



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

March 9, 2015

EA-14-236

Ms. Kay Winokur
Vice President, Quality, Safety and
Professional Services
Beaumont Health System
3601 W. 13 Mile Road
Royal Oak, MI 48073

SUBJECT: NOTICE OF VIOLATION – BEAUMONT HEALTH SYSTEM;
NRC REACTIVE INSPECTION REPORT NO. 03002006/2014001(DNMS)

Dear Ms. Winokur:

This letter refers to the reactive inspection conducted at your facilities in Royal Oak, Michigan, on November 4, 2014, with continued in-office review through January 8, 2015. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for a medical event that occurred on October 30, 2014. The in-office review included a review of your written report provided on November 13, 2014, and proposed corrective actions taken in response to the reported medical event. 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 were discussed with your staff during the telephonic exit meeting that was held on January 8, 2015. Details regarding the apparent violation were provided in NRC Inspection Report No. 03002006/2014001(DNMS) dated January 27, 2015.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either providing a written response or requesting a predecisional enforcement conference. In a letter dated February 17, 2015, you provided a response to the apparent violations.

Based on the information developed during the inspection, the information that you provided in your event report dated November 13, 2014, and your response dated February 17, 2015, 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. Specifically, the NRC identified that your staff failed to develop written policies and procedures that provided high confidence that each yttrium-90 (Y-90) microspheres administration was in accordance with the physician's written directive, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.41(a)(2). This resulted in a medical event where a patient received an overdose to the posterior portion of the liver. The root cause of the violation was human error in that a checklist to be used during the administration was labeled with an incorrect colored sticker. This is of concern to the NRC because of the potential for other medical events occurring during dual dosage procedures. Therefore, this violation has been categorized, in accordance with the NRC Enforcement Policy, at Severity Level III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a Severity Level III violation.

Because your facility has not been the subject of escalated enforcement actions within the last two years or 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 to the inspector at the time of the inspection and the information in your November 13, 2014, written event report as referenced in your February 17, 2015, letter. Your corrective actions included: (1) discontinuing the use of color coding dual doses of microsphere; (2) permitting only one dosage of Y-90 SIR-Spheres® in the interventional radiology suite at any one time, (3) revising labels and forms to reduce complexity and ease verification of the dose, and (4) adding a "time-out" prior to the administration to verify the treatment parameters listed on the written directive. As a longer-term corrective action, you revised your policies and procedures to reflect the above and provided training to all staff directly involved in microsphere administrations. On the basis of these corrective actions, the NRC determined that *Corrective Action* credit was 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 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 the inspection report, in your written event report dated November 13, 2014, and in your letter dated February 17, 2015. 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, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the

K. Winokur

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NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

Sincerely,

/RA Darrell J. Roberts Acting for/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-02006
License No. 21-01333-01

Enclosure:
Notice of Violation

cc: State of Michigan
Cheryl M. Culver Schultz
Radiation Safety Officer
Darlene Fink-Bennett, M.D.
Chair, Radiation Safety Committee
Stephen A. Vartanian, M.D.

NOTICE OF VIOLATION

Beaumont Health System
Royal Oak, Michigan

Docket No. 03002006
License No. 21-01333-01
EA-14-236

During an NRC inspection conducted on November 4, 2014, with continued in-office review through January 8, 2015, 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) 35.41(a) states, in part, that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each directive is in accordance with the written directive. 10 CFR 35.41(b)(2) requires, in part, that, as a minimum, the procedures required by 10 CFR 35.41(a) address verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive.

Contrary to the above, as of October 30, 2014, the licensee failed to have written procedures that provided high confidence that each administration was in accordance with the written directive and the procedures did not require verifying that the administration was in accordance with the applicable treatment plan and written directive. Specifically, on October 30, 2014, the licensee administered yttrium-90 SIR-Spheres® to the posterior right lobe of a patient's liver, and the licensee's procedures did not require verification for administrations using multi-doses or dual doses that the doses were in accordance with the applicable treatment plan and written directive.

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. 03002006/2014001(DNMS) dated January 27, 2015, in your written event report dated November 13, 2014, and in your response dated February 17, 2015. 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-14-236" 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, 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.

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, your response

Enclosure

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 9th day of March, 2015.

K. Winokur

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NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

Sincerely,

/RA Darrell J. Roberts Acting for/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-02006
License No. 21-01333-01

Enclosure:
Notice of Violation

cc: State of Michigan
Cheryl M. Culver Schultz
Radiation Safety Officer
Darlene Fink-Bennett, M.D.
Chair, Radiation Safety Committee
Stephen A. Vartanian, M.D.

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OFFICE	RIII	RIII	RIII	D:OE	RIII	RIII
NAME	Lougheed	McCraw	Louden	Holahan ¹ Norman for	Skokowski	Roberts for Pederson
DATE	02/24/15	02/24/15	02/24/15	02/27/15	03/06/15	03/09/15

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¹ OE concurrence provided via e-mail from K. Norman on February 27, 2015