

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Michiana Hematology-Oncology, P.C.
100 East Wayne Street, Suite 510
South Bend, IN 46601

REPORT NUMBER(S) 2018001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-37858

4. LICENSE NUMBER(S)

13-32719-01

5. DATE(S) OF INSPECTION

FEBRUARY 23, 2018

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

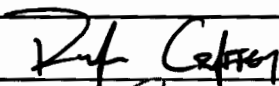
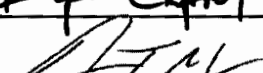
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☒ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(s):

- ☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Ryan Craffey		2/23/18
BRANCH CHIEF	Aaron McCraw		03/05/2018

Docket File Information**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

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February 23, 2018

6. INSPECTION PROCEDURES USED

87131, 87132

7. INSPECTION FOCUS AREAS

FE 6-8

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02230

2. PRIORITY

2

3. LICENSEE CONTACT

Stacie Godin, MS - RSO

4. TELEPHONE NUMBER

(574) 204-7885

☐ Main Office Inspection Next Inspection Date: No Change

☒ Field Office Inspection 5340 Holy Cross Parkway, Mishawaka, IN

☐ Temporary Job Site Inspection
PROGRAM SCOPE

This was an unannounced escalated enforcement followup inspection of a cancer treatment center authorized to use byproduct material to perform diagnostic and therapeutic administrations of radiopharmaceuticals and to perform radiation oncology treatments using a high dose-rate remote afterloader brachytherapy (HDR) unit at its facilities in Mishawaka and Westville, Indiana. The purpose of this inspection was to verify the completion and assess the effectiveness of corrective actions for apparent violations identified during a routine inspection on February 17, 2017 (IR 03037585/2017001(DNMS)). As a result of that inspection, the NRC identified a SLIII problem for lack of a Radiation Safety Officer (RSO) and for failure to notify the NRC that the previous RSO had permanently discontinued the performance of those duties.

PERFORMANCE OBSERVATIONS

The inspector confirmed that the licensee had taken corrective actions as described in its written response dated September 1, 2017. The inspector noted that the licensee's revised change of RSO procedure adequately addressed various scenarios in which compensatory measures to maintain oversight, including notification to the NRC, would be required, that the licensee's monthly education meetings had addressed and would continue to address relevant and constructive topics for the foreseeable future, and that the RSO had completed a 40-hour training course specifically tailored to medical RSOs in January 2018. The inspector also observed one fraction of an HDR treatment, for which the RSO was the attending medical physicist, and reviewed and discussed with the licensee a selection of additional records related to the oversight of the program, including quarterly nuclear medicine audits by a health physics consultant, quarterly RSC meeting minutes, and annual HDR audits.

The inspector identified no additional examples of the violations previously identified, and determined that the licensee had implemented effective corrective actions to restore compliance and address the potential for recurrence of each. Therefore, the SLIII problem is closed. No other violations of NRC requirements were identified as a result of this inspection.