

Enclosure 6 – Inspection Record

Region III

NMED No. 110033 (closed)

Inspection Report No. 2011-01

License No. 21-08892-01
Docket No. 030-02077

Licensee:
Botsford General Hospital
28050 Grand River Avenue
Farmington Hills, MI 48336-5933

Location Being Inspected: Cancer Center, 27900 Grand River Ave. and Main Hospital 28050 Grand River Ave., Farmington Hills, MI

Licensee Contact: Stephan Morse, D.O., RSO Telephone No.: (248) 471-8000

Priority: 2 Program Code: 02230

Date of Last Inspection: September 22, 2008

Date of This Inspection: February 8, 2011 (with continued in-office review through February 18, 2011)

Type of Inspection: () Initial () Announced (X) Unannounced
(X) Routine () Special

Next Inspection Date: 2/2013 (X) Normal () Reduced

Justification for reducing the routine inspection interval: None

Summary of Findings and Actions:

- (X) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- (X) Non-cited violations (NCVs)
- () Violation(s), Form 591 issued
- () Violation(s), regional letter issued
- () Follow up on previous violations

Inspector(s): Tamara Bloomer for
Deborah A. Piskura, Health Physicist

Date March 14, 2011

Approved: Tamara Bloomer
Tamara E. Bloomer, Chief, MIB

Date March 14, 2011

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Inspector(s): /RA by Tamara E. Bloomer for/
Deborah A. Piskura, Health Physicist

Date March 14, 2011

Approved: /RA/
Tamara E. Bloomer, Chief, MIB

Date March 14, 2011

Issue Date: 07/27/10
Effective Date: 10/01/10

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

1. AMENDMENTS AND PROGRAM CHANGES:

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
60	02/18/2009	Add HDR unit, CA center, respective AUs & AMP
61	08/04/2009	Add AMPs
62	10/27/2009	Add AMPs
63	08/30/2010	Add AU
64	12/09/2010	Add Zevalin to authorization

2. INSPECTION AND ENFORCEMENT HISTORY:

No violations were identified during the last two routine inspections conducted on December 2, 2005, and September 22, 2008.

3. INCIDENT/EVENT HISTORY:

This routine inspection included a review of the licensee's notification that a member of the hospital staff (a member of the public) received an inadvertent radiation exposure during a patient high dose-rate remote afterloader (HDR) treatment on January 19, 2011. On January 19, 2011, the licensee's AMP notified the Headquarter Operations Officer that a staff member, attending to the patient, was inadvertently left behind in the HDR treatment room while the source was exposed for the patient treatment (NMED No. 110033). In a letter dated February 7, 2011 (ML 110380407), the licensee described the circumstances of the event and the licensee's corrective actions.

On January 19, 2011, a patient was scheduled to receive the first of two fractions for a prostate HDR treatment course. The patient was brought to the HDR suite at approximately 9:00 am. The patient was under general anesthesia during the treatment setup and the treatment. An anesthesia technologist attended the patient and focused on monitoring the patient's vital signs displayed on the anesthesia unit which was located near the patient's head. For a period of time, the technologist sat in a chair near the patient's head while attending him (the distance from the HDR source set up was approximately 7 feet). Meanwhile, the radiation oncology staff set up the patient and connected the treatment unit channels to the respective catheters on the applicator/prostate template. At the completion of these preparation activities, the authorized medical physicist (AMP), the authorized user, the therapist, and the nurse exited the treatment room. The AMP checked the treatment room to verify that only the patient remained in the room and made a verbal statement that the team was ready to start the treatment. However, the AMP did not see the technologist, who was sitting in the chair beside patient, because a surgical draping obscured the view. Therefore, the AMP mistakenly concluded that only the patient remained in the treatment room. The staff initiated the patient's treatment at approximately 9:49 am. The written directive and the treatment plan specified a dose of 1,200 cGy to the prostate utilizing 15 channels with a total treatment time of approximately 11.83 minutes. During the treatment, the AMP monitored the patient via closed circuit television (CCTV); however, the anesthesia technologist was not visible because the cameras were focused on the patient's face

and the HDR unit. At approximately 9:52 am (1.855 minutes into the treatment) the team noted an error code on the unit console and recognized that the treatment room door was opening from the inside. The treatment was interrupted and the source automatically retracted into the shielded position, as designed. The anesthesia technologist emerged from the treatment room and indicated that he did not realize they were in the process of treating the patient until he noticed the radiation monitor within the room was flashing red. At approximately 9:53 am, the staff resumed the patient treatment and completed the treatment without further incident.

The licensee performed a reenactment of the event and calculated the exposure to the individual. Note that the individual was not a radiation worker and not required to wear personnel monitoring. According to the licensee's initial calculations, the exposed individual received about 23 mrem. In addition, the AMP used an energy-compensated GM instrument capable of measuring cumulative exposure during set time intervals in effort to duplicate the exposure event to measure. Based on the measured dose, the licensee concluded that the anesthesia technologist received 5.6 mrem during the exposure event.

Based on the inspector's independent inverse-square dose calculation, the exposed individual received approximately 40 mrem if the individual was 6 feet away from the exposed source during the exposure event (without accounting for patient attenuation of the source).

The licensee implemented several corrective actions to address the violation which included: (1) revising its policies and procedures to require the medical physicist to physically check the treatment room and ensure that no unauthorized personnel are present prior to initiating at patient treatment; (2) requiring the medical physicist or other team member to verbally announce that the staff must exit the treatment room; (3) verbally announcing (over the intercom) that the treatment is starting; and (4) requiring the treatment team to minimize conversations at the treatment console (during a patient treatment) in effort to account for all personnel attending to the patient.

One non-cited violation of NRC requirements was identified during this inspection concerning the licensee's failure to permit only individuals approved by the authorized user, radiation safety officer, or authorized medial physicist to be present in the HDR treatment room during a patient treatment on January 19, 2011, as required by Title 10 of the Code of Federal Regulations (CFR) 35.610(a)(2).

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

This licensee was a community hospital (300 beds). The nuclear medicine department was staffed with three full-time technologists who performed approximately 180-200 diagnostic nuclear medicine procedures per month. The majority of these procedures were bone, gastric emptying, cardiac, gall bladder, and lung imaging (using Xe-133). The licensee received unit doses and bulk Tc-99m for kit preparation. Typically, in a year the hospital administered 10-12+ cases of hyperthyroidism and 5-10 whole body cancer follow up studies. Radioiodine was obtained from the radiopharmacy in capsule form. The hospital released I-131 patients in accordance with the provisions of Section 35.75.

The radiation therapy activities were limited to Ir-192 within an HDR unit. The HDR unit was located within a free-standing cancer clinic on the hospital grounds. The patient treatments were performed by one authorized user supported by two contract medical physicists and four therapists. The licensee used its HDR unit to administer approximately 50 patient treatments per year; these treatments were limited to breast and prostate 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 licensee personnel, a review of selected records, a tour of the nuclear medicine department, and independent measurements. The inspection included observations of dose calibrator QA checks, security of licensed material, and use of personnel monitoring. At the time of this inspection, no authorized medical physicist was on-site; therefore, no HDR safety checks could be confirmed. The inspection of the HDR unit was limited to reviewing security, room postings, unit labeling, the treatment viewing and intercom systems.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87103, 87130, 87131, and 87132

Focus Areas Evaluated: 05.01.b.1 (a) – (h)

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector performed direct radiation measurements in and around the licensee's nuclear medicine hot lab and HDR unit storage area which indicated similar results as noted in the licensee's survey records. Maximum levels were measured at the surface of the L-block within the hot lab. Radiation levels in the unrestricted areas outside the hot lab, the imaging room, and the HDR treatment room were indistinguishable from background. The inspector concluded that these radiation levels in the hospital complied with the 10 CFR Part 20 limits. All survey measurements in the restricted areas were comparable to the licensee's survey results.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

One non-cited violation of NRC requirements was identified during this inspection concerning the licensee's failure to ensure that all personnel, (not approved by the authorized user) were evacuated from the HDR treatment room prior to the initiation of a patient treatment on January 19, 2011, as required by 10 CFR 35.610(a)(2). This violation was identified by the licensee's staff on January 19, 2011. The licensee implemented several corrective actions to address the violation which included: (1) revising its policies and procedures to require the medical physicist to physically check the treatment room and ensure that no unauthorized personnel are present prior to initiating at patient treatment; (2) requiring the medical physicist or other team member to verbally announce that the staff must exit the treatment room; (3) verbally announcing (over the intercom) that the treatment is starting; and (4) requiring the treatment team to minimize conversations at the treatment console (during a patient treatment) in effort to account for all personnel attending to the patient. This violation is categorized as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy.

5. PERSONNEL CONTACTED:

*Sandra Adkins, CNMT
*Gilbert Davis, RT(R), Director, Radiology
James Fontanesi, M.D., Radiation Oncologist
Erjona Jusulfi, RT(T)
#*Nichole Mehr, Director, Botsford Cancer Center
Richard H. Morris, CNMT
*Stephan Morse, D.O., RSO& Radiologist
*William Scheuber, MBA, Vice President, Ancillary Services
#Margaret Syrian, M.S., Authorized Medical Physicist
Roland Tuquero, RN, Anesthesia Technologist

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting