NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Michiana Hematology-Oncology, P.C. 100 East Wayne Street Suite 510 South Bend, IN 46601 REPORT NUMBER(S) 2018001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-37858	13-32719-01	October 25, 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 violations(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	Dennis P. O'Dowd	Dennis P. O'Dowd	10/25/18
BRANCH CHIEF	Aaron T. McCraw		11/15/18

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Michiana Hematology-Oncology, P.C. 100 East Wayne Street Suite 510 South Bend, IN 46601 REPORT NUMBER(S) 2018002	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-37858	13-32719-01	October 25, 2018

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131, 87132	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Stacie Godin, M.S. - RSO	(574) 204-7885

☑ Main Office Inspection Next Inspection Date: 10/25/2020

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced, routine inspection of a physician-owned cancer treatment center with two locations of use in northern Indiana, authorized for medical uses under 10 CFR 35.200, 35.300, and 35.600 (Ir-192 in an HDR unit). Both locations of use maintained a dedicated PET center. Although both of the licensee's locations of use are authorized for all uses authorized by the license, only the Mishawaka, Indiana facility performed therapeutic administrations of radiopharmaceuticals and radiation oncology treatments using a high dose-rate remote afterloader brachytherapy (HDR); the Westville, Indiana facility performed only diagnostic uses, specifically, PET studies using F-18; the Varian HDR unit at the Westville, Indiana facility had not been re-sourced in several months. The licensee's PET centers were staffed with 4 full-time nuclear medicine technologist (NMTs) who performed approximately 20 – 22 PET studies weekly at its main location in Mishawaka, and approximately 7 PET studies weekly at its Westville location. Therapy procedures were limited to the use of Ra-223 Xofigo, approximately 60 treatments per year. The radiation therapy department was staffed with four physician authorized users and one medical physicist. The majority of HDR procedures were for treatment of breast and gynecological cancers. There were approximately 150 treatment fractions administered per year. The licensee has an active RSC, and retained a consulting physicist who audited the licensee's program on a quarterly basis.

PERFORMANCE OBSERVATIONS

The inspector toured the Mishawaka facility to evaluate the licensee's measures for materials security, hazard communication and exposure control. In the nuclear medicine department, the inspector observed the preparation and administration of two F-18 PET doses and the preparation and a therapeutic administration of Ra-223 Xofigo. These observations, combined with interviews with licensee staff, revealed an adequate level of understanding of radiation safety, emergency and material handling procedures and techniques. Licensee staff successfully demonstrated routine equipment QA/QC checks, daily package receiving and check-in procedures, daily and weekly area surveys, and waste handling and disposal procedures. The inspector noted no concerns with these activities. The inspector observed one HDR treatment fraction, in which the RSO/medical physicist was attending, along with the licensee's primary

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PROGRAM SCOPE

(cont'd. from previous page)

authorized physician user. The RSO/medical physicist demonstrated/discussed, HDR QA and safety checks, source exchanges, and emergency procedures. Service, maintenance, and source exchanges were performed by the HDR device manufacturer. The inspector reviewed HDR written directives and treatment plans, and as well as written directives and other relevant records and procedures for Xofigo administrations. Review of licensee dosimetry and survey records indicated no concerns with exposures to radiation workers or general public. The inspector performed independent and confirmatory radiation measurements that indicated results consistent with licensee survey records and postings.

No violations of NRC requirements were identified during this inspection.