



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352
October 31, 2017

EA-17-091

Ms. Jennifer Ewing
Clinical Operations Officer
Michiana Hematology Oncology, PC
3975 William Richardson Drive
South Bend, IN 46628

SUBJECT: NOTICE OF VIOLATION - MICHIANA HEMATOLOGY ONCOLOGY, PC;
NRC ROUTINE INSPECTION REPORT NO. 03037858/2017001(DNMS)

Dear Ms. Ewing:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on February 17, 2017, at your Mishawaka, Indiana location with continued in-office through July 5, 2017. The purpose of the inspection was to review activities performed under your NRC license to ensure that those activities were being performed in accordance with NRC requirements. During the inspection, apparent violations of NRC requirements were identified. The significance of the issue and the need for lasting and effective corrective actions were discussed with you during the inspection exit meeting on July 5, 2017. Details regarding the apparent violations were provided in NRC Inspection Report No. 03037858/2017001(DNMS) dated July 21, 2017. The inspection report is available electronically in the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession Number ML17206A433.

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 September 1, 2017, you provided a response to the apparent violations. Your letter is available electronically in the NRC's ADAMS at Accession Number ML17249A931.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report dated September 1, 2017, the NRC has determined that violations of NRC requirements have occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations involved: (1) the failure to have the individual named on the license perform the duties and responsibilities of Radiation Safety Officer (RSO) for the period of October 29, 2016, to April 16, 2017, as required by License Condition No. 11 of NRC License No. 13-32719-01; and (2) the failure to notify the Commission no later than 30 days after the RSO permanently discontinued performance of duties under the license as required by Title 10 of the *Code of Federal Regulations* (CFR) 35.14(b)(1). Specifically, the RSO listed on the license left your employment on October 28, 2016, and the license was not amended to name a new RSO until April 18, 2017, and the NRC was not notified of this change in RSO. The root cause of the apparent violations was that licensee management was unaware of the 30-day requirement to amend the NRC license to reflect a change in RSO.

The failure to have an RSO is of regulatory concern because you could have performed services under your NRC license without ensuring you are meeting the conditions of your license. This was evident by the lack of having a qualified person appointed as RSO leading to poor management oversight regarding the High Dose-Rate Remote Afterloader (HDR) brachytherapy program. Specifically, your management was unaware of the location of one the units and its HDR source, which could have led to loss of control or improper disposal of the radioactive source. Therefore, these violations have been categorized in accordance with the NRC Enforcement Policy as a Severity Level III problem. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$7,000 is considered for a Severity Level III problem.

Because your facility has not been the subject of 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 considered the information that you provided to the NRC inspector and your response dated September 1, 2017. Your corrective actions included requesting an amendment to your license to appoint a qualified person as RSO, and you added detailed steps to be taken when a change in RSO is necessary to your Policy and Procedure document. For long-term corrective actions to prevent recurrence of similar violations, you committed to refer to the NRC's website or the NRC staff directly for any questions regarding the NRC license requirements. In addition, the current permanent RSO listed on the license is scheduled to take an RSO class focusing on the duties of an RSO. Also, at the department level, monthly meetings will be held with topics from the NRC website and publications to keep informed on the regulations and changes therein. Based on these actions, 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 problem 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 violations (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 response dated September 1, 2017, and this letter. 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 ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

/RA by Kenneth G. O'Brien acting for/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-37858
License No. 13-32719-01

Enclosure:
Notice of Violation

cc w/encl: State of Indiana

Letter to Ms. Jennifer Ewing from John B. Giessner, dated October 31, 2017.

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03037858/2017001(DNMS)
MICHIANA HEMATOLOGY ONCOLOGY, PC

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OFFICE	RIII	RIII	RIII	RIII	RIII
NAME	Bakhsh	AMcCraw	JGiessner	RSkokowski	CPederson: KGO for
DATE	10/17/17	10/17/17	10/18/17	10/31/17	10/31/17

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NOTICE OF VIOLATION

Michiana Hematology, Oncology, PC
South Bend, Indiana

Docket No. 030-37858
License No. 13-32719-01
EA-17-091

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted February 17, 2017, at your Mishawaka, Indiana location, with continued in-office review through July 5, 2017, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. License Condition No. 11 of Amendment No. 08 of NRC License 13-32719-01 named an individual as the Radiation Safety Officer (RSO) for this license.

Contrary to the above, from October 28, 2016, through April 18, 2017, the licensee failed to have the named individual on the license perform the duties and responsibilities of the RSO. Specifically, the RSO listed on the license left the licensee's employment on October 28, 2016, and the license was not amended to name a new RSO until April 18, 2017.

- B. Title 10 of the *Code of Federal Regulations* (CFR) 35.14(b)(1) requires, in part, that a licensee shall notify the Commission no later than 30 days after an authorized user, an authorized nuclear pharmacist, a RSO, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

Contrary to the above, as of November 27, 2016, the licensee failed to notify the Commission no later than 30 days after the RSO permanently discontinued performance of duties under the license. Specifically, the RSO listed on the license left the licensee's employment on October 28, 2016.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03037858/2017001(DNMS) dated July 21, 2017, in your response dated September 1, 2017, 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-17-091" 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).

Enclosure

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, 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 31st day of October, 2017.