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 REPORT NUMBER(S) 13-001	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 25-26, 2013

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	Deborah A. Piskura, Health Physicist	Deborah A Piskura	4/26/13
BRANCH CHIEF	Tamara E. Bloomer, Chief, MIB	Tamara Bloomer	4/29/13

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
87130, 87131, 87132	03.01- 03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Eric B. Ramsay, Ph.D., RSO	(574) 204-7727

☑ Main Office Inspection Next Inspection Date: April 2015

☑ Field Office Inspection 1668 S US 421, Westville, IN &

☐ Temporary Job Site Inspection 5340 Holy Cross Parkway, Mishawaka, IN

PROGRAM SCOPE

This licensee was a doctors owned cancer treatment center with two locations of use in northern Indiana. This licensee's authorization included materials in Sections 35.200, 35.300, and Ir-192 in an HDR unit. Each location of use maintained a dedicated PET center and possessed a Varian HDR unit. The diagnostic departments employed six technologists who performed approximately 250-275+ diagnostic PET procedures monthly. Although authorized, the licensee had not initiated use of 35.300 material; the licensee anticipated use of this material in the future.

Collectively, the radiation oncology departments were staffed with 4 AMPs and 2 authorized users, and several therapists. The licensee administered approximately 25-30 patient treatments annually; the majority of these treatments were for breast and gynecological cancers. All HDR patient treatments were administered by the attending radiation oncologist, the authorized medical physicist, and a therapy technologist. Service, maintenance, and source exchanges were performed by the HDR device manufacturer.

This inspection consisted of interviews with select licensee personnel; a review of select records; tours of the nuclear medicine and radiation oncology departments; and independent measurements. The inspector observed licensee personnel administer one F-18 FDG unit dose for a CA follow up study. The inspection included observations of source inventories, dose calibrator QA checks, HDR QA and safety checks, security of byproduct material, and use of personnel monitoring.

The maximum TEDE and SDE dose (in millirem) to a worker was reported as:

	2011	2012	YTD 2013
TEDE	839	708	129
SDE	8,930	5,570	1,280