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

July 21, 2017

EA-17-091

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

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

Dear Ms. Ewing:

On February 17, 2017, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Mishawaka, Indiana location with continued in-office review through July 5, 2017. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of your new radiation safety officer's (RSO) qualifications. The enclosed inspection report presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, two apparent violations of NRC requirements were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations concerned: (1) the licensee's apparent failure for the individual specifically authorized by Condition 11 of your NRC Materials License to fulfill the duties and responsibilities of RSO and (2) the licensee's apparent 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) Section 35.14(b)(1).

Because the NRC has not made a final determination in this matter, the NRC is not issuing a Notice of Violation for these inspection findings at this time. Mr. Luis Nieves of my staff discussed the circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective actions with you at the inspection exit meeting on July 5, 2017. Your corrective actions are also described in the enclosed report. As a result, it may not be necessary for you to provide a written response.

However, before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) provide no additional response if the description in the enclosed report accurately describes the corrective actions; (2) respond in writing to the apparent violations addressed in this inspection report within 30 days of the date of this letter; or (3) request a Predecisional Enforcement Conference (PEC). **Please contact Aaron T. McCraw at 630-829-9650 within ten days of the date of this letter to notify the NRC of your intended response.**

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violations in Inspection Report No. 030-37858/2017001(DNMS); EA-17-091," and should include, for the apparent violations: (1) the reason for the apparent violations, or, if contested, the basis for disputing the apparent violations; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance was or will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, it will afford you the opportunity to provide your perspective on the apparent violations and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. If a PEC is held, the NRC will issue a press release to announce the time and date of the PEC and the PEC will be open to public observation.

Because your facility has not been the subject of escalated enforcement action within the last two inspections, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. In addition, based upon NRC's understanding of the facts and your corrective actions, it may not be necessary to conduct a PEC in order to enable the NRC to make a final enforcement decision.

Please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

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's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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 publicly available without redaction.

Please feel free to contact Mr. Nieves if you have any questions regarding this inspection. Mr. Nieves can be reached at 630-829-9571.

Sincerely,

/RA Christine Lipa Acting for/

John B. Giessner, Director
Division of Nuclear Materials Safety

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

Enclosure:
IR No. 03037858/2017001(DNMS)

cc w/encl: State of Indiana

Letter to Ms. Jennifer Ewing from John B. Giessner, dated July 21, 2017.

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

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-37858
License No.	13-32719-01
Report No.	03037858/2017001(DNMS)
EA No.	EA-17-091
Licensee:	Michiana Hematology Oncology, PC
Facility:	5340 Holy Cross Parkway Mishawaka, Indiana
Inspection Dates:	February 17, 2017, with continued in-office review through July 5, 2017.
Exit Meeting Date:	July 5, 2017
Inspector:	Luis Nieves, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Michiana Hematology Oncology, PC
NRC Inspection Report 030-37858/2017001(DNMS)

On February 17, 2017, with continued in-office review to July 5, 2017, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection of Michiana Hematology Oncology, PC (licensee). The purpose of the inspection was to review activities performed under the NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of your new radiation safety officer's (RSO) qualifications.

During the inspection, the inspector identified two apparent violations of NRC requirements. First, the inspector determined that on October 28, 2016, the individual listed as the RSO for the license left the licensee's employment. The licensee did not notify the NRC until January 25, 2017, when the licensee requested amendment to its license to change the RSO. In its request, the licensee did not indicate that the individual listed on the license as RSO had left the licensee's employment. The NRC approved the request and amended the license to name a new RSO on April 17, 2017, following a review of the newly appointed individual's qualifications. Therefore, from October 29, 2016, to April 16, 2017, the individual listed as RSO on the license did not perform the duties and responsibilities of the RSO. This is an apparent violation of License Condition 11 of NRC License No. 13-32719-01. In addition, as of November 28, 2017, and until the inspection on February 17, 2017, the licensee had not notified the NRC no later than 30 days after the RSO permanently discontinued performance of duties under the license. This is an apparent violation of Title 10 of the *Code of Federal Regulations* (CFR) Section 35.14(b)(1).

During the routine inspection, the inspector determined that, although the licensee was operating without a qualified person formally appointed as RSO, security and control of material was achieved, general radiation safety practices were followed, dosimetry for the employees was used and under the regulatory limits, instruments were calibrated at the required frequency, and training was up to date for the staff. Interviews with staff demonstrated their knowledge of operating and emergency procedures, providing a basis for confidence that the licensee would have been able to appropriately respond to incidents involving the high dose-rate remote afterloader (HDR) unit in the absence of an appointed RSO. However, the absence of an appointed RSO appeared to create a lack of adequate oversight of the licensee's HDR program. For instance, the licensee management was under the impression that the HDR unit at the Westville, Indiana location had its source removed and the HDR unit had been decommissioned; however, at the time of the inspection, the source remained inside the HDR unit, and the HDR unit had not been decommissioned.

The root cause of the apparent violations was that licensee management was unaware of the time requirements to amend the NRC license to reflect a change in RSO. Specifically, the licensee believed that it had 90 instead of 30 days to notify the NRC of the change of RSO.

As corrective actions, the licensee requested an amendment to its license to appoint a qualified person as RSO on January 25, 2017. The NRC approved the request and amended the license on April 17, 2017. For long-lasting corrective actions to prevent recurrence of similar violations, the licensee committed to refer to NRC website or NRC staff directly for any questions regarding its NRC license requirements and revising its internal policies and procedures accordingly to prevent similar occurrences.

REPORT DETAILS

1.0 Program Overview and Inspection History

Michiana Hematology Oncology, PC is a medical institution with two similar locations in Westville and Mishawaka, Indiana. The licensee is authorized to use radioactive materials for medical uses under 10 CFR 35.200, 35.300, and 35.600 at both locations. At the Mishawaka location, the licensee only performed positron emission tomography (PET) scans, Xofigo radium-223 dichloride administrations, and HDR treatments. Their nuclear medicine department was staffed with three nuclear medicine technologists. The licensee conducted operations every day, Monday to Friday. The licensee performed approximately 20 Xofigo administrations in 2016 and 5 in 2017. The licensee conducted approximately 10 HDR treatments per month.

The NRC conducted a routine inspection of the licensee on April 30, 2015. A Non-cited Violation of NRC safety requirements was identified for not having all the information required in a written directive. During the previous routine inspection on April 25-26, 2013, the NRC did not identify any violations.

2.0 Radiation Safety Program

2.1 Inspection Scope

During this inspection, the inspector reviewed the elements of the licensee's radiation safety program including the following: oversight, security, physical inventories, leak tests, dosimetry records, training records, and shipping papers.

2.2 Observations and Findings

On February 17, 2017, the inspector conducted an unannounced routine inspection to review activities performed under the NRC license to ensure that activities were being performed in accordance with NRC requirements. The inspection also included a review of the facts and circumstances surrounding a license amendment request that was received by the NRC on January 25, 2017, requesting a change in the RSO.

Based on information gathered during the inspection, the inspector determined that: (1) from October 29, 2016, through April, 16, 2017, the licensee apparently failed to have the individual named on the license as RSO perform the duties and functions of RSO, as required by License Condition 11; and (2) the licensee apparently failed to notify the Commission no later than 30 days after the RSO permanently discontinued performance of duties under the license, as required by 10 CFR 35.14(b)(1). Specifically, the inspector determined that the individual listed as RSO on the license left the employment of the licensee on October 28, 2016, and the licensee did not notify the NRC or appoint a new, qualified RSO until January 2017.

During the routine inspection, the inspector determined that, although the licensee was operating without a qualified person formally appointed as RSO, security and control of material was achieved, general radiation safety practices were followed, dosimetry for the employees was used and under the regulatory limits, instruments were calibrated at the required frequency, and training was up to date for the staff. Interviews with staff demonstrated their knowledge of operating and emergency procedures, providing a

basis for confidence that the licensee would have been able to appropriately respond to incidents involving the HDR unit in the absence of an appointed RSO. However, the absence of an appointed RSO appeared to create a lack of adequate oversight of the licensee's HDR program. For instance, the licensee management was under the impression that the HDR unit at the Westville, Indiana location had its source removed and the HDR unit had been decommissioned; however, at the time of the inspection, the source remained inside the HDR unit, and the HDR unit had not been decommissioned.

The root cause of the apparent violations was that licensee management was unaware of the time requirements to amend the NRC license to reflect a change in RSO. Specifically, the licensee believed that it had 90 instead of 30 days to notify the NRC of the change of RSO.

As corrective actions, the licensee requested an amendment to its license to appoint a qualified person as RSO on January 25, 2017. The NRC approved the request and amended the license on April 17, 2017. For long-lasting corrective actions to prevent recurrence of similar violations, the licensee committed to refer to NRC website or NRC staff directly for any questions regarding its NRC license requirements and revising its internal policies and procedures to address the timeliness requirements to prevent similar occurrences.

The inspector also observed the preparation and administration of one PET scan using fluorine-18 and three HDR treatments, as well as the receipt of packages containing radiopharmaceuticals and demonstrations of restricted area surveys, HDR spot checks, and the treatment planning and verification process for HDR treatments. Through these observations, demonstrations, and other discussions, the licensee's staff demonstrated adequate knowledge of radiation protection principles and regulatory requirements.

2.3 Conclusions

The inspector identified two apparent violations: (1) one of License Condition No. 11 of NRC License No. 13-32719-01 for the licensee's apparent failure to have the individual named on the license perform the duties and responsibilities of RSO for the period of October 29, 2016 to April 16, 2017; and (2) one of 10 CFR 35.14(b)(1) for the licensee's apparent failure to notify the Commission no later than 30 days after the RSO permanently discontinued performance of duties under the license.

3.0 Exit Meeting Summary

The NRC inspector presented the preliminary inspection findings following the onsite inspection on February 17, 2017. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. A final telephonic exit meeting was conducted on July 5, 2017. The licensee acknowledged the findings presented.

ATTACHMENT: SUPPLEMENTAL INFORMATION

SUPPLEMENTAL INFORMATION

LIST OF PERSONNEL CONTACTED

#* Jennifer Ewing, Clinical Operation Officer
Stacie Godin, RSO

#* Attended exit meeting on July 5, 2017, and telephonic exit meeting on July 5, 2017.

LIST OF PROCEDURES USED

87131: Nuclear Medicine Programs, Written Directive Required
87132: Brachytherapy Programs