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
West Branch Regional Medical Center **2463 South M-30** **West Branch, MI 48661** REPORT NUMBER(S) **2011-01**	**U.S. Nuclear Regulatory Commission** **Region III** **2443 Warrenville Road, Suite 210** **Lisle, Illinois 60532-4351**

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-17321	21-18892-01	June 22 and July 28, 2011

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

Title 10 Code of Federal Regulations (CFR) 35.67(g) requires that a licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with § 35.2067(b).

Continued on Part 2

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			9-6-2011
NRC INSPECTOR	Robert P. Hays		8/19/2011
Branch Chief	Tamara E. Bloomer		9/8/11

NRC FORM 591M PART 1(06-2010)

NRC FORM 591M PART 2 (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
West Branch Regional Medical Center 2463 South M-30 West Branch, MI 48661 REPORT NUMBER(S) 2011-01	U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4351

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(Continued)

Contrary to the above, the licensee has not conducted a semi-annual inventory of brachytherapy sources as required. Specifically, the licensee has not conducted a semi-annual inventory of the brachytherapy seeds used for prostate implants since January 20, 2008. The licensee has maintained a record of unused brachytherapy seeds placed in storage, but failed to conduct a semi-annual inventory of those seeds in storage to ensure that no seeds have become lost or unaccounted for.

This is a Severity Level IV violation (Section 6.3).

The licensee's medical physicist believed that an annual inventory was required rather than a semi-annual inventory. The licensee's corrective actions will be to conduct an inventory of the brachytherapy seeds with the next 30 days and will continue to conduct an inventory of the brachytherapy seeds semi-annually as required.

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
West Branch Regional Medical Center 2463 South M-30 West Branch, MI 48661 REPORT NUMBER(S) 2011-01	U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4351

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03017321	21-18892-01	June 22, 2011

6. INSPECTION PROCEDURES	7. INSPECTION FOCUS AREAS
87131 (10/24/02)	03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1.PROGRAM	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2120	3	M. Waack, M.D., RSO	989-345-3660

X Main Office Inspection — Next Inspection Date: June 2014

☐ Field Office Inspection

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

The licensee was authorized for two locations in West Branch, Michigan, with authorization by the license at the main campus, 2463 S. M-30, to use any byproduct materials for diagnostic and therapeutic medical procedures under 10 CFR 35.100, 35.200, 35.300, and 35.400. The second location, West Branch Regional Cancer Center, 2431 S. M-30, is authorized to use any byproduct materials for diagnostic medical procedures under 10 CFR 35.100 and 35.200, excluding PET isotopes and Xe-133. Cardiac stress testing at the Cancer Center was inspected during the prior inspection and was not reviewed during the current inspection.

The licensee's main Nuclear Medicine Department routinely conducts a daily average of 4-6 patient studies with a staff of 2 nuclear medicine technologists. Iodine-131 procedures requiring a written directive average one or two procedures per year. One administration of Sr-89 has been performed since the previous inspection. The licensee receives licensed material as unit doses and bulk pertechnetate from an area local nuclear pharmacy as needed.

The licensee periodically performs iodine-125 seed implant procedures and averages 3 cases per year. Implant records are maintained in the dosimetry files in the Cancer Center for review. Unused seeds are stored for decay in the main campus hot lab.

Performance Observations

During the inspection, the licensee's NMT staff demonstrated/discussed: (1) survey instruments and required surveys; (2) package receipt and check-in procedures; (3) wipe test counting; (4) unit dose and safe handling procedures; (5) I-131 procedures and written directives; (6) waste handling; (7) sealed source inventories and leak tests; (8) security and storage of licensed material; (9) radiation safety program audit results; (10) dosimetry for CY 2009: 472mr-DDE; 1830mr-finger; and CY 2010: 425mr-DDE; 1380mr-finger. The inspector performed independent and confirmatory radiation measurements, which indicated results consistent with licensee survey records and postings. A SL IV violation of 10 CFR 35.76(g) was identified for a failure to perform semi-annual inventories of brachytherapy seeds.