enforcement Policy as a Severity Level III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$ 7,000 is considered for a Severity Level III.

Because your facility has not been the subject of escalated enforcement actions within the 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. The NRC considered the information that you provided at the time of the inspection and your response dated December 12, 2016. Your staff's corrective actions included revision of the in-room checklist for microsphere treatments to more explicitly describe how the existing verification of catheter position should be done, which you implemented beginning April 28, 2016. In addition, your staff also committed to discussing the checklist revisions with staff and to solicit suggestions for any additional revisions, as warranted. Based on this, the NRC determined that *Corrective Action* credit is warranted.

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 violation constitutes escalated enforcement action that may subject you to increased inspection effort. The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

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 achieved is already adequately addressed on the docket in Inspection Report No. 03001989/2016001(DNMS) and in your response dated December 12, 2016. 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 "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 and in 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. 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

L. Genzink

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required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-01989
License No. 21-00243-06

Enclosure:
Notice of Violation

cc: Evan J. Boote, Ph.D.,
Radiation Safety Officer
State of Michigan

Letter to L. Genzink from Cynthia D. Pederson dated February 2, 2017

SUBJECT: NOTICE OF VIOLATION – SPECTRUM HEALTH HOSPITALS;
NRC REACTIVE INSPECTION REPORT NO. 03001989/2016001(DNMS)

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¹ OE concurrence provided via e-mail from Leelavathi Sreenivas on 1/31/2017.

NOTICE OF VIOLATION

Spectrum Health Hospitals
Grand Rapids, Michigan

Docket No. 030-01989
License No. 21-00243-06
EA-16-214

During a U.S. Nuclear Regulatory Commission (NRC) reactive inspection conducted on May 3, 2016, at your facility in Grand Rapids, Michigan, with continued in-office review through August 25, 2016, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the *Code of Federal Regulations* (10 CFR) Section 35.41(a)(2) states that, for any administration requiring a written directive, the licensee develop, implement and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Licensee procedure 'TheraSphere Checklist' was developed to provide high confidence that each administration is in accordance with the written directive. Section 5, Final Assembly, of the 'TheraSphere Checklist' contains a step for the interventional radiologist to verify catheter position.

Contrary to the above, on April 27, 2016, Spectrum Health Hospitals failed to implement the written procedures to provide high confidence that an administration of approximately 89.7 millicuries of yttrium-90 microspheres was in accordance with the written directive. Specifically, the licensee failed to follow its procedure to verify the catheter position prior to administration of the yttrium-90 microspheres that resulted in a medical event.

This is a Severity Level III violation (Section 6.3).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned 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. 03001989/2016001(DNMS) dated November 1, 2016, in your response dated December 12, 2016, and the letter transmitting this Notice of Violation (Notice). 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, EA-16-214" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, Suite 210, 2443 Warrenville Rd, Lisle IL, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Enclosure

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 Web site at <http://www.nrc.gov/reading-rm/adams.html>. 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 2nd day of February, 2017.