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. 3975 William Richardson Drive South Bend, IN 46628 Location inspected: Mishawaka, Indiana REPORT NUMBER(S) 2015-001	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	April 30, 2015

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.

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

10 CFR 35.40(b)(2) states that a written directive must contain the patient or human research subject's name and, for an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131, the radioactive drug, dosage, and route of administration.

☐ 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	Ryan Craffey	5/5/15
BRANCH CHIEF	Aaron McCraw		5/6/15

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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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	Yuntao Feng, PhD - RSO	(419) 480-7263

☐ Main Office Inspection Next Inspection Date: 04/30/2017

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

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine inspection of a cancer treatment center authorized to perform diagnostic and therapeutic administrations of radiopharmaceuticals and to conduct fractionated HDR treatments at its facilities in Westville and Mishawaka, Indiana. At the time of the inspection, the licensee performed 4-8 PET scans daily, around 150 HDR fractions annually, and has completed several courses of Ra-223 Xofigo to date at the Mishawaka facility. The licensee performed only 10-15 HDR fractions annually at the Westville location, and has not performed any therapeutic administrations there to date. The licensee's Radiation Safety Committee (RSC) met semiannually, and a medical physics consultant performed audits of the nuclear medicine lab quarterly.

PERFORMANCE OBSERVATIONS

The inspector toured the Mishawaka facility to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent and confirmatory surveys of the facility, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The inspector observed the preparation and administration of one PET scan using F-18, as well as the receipt of packages containing radiopharmaceuticals and demonstrations of restricted area surveys, remote afterloader spot checks, and the treatment planning and verification process for remote afterloading brachytherapy. Through these observations, demonstrations, and other discussions, the licensee's staff demonstrated adequate knowledge of radiation protection principles and regulatory requirements. The inspector also reviewed a selection of records, including RSC meeting minutes, quarterly audits, dosimetry, instrument quality control, as well as a representative sample of written directives for administrations of Xofigo and for a variety of HDR treatments.

The inspector noted a licensee-identified violation of 10 CFR 35.40(b)(2) for the failure to clearly indicate the route of administration on written directives for Xofigo prepared on 8/12/14, 8/20/14, 9/3/14 and 9/16/14, among others. The inspector determined the root cause to be an oversight by licensee personnel. As corrective action, the licensee revised the written directive template for Xofigo to always indicate an intravenous route of administration. The inspector determined that the violation was self-identified, non-repetitive, non-willful and adequate corrective action had been taken, and therefore met the criteria for the NRC to not cite this violation.