

Enclosure 6

INSPECTION RECORD

Region III

EA-08-327

NMED no. **080618**

Inspection Report No. **2008-001**

License No. **21-01333-01**

Docket No. **030-02006**

Licensee (Name and Address):

William Beaumont Hospital
3801 W. 13 Mile Road
Royal Oak, MI 48073-6769

Location (Authorized Site) Being Inspected: **Main Hospital Royal Oak, MI; BHC 4949 Coolidge Highway, Royal Oak, MI; BMC-St. Clair Shores, 25631 Little Mack Avenue, St. Clair Shores, MI; and North Macomb Ambulatory Care Center, 15979 Hall Road, Macomb, MI**

Licensee Contact: **Cheryl Culver-Schultz, M.S., RSO** Telephone No. **248-551-0548**

Priority: **2** Program Code: **02110**

Date of Last Inspection: **11/14-17/2006 (with in office review thru 1-10/2007)**

Date of This Inspection: **November 4-6, 2008**

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

Next Inspection Date: **Nov. 2010** (X) 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
- (X) Violation(s), regional letter issued
- () Follow up on previous violations

Inspector(s): *Deborah A. Piskura*
Deborah A. Piskura, Health Physicist

Date *12/3/08*

Approved: *John R. Madera*
John R. Madera, Chief, MIB

Date *12/4/08*

Issue date: 09/28/05

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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>
83	10/4/2007	two new locations of use
84	1/17/2008	Assist RSO named, changes to Ir-192 limits
85	3/13/2008	add location of use (St. Clair Shores clinic)
86	11/1/2008	changes in HDR make, model and source act.

2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

No violations were identified during the last inspection on November 14-17, 2006. The last inspection included a review of a potential medical event involving a SIRSpheres treatment administered on 11/07/2006. The AU terminated the treatment due to the patient's vasculature within the liver tumor, specifically the patient's blood pressure resistance prevented delivery of the intended dosage. At the conclusion of delivering the treatment, the AU noted a change in the physical characteristics of the microspheres within the delivery system. After further review, the NRC determined that the event did not meet the criteria of a medical event. No violations were identified during the previous inspection conducted November 2-4, 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.)

This routine inspection included a review of a lost I-125 seed. In letter dated September 19, 2008, the licensee's RSO reported a loss of one 0.481 millicurie (8/25/08) I-125 seed which occurred on September 8, 2008. The licensee administered a permanent I-125 prostate implant, using a Nucletron seedSelectron brachytherapy system. The written directive prescribed a treatment using 62 seeds in 20 needles. A quantity of 70 seeds in a pre-loaded cartridge was ordered from the vendor for this procedure, however when the licensee initially received the sources, the staff did not confirm the source count. Prior to treatment, one of the seeds was expelled from the cartridge, used for calibration, and placed in storage. The seedSelectron is an automated system which builds the source train, delivers the source train into the implant needle (one needle at a time) using a guide wire, and retracts the drive wire into the device. To progress between needles the Authorized User connects the drive tube to the needle.

During treatment delivery on the 6th needle, as the authorized user disconnected the needle connector he noticed the link was not as secure as expected. Concerned that a source may have exited the system, the staff surveyed the patient, linens, various equipment, the floors and personnel. Patient images accounted for all seeds implanted up to the 6th needle. The needle was repositioned in the prostate gland under ultrasound guidance and the sources were redelivered without incident. All other needles were implanted without incident. Upon completion of the implant procedure, a radiograph was taken of the source cartridge and a count of the non-implanted seeds revealed that 7 seeds remained, as expected. The seedSelectron system is equipped with an automatic seed counter which indicated to the staff that 62 seeds were implanted. Patient radiographs were taken and the staff counted the seeds on the radiographs; the staff determined that only 61 seeds could be seen on the images. At this point the staff concluded that the seed was either lost in the treatment room or the seed had migrated within the patient and could not be seen on x-ray. The staff re-surveyed the treatment room, and surveyed the department, all associated equipment, linens and trash, as well as personnel but could not locate the seed.

On September 10, 2008, patient returned to the hospital for a follow up exam. The patient had excreted four seeds, which were retrieved and placed in the storage area. Additional x-rays of the patient identified 57 seeds in the patient. Note if 62 seed were implanted as originally prescribed then the licensee would expect 58 seeds remaining in the patient (62 seeds implanted - 4 excreted = 58 seeds remaining). Since the seed cartridge was not radiographed prior to treatment, the initial source count (70 seeds) was not confirmed. The licensee contacted the source manufacturer who provided confirmation showing that they had shipped 70 seeds. The licensee's corrective actions included refresher training for all personnel involved in prostate implants, obtaining images of the loaded cartridges prior to implant procedures to verify the receipt of the correct number of seeds, and making every effort to obtain an implanted seed count prior to the discharge of the patient (e.g. independent verification by a physicist/physicain not directly involved in the procedure).

The licensee's loss of the iodine-125 seed, was a violation of 10 CFR 20.1802 for failure to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. Due to the low actual safety significance associated with the small amount of material, the fact that the quantity was less than 1000 times the 10 CFR Part 20, Appendix C value, and the licensee had a functional brachytherapy program, the Region coordinated this case with OE with the consensus that this violation be categorized as a Severity Level IV violation.

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)

This licensee was a large medical institution (1,000+ bed hospital) and conducted licensed activities at eight locations in the suburban Detroit area. This licensee operated as a Type A medical broad scope program and authorized to use licensed material with atomic numbers 3-83, Ir-192 in two HDR brachytherapy units and Y-90 microspheres. In addition, the licensee was authorized to conduct laboratory and human research studies; no research protocols were conducted at the time of this inspection. The licensee established an RSC to review and approve users, uses, and facilities as required for a medical broad scope licensee. All human research protocols were reviewed by the licensee's Institutional Review Board. The daily radiation safety activities were managed by the corporate RSO, an assistant RSO, RSO delegates at each off-site location of use, and two office assistants.

Collectively, the nuclear medicine departments performed approximately 70,000 diagnostic nuclear medicine procedures annually which included a full spectrum of diagnostic imaging studies. The majority of licensed activities were performed by the main hospital (100 studies daily). The licensee's on-site radiopharmacy prepared all dosages for the main hospital and other satellite sites. Typically in a year, the licensee administered 250+ whole body thyroid CA follow up studies and treated 300+ cases of hyperthyroidism and 100+ cases of thyroid carcinoma. Radioiodine dosages were prepared on site by the nuclear pharmacy staff (all liquid I-131 usage). The department administered approximately 70-80 Y-90 microsphere SIRTs annually. Occasionally, the department administered P-32 (sodium phosphate), Sr-89 Metastron, Sm-153 Quadramet, and Y-90 Zevalin dosages; 10-15 treatments collectively in a year

The radiation therapy activities under this license were performed at the main hospital in Royal Oak. The department possessed two HDR units and administered approximately 700 patient treatments per year; the majority of these treatments were for breast, prostate, bronchial/lung, and gynecological cancers. All HDR patient treatments were administered by the attending radiation oncologist, the medical physicist, and a therapy technologist. Service, maintenance, and source exchanges were performed by the HDR device manufacturer. The department performed 2-5 permanent prostate implants per year using the seedSelectron system. The licensee also administered 1-2 I-125 temporary ocular implants annually.

2. SCOPE OF INSPECTION:

(Identify the inspection procedure(s) used and focus areas evaluated. If records were reviewed, indicate the type of record and time periods reviewed)

Inspection Procedure(s) Used: 87134

Focus Areas Evaluated: 03.01-03.09

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 the administration of several diagnostic nuclear medicine procedures. The inspector observed the administration of a dosage of Y-90 Theraspheres SIRT brachytherapy system for treatment of liver tumors. The inspector also observed the licensee staff administer two patient treatments utilizing its HDR units. The inspection included observations of dose calibrator QA checks, security of byproduct material, use of personnel monitoring, package receipts, and patient surveys.

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)

NRC survey instrument used: Ram Gam 1, Tag No. 046809, last calibrated 09/26/2008.

The inspector performed direct radiation measurements in and around the licensee's radiopharmacy hot lab which indicated similar results as noted in the licensee's survey records. Maximum levels were measured at the surface of the generator storage area, (2 mRhr). Radiation levels in the unrestricted areas outside the hot lab, and the imaging areas were indistinguishable from background, (~0.02m Rhr). The inspector also conducted direct radiation measurements around the licensee's HDR treatment rooms with the respective sources exposed. These surveys indicated similar results as the licensee's survey records. Radiation levels at the treatment consoles and in the unrestricted areas outside the treatment rooms were indistinguishable from background (< 0.02 mR/hr). No violations of NRC requirements were identified.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

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

One violation of NRC requirements was identified during this inspection:

10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Contrary to the above, on September 8, 2008, the licensee did not control one seed containing 0.481 millicuries of iodine-125 located in the HDR suite, which is a controlled area. Specifically, the licensee lost the iodine-125 seed during a patient implant and cannot account for the seed.

This is a Severity Level violation (Supplement IV).

5. PERSONNEL CONTACTED:

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

Use the following identification symbols:

Individual(s) present at entrance meeting

* Individual(s) present at exit meeting

+ Individual contacted by phone on November 13, 2008

***#Kay Beauregard, R.N., Administrative Director**

***Conrad Nagle, M.D., Corporate Medical Director**

John Robertson, M.D., Authorized User

Karen Houghton, Director (Administration)

***#+Cheryl Culver-Schultz, M.S., Radiation Safety Officer**

***#Shannon Robertson, Radiation Safety Coordinator**

***Michael Savin, M.D., Interventional Radiologist**

Charles Romano, M.D., Interventional Radiologist

Mihai Ghilezan, M.D., Authorized User/Radiation Oncologist

***Michelle Beauvais, R.Ph., ANP**

***#Wayne Melchior, Pharm.D., ANP**

***Evelyn Sebastian, M.S., Medical Physicist**

***#Janice Campbell, Ph.D., Assistant RSO, Medical Physicist**

Wenzheng Feng, M.S., Medical Physicist

Leonard Kim, M.S., Medical Physicist

***Subhash Damak, M.S., Medical Physicist**

Scott Emerson, M.S. Medical Physicist

Yongguang Liang, Ph.D., Medical Physicist

Amy Limbacher, RT(T), Brachytherapy Specialist

Several other nuclear medicine technologists and other professional staff were also contacted during this inspection