NRC FORM 591M PART 1
(06-2010)
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. 5340 Holy Cross Parkway Mishawaka, IN 46556 REPORT NUMBER(S): 11-01	U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-37858	13-32719-01	2/18/11

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, NUREG-1600, 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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11

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	Ken Lambert	Ken Lambert	2/18/11
Branch Chief	Tamara E. Bloomer	T E Bloomer	2/28/11

NRC FORM 591 M PART 3
(06-2010)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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1. LICENSEE	2. NRC/REGIONAL OFFICE
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3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-37858	13-32719-01	02/18/2011

6. INSPECTION PROCEDURES	7. INSPECTION FOCUS AREAS
8713o; 87132	03.01 – 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1.PROGRAM	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2230	2	Greg Quiroz, Radiology Director	219-785-3420

☒ Main Office Inspection — Next Inspection Date: 02/2013

☒ Field Office Inspection — 1668 South US 421, Westville, Indiana

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

The licensee is a private corporation with two locations of use; one in Mishawaka, Indiana and the other in Westville, Indiana. The license authorizes activities under 10 CFR 35.200 and 35.600. The licensee recently moved to the new locations on the license and this was the first inspection at these locations. The Mishawaka facility opened in August 2010 and employs 3 full time technologists performing approximately 170 studies per month using FDG. The licensee is schedule to begin studies using F-18 tagged sodium fluoride in the near future. The facility also performs cancer treatments using a Varian VariSource IX HDR afterloader unit and has treated 18 patients since August 2010. Treatments were mostly vaginal cylinder; however also used tandem and ovoid, mamosite, and savvy applicators. The licensee has two full time medical physicists at this facility, one authorized and one junior. The Westville, Indiana facility began operations in November 2010 and employs one full time and one part time technologists performing approximately 3 studies per day using FDG. The Westville, IN, facility is authorized for HDR treatments, but at the time of the inspection had not initiated treatments. The licensee has one full time authorized medical physicist at this facility; however the licensee's physicists support each other. The licensee uses a consultant to perform quarterly audits of the radiation safety program.

Performance Observations

The inspector observed one administration of licensed material including dose preparation and disposal. Licensee staff demonstrated/discussed survey meter and well counter QC, dose calibrator daily constancy, package receipt surveys, response to spills, daily surveys, weekly wipes and disposal/decay-in-storage activities. The medical physicist demonstrated daily treatment room and HDR checks. The inspector reviewed 6 HDR treatments of the 18 performed and did not identify any issues or concerns. Interviews with licensee personnel indicated an adequate knowledge of radiation safety concepts and procedures.

The inspector reviewed dosimetry data for 2010 and noted that the maximum exposures were 492 mrem whole body and 4930 mrem extremity.

No violations of regulatory requirements were identified.