



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

Region III
2443 Warrenville Road, Suite 210
Lisle IL 60532-4352

January 29, 2013

EA-12-242
NMED 120643 (closed)

Dr. Timothy Ramney
Vice President and Chief Medical Officer
Missouri Baptist Medical Center
3015 North Ballas Road
St. Louis, MO 63131

**SUBJECT: NOTICE OF VIOLATION – MISSOURI BAPTIST MEDICAL CENTER;
NRC ROUTINE INSPECTION REPORT NO. 03008325/2012001(DNMS)**

Dear Dr. Ramney:

This refers to a Nuclear Regulatory Commission (NRC) routine inspection conducted on October 18 and 19, 2012, at your facility located in St. Louis, Missouri, with continued in-office review through November 9, 2012. 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 telephonic exit meeting on November 13, 2012. Details regarding the apparent violation were provided in NRC Inspection Report No. 03008325/2012001(DNMS) dated December 10, 2012.

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 our final enforcement decision. In a letter dated December 21, 2012, you provided a response to the apparent violation. In that response you referred to faxes submitted on December 3, 2012. We also considered the information provided in your 30-day report, submitted on November 1, 2012.

Based on the information developed during the inspection and the information that you provided in the above mentioned documents, 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 our inspection report dated December 10, 2012. Specifically, the NRC determined that Missouri Baptist Medical Center's procedures did not provide high confidence that administrations would occur in accordance with the written directives.

The failure to have procedures that provide high confidence that administrations are in accordance with the written directive is of concern to the NRC because of the potential for a patient to have received an incorrect dose. In this case, it appeared that the medical event was a simple transcription error, and that the patient actually received the correct medical treatment. However, there was insufficient attention to detail to recognize that the dose that was on the written directive did not agree with the dose that was actually delivered to the patient. In a second case, the intended dose was left blank on the written directive, and the authorized user

signed the written directive without indicating the intended dose. 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 \$3500 is normally considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process described in Section 2.3.4 of the Enforcement Policy. The NRC determined that credit was warranted for the corrective actions taken. Your corrective actions included: (a) revising your written procedure to include having a second verifier complete a radiopharmaceutical pre-treatment checklist; (b) performing a 100 percent audit of all procedures, with results reported quarterly to the radiation safety officer and to the Radiation Safety Committee; (c) conducting training for the Radiation Oncology Staff on the revised procedures; and (d) revising the Radiopharmaceutical Therapy Record to add a block to compare the prescribed activity to the assayed activity and record any differences.

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, to not 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 the reason for the violation, the corrective actions taken and planned to correct the violation, and the date when full compliance was achieved, was adequately addressed on the docket in NRC Inspection Report No. 03008325/2012001(DNMS) dated December 10, 2012, and in your correspondence dated November 1, December 3, and December 21, 2012. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective action 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 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, 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

T. Ramney

-3-

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

Charles A. Casto
Regional Administrator

Docket No. 030-08325
License No. 24-11128-02

Enclosure:
Notice of Violation

cc w/encl: Thomas J. Moenster, Radiation
Safety Officer
State of Missouri

NOTICE OF VIOLATION

Missouri Baptist Medical Center Hospital
St. Louis, Missouri

Docket No. 030-08325
License No. 24-11128-02
EA-12-242

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 18 and 19, 2012, at the St. Louis, Missouri facility, with continuing in-office review through November 9, 2012, 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)(2) requires that, for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

10 CFR 35.41(b)(2) requires that, as a minimum, the procedures required by paragraph 35.41(a) must address verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive.

Contrary to the above, the licensee did not develop written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, as of October 19, 2012, the licensee's procedures failed to address verification that the administered dosage was in accordance with the prescribed dosage on the written directive prior to administration:

1. On or about May 1, 2012, a yttrium-90 (Y-90) procedure was performed, and the written directive indicated that 23 mCi should be administered. The calculations for this procedure indicated that the physician authorized user intended to administer 32 mCi Y-90, but the physicist had filled out the written directive incorrectly, reversing the two digits. The authorized user electronically signed and dated the written directive immediately before the administration of the dose without verifying that the written directive indicated the activity he intended to prescribe. The physicist then administered a 31.8 mCi Y-90 dosage.
2. On or about May 31, 2012, a medical procedure involving samarium-153 (Sm-153) was performed and the "prescribed activity" section was blank in the written directive as no data had been entered into the applicable area. The calculations attached to the written directive indicate that the authorized user intended to give a dosage that was within 20 percent of the administered dosage.

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 be taken to correct the violation, and the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03008325/2012001(DNMS) dated December 10, 2012, and in your correspondence dated November 1, December 3, and December 21, 2012. 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

Enclosure

respond, clearly mark your response as a "Reply to a Notice of Violation, EA-12-242," 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.

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, or proprietary, 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 of Violation within two working days of receipt.

Dated this 29th day of January, 2013

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

Charles A. Casto
Regional Administrator

Docket No. 030-08325
License No. 24-11128-02

Enclosure:
Notice of Violation

cc w/encl: Thomas J. Moenster, Radiation
Safety Officer
State of Missouri

DISTRIBUTION:
See next page

SEE PREVIOUS CONCURRENCE

FILE NAME: G:\ORAI\IEICS\ENFORCEMENT\Cases\Enforcement Cases 2012\EA-12-242 Missouri Baptist Medical Center\EA-12-242 Missouri Baptist FINAL action.docx

OFFICE	RIII	RIII	RIII	D:OE	RIII	RIII
NAME	Lougheed	Bloomer RGattone for	Boland	Zimmerman ¹ KDay	Orth	Casto CPederson for
DATE	01/04/13	01/04/13	01/07/13	01/25/13	01/29/13	01/29/13

OFFICIAL RECORD COPY

1 OE concurrence received via e-mail from K. Day on January 25, 2013.

Letter to Timothy Ramney from Charles A. Casto dated January 29, 2013

SUBJECT: NOTICE OF VIOLATION – MISSOURI BAPTIST MEDICAL CENTER
NRC ROUTINE INSPECTION REPORT NO. 03008325/2012001(DNMS)

DISTRIBUTION:

RidsSecyMailCenter Resource
OCADistribution
Bill Borchardt
Michael Weber
Roy Zimmerman
Nick Hilton
Kerstun Day
Chuck Casto
Cynthia Pederson
Marvin Itzkowitz
Mary Spencer
Mark Satorius
Brian McDermott
Michele Burgess
Daniel Holody
Carolyn Evans
Heather Gepford
Holly Harrington
Hubert Bell
Cheryl McCrary

Seth Coplin
Anne Boland
Mark Rubic
Tamara Bloomer
MIB Inspectors
Steven Orth
Allan Barker
Harral Logaras
James Lynch
Viktoria Mitlyng
Prema Chandrathil
Patricia Lougheed
Paul Pelke
Magdalena Gryglak
Sarah Bakhsh
Patricia Buckley
Tammy Tomczak
OEMAIL Resource
OEWEB Resource