



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, IL 60532-4352

January 6, 2012

EA-11-228  
NMED 110133 (closed)

Mr. Steven Benedict, Director  
Occupational Safety & Environmental Health  
Regents of the University of Michigan  
1239 Kipke Drive  
Ann Arbor, Michigan 48109

**SUBJECT: NOTICE OF VIOLATION – REGENTS OF THE UNIVERSITY OF MICHIGAN;  
NRC INSPECTION REPORT NO. 03001988/2011001(DNMS)**

Dear Mr. Benedict:

This refers to a U.S. Nuclear Regulatory Commission (NRC) reactive inspection conducted on March 15 and 16, 2011, at your facility located in Ann Arbor, Michigan, with continued in-office review through October 6, 2011. The purpose of the inspection was to determine whether activities authorized under your license were conducted safely and in accordance with NRC requirements. 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 you at the final inspection exit meeting on October 6, 2011. Details regarding the apparent violation were provided in NRC Inspection Report No. 03001988/2011001(DNMS) dated October 28, 2011.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report by either attending a Predecisional Enforcement Conference or by providing a written response before we made an enforcement decision. In a letter dated November 22, 2011, you provided a response to the apparent violation. We appreciate the clarifications and corrections that you provided in your response and have considered that information in determining our final action.

Based on the information developed during the inspection, the information provided in your 15-day report dated March 22, 2011, and the information provided in your response dated November 22, 2011, 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 develop written procedures to provide high confidence that each brachytherapy treatment was in accordance with the written directive, contrary to the requirements of Title 10 of the Code of Federal Regulations (10 CFR) 35.41(a) and 35.41(b)(2). During preparations for a yttrium 90 (Y-90) TheraSphere™ treatment, an incorrect liver segment volume was used to calculate the activity needed to deliver the prescribed dose. This resulted in the actual dose delivered being substantially greater than the intended dose.

The root cause of the violation was miscommunication between the medical physicist, authorized user and interventional radiologist. Contributing factors for the medical event were unclear written instructions to the medical physicist regarding the treatment site and use of

documentation that made various aspects of the planning phase ambiguous. The violation was of concern to the NRC because it resulted in a patient receiving a radiation dose to the left lateral lobe of the liver that was more than twice the intended dose. Therefore, the violation has been categorized, in accordance with the NRC Enforcement Policy, as a Severity Level III violation.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3500 is considered for a Severity Level III violation. Because your facility has not been the subject of an escalated enforcement action 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 determined that credit was warranted for your corrective actions which included: (1) modification of the Interventional Radiology (IR) worksheet to clearly designate the necessary diagnostic, pathological, and anatomical information needed to prepare for a treatment and to require signature by the interventional radiologist, with a separate section completed and signed by the radiation oncologist; (2) modification of the written directive form for Y-90 TheraSpheres™ to require entry of the specific treatment site, (3) development of a TheraSphere™ Infusion Checklist signed by the prescribing physician and a second medical physicist to confirm that the treatment site and the treatment volume identified in the written directive are consistent with the information supplied in the IR worksheet; and (4) modification of the Operating Room checklist to include confirmation immediately before the procedure that the treatment infusion site and associated volume described in the written directive are correct.

Therefore, to encourage prompt identification 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, which may subject you to increased inspection effort.

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03001988/2011001(DNMS), in your 15-day report dated March 22, 2011, and your response dated November 22, 2011. 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.

S. Benedict

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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 any, will be made available electronically for public inspection in the NRC Public Document Room or from 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>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Sincerely,

***/RA by J. Uhle for/***

Cynthia D. Pederson  
Acting Regional Administrator

Docket No. 030-01988  
License No. 21-00215-04

Enclosure:  
Notice of Violation

cc w/encl: State of Michigan

## NOTICE OF VIOLATION

Regents of the University of Michigan  
Ann Arbor, Michigan

Docket No. 030-01988  
License No. 21-00215-04  
EA-11-228

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on March 15 and 16, 2011, with continued in-office review through October 6, 2011, 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) requires, for any administration requiring a written directive, that the licensee develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Title 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 March 9, 2011, the licensee failed to have written procedures that provided high confidence that each administration was in accordance with the written directive. Specifically, the licensee administered a yttrium-90 TheraSphere™ liver treatment, and the licensee's procedures did not require verifying that the administration was in accordance with the applicable treatment plan and written directive. The written directive differed in regard to the treatment site and liver segment volume.

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

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03001988/2011001(DNMS), in your 15-day report dated March 22, 2011, and your response dated November 22, 2011.

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-11-228," 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, 2443 Warrenville Road, Suite 210, Lisle, IL 60532, 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, U.S. 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 from 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 6<sup>th</sup> day of January 2012

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 any, will be made available electronically for public inspection in the NRC Public Document Room or from 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>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Sincerely,

***/RA by J. Uhle for/***

Cynthia D. Pederson  
Acting Regional Administrator

Docket No. 030-01988  
License No. 21-00215-04

Enclosure:  
Notice of Violation

cc w/encl: State of Michigan

DISTRIBUTION:  
See next page

\*See previous concurrences

FILE NAME: G:\ORAI\IICS\ENFORCEMENT\Enforcement Cases 2011\EA-11-228 University of Michigan\EA-11-228 University of Michigan draft final action.docx

Publicly Available, non-sensitive

OFFICE	RIII	RIII	RIII	OE	RIII	RIII
NAME	PP for Lougheed*	Bloomer*	Boland*	Zimmerman <sup>1</sup>	Orth Via email	Uhle for Pederson
DATE	12/05/11	12/06/11	12/08/11	12/28/11	01/06/12	01/06/12

**OFFICIAL RECORD COPY**

<sup>1</sup> OE concurrence received via e-mail from K. Day on December 28, 2011.

Letter to Steven Benedict from Cynthia D. Pederson dated January 6, 2012

SUBJECT: NOTICE OF VIOLATION – REGENTS OF THE UNIVERSITY OF MICHIGAN;  
NRC INSPECTION REPORT NO. 03001988/2011001(DNMS)

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