

ENCLOSURE 6

INSPECTION RECORD

Region III

Inspection Report No. 2006-001

License No. 21-32501-01

Licensee (Name and Address):
West Michigan Cancer Center
200 North Park Street
Kalamazoo, MI 49007

Docket No. 030-36539

Location (Authorized Site) Being Inspected: 200 North Park Street, Kalamazoo, Michigan

Licensee Contact: Paul Jursinic, Acting RSO

Telephone No. 269.382.2500

Priority: 2 Program Code: 02230

Date of Last Inspection: 11/15/2004

Date of This Inspection: 8/23/2006

Type of Inspection: ☐ Announced ☒ Unannounced
☒ Routine ☐ Special
☐ Initial

Next Inspection Date 8/2008 ☒ Normal ☐ Reduced

Justification for reducing the routine inspection interval:

Summary of Findings and Actions:

- ☐ No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- ☐ Non-cited violations (NCVs)
- ☐ Violation(s), Form 591 issued
- ☒ Violation(s), **regional letter** issued
- ☐ Followup on previous violations

Inspector(s) Deborah A. Piskura

Date 9/7/2006

Approved Kenneth J. Lambert, Acting Chief, MIB

Date 9/24/06

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

(License amendments issued since last inspection, or program changes noted in the license)

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
02	12/29/2004	add new Sr-90 calibration source
03	10/11/2005	add 35.300 material

2. INSPECTION AND ENFORCEMENT HISTORY:

(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders) **No violations were identified during the previous, initial inspection on 11/15/2004.**

3. INCIDENT/EVENT HISTORY:

(List any incidents, or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.) **NONE**

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

The Western Michigan Cancer Center was a private out-patient cancer treatment clinic. The clinic was authorized for Ir-192 within an HDR unit, Sr-90 calibration source and 35.300 material limited to out-patient, beta-emitting radiopharmaceutical therapy. The radiation therapy activities were performed by one authorized physician user, 3 medical physicists, two dosimetrists, and two radiation therapy technologists. The licensee administered approximately 2-3 patient treatments per month using its HDR unit; the majority of these treatments were for gynecological cancers. All HDR patient treatments were administered by the attending oncologist, the medical physicist and a therapy technologist (note that the technologist operated the controls to the HDR unit). All source exchange, maintenance, and repairs on the HDR unit was performed by the manufacturer. To date the clinic had not used Section 35.300 materials.

This inspection consisted of interviews with licensee personnel, a review of select records, tour of the facility, and independent measurements. The inspector also observed a medical physicist performing daily QA/safety checks on the HDR unit.

During the entrance meeting, the licensee staff informed the inspector that the individual listed on the license as RSO was no longer employed with the company; the individual departed in February 2006. On February 14, the licensee submitted an amendment request to NRC to change the RSO. In the meantime, one individual, an authorized medical physicist, other than that named on the license, was acting as RSO. On March 21, the MLB contacted the physicist and informed him that additional information on his training and experience was required for the review. The licensee agreed to void the amendment request and resubmit in April when an additional physicist would be on staff and satisfy the Part 35 requirements for RSO. In April the proposed RSO assumed the duties. However,

to date, the licensee failed to follow through with the re-submission of an amendment request. The inspector discussed this matter with the licensee and emphasized the need to promptly re-file a license amendment request to change the RSO. The Acting RSO forgot to file an amendment request due to focuses on the commissioning of a new LINAC unit.

One violation of NRC requirements was identified during this inspection.

2. **INSPECTION SCOPE**

INSPECTION PROCEDURE(S) USED: **87132**

INSPECTION FOCUS AREAS: **03.01, 03.02, 03.04, 03.05, 03.06, and 03.07**

3. **INDEPENDENT AND CONFIRMATORY MEASUREMENTS:**

(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

The inspector conducted direct radiation measurements around the licensee's HDR treatment room with the source exposed. This survey indicated similar results as the licensee's survey records. Radiation levels at the treatment console and in the unrestricted areas outside the treatment room were at background, 0.03 mR/hr. Maximum radiation levels on the HDR unit's main source safe were 1.5 mR/hr, background, 0.02 mR/hr at 3 feet.

4. **VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:**

(State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

Condition 11 of License No. 21-32501-01 names Jeffery T. Colvin, M.S., as the Radiation Safety Officer for this license.

Contrary to the above as of February 2006, Jeffery T. Colvin, M.S., has not served as the Radiation Safety Officer for this license.

This is a Severity Level IV Violation (Supplement VI).

On August 28, 2006, the license submitted an amendment request via facsimile to its NRC license to change the RSO.

5. **PERSONNEL CONTACTED:**

[Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone).]

#*Zubin H. Bharucha, M.S., Medical Physicist

#*Paul Jursinic, Ph.D., Medical Physicist, Acting RSO

+Teresa McKay, President and CEO

Use the following identification symbols:

Individual(s) present at entrance meeting

* Individual(s) present at exit meeting

+Individual contacted by telephone