ENCLOSURE 6

INSPECTION RECORD

Region **III**

NMED No 060688

Inspection Report No. **2006-002, and -003** License No. **21-01333-01**

Licensee (Name and Address): Docket No. **030-02006**
William Beaumont Hospital
3801 West 13 Mile Road
Royal Oak, MI 48073-6769

Location (Authorized Site) Being Inspected: **Main Hospital, Royal Oak, Michigan (-002), and the William Beaumont Hospital - West Bloomfield Medical Office Building, West Bloomfield, Michigan (-003)**

Licensee Contact: **Cheryl Culver-Schultz, M.S., RSO** Telephone No. **248.551.0548**

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

Date of Last Inspection: **11/2-4/2004**

Date of This Inspection: **11/14-17/2006, with continued in-office review through 1/10/2007 to review the licensee's written report on a potential medical event and to review and discuss the reportability of the potential medical event with FSME**.

Type of Inspection: (X) Announced ( ) Unannounced
(X) Routine (X) Special (to review potential medical event)
( ) Initial

Next Inspection Date **11/2008** (X) Normal ( ) Reduced

Justification for reducing the routine inspection interval:

Summary of Findings and Actions:

(X) 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) D A Piskura Date 1/10/2007
Deborah A. Piskura

Approved John R. Madera Date 1/12/2007
John R. Madera, Chief, MIB

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)

AMENDMENT #	DATE	SUBJECT
76	**2/24/2005**	**increase possession limits for Mo-99/Tc-99m**
77	**7/15/2005**	**new location of use**
78	**11/04/2005**	**remove/disposal of Cs-137 irradiator unit**
79	**02/14/2006**	**new location of use**
80	**7/28/2006**	**new gamma knife unit & facility shielding plan**
81	**10/10/2006**	**Installation of new gamma knife unit (possession only)**

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 11/2-4/2004. One violation was identified during the previous inspection on 6/10/2004 conducted to review a medical event.. The event involved an unintended administration of 915 uCi I-131 rather than the prescribed dosage of 10 uCi for a patient thyroid uptake study. An NOV was issued 9/14/2004 (EA-04-129) city the licensee against 10 CFR 35.63(d), for administering an I-131 dosage (915 uCi) which differed from the prescribed dosage (10 uCi) by more than 20 percent.

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.)

On 11/8/2006, the licensee reported a potential medical event to the NRC Operations Center in accordance with 10 CFR 35.3045. The incident involved an investigational/experimental Selective Internal Radiation Therapy (SIRT) utilizing Y-90 microspheres (SIRTex SIRSpheres) that occurred on 11/07/2006. The licensee submitted a written report dated 11/17/06 describing the circumstances of the event. The event is described in detail in Part II, 4. of this report. After further review, the NRC determined that this event did not meet the criteria of a medical event. The authorized user (AU) terminated the procedure due to the medical condition of the patient.

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 (1,300+ bed hospital) and conducted licensed activities at five 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 Co-

60 in a gamma knife unit. In addition, the licensee was authorized to conduct laboratory and human research studies. 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, a site RSO for the Troy hospital, and an office assistant.

Collectively, the nuclear medicine departments performed approximately 60,000 diagnostic nuclear medicine procedures annually which included a full spectrum of diagnostic imaging studies. The majority of licensed activities was 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 50-75 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 treatments collectively in a year. Patient

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 and the medical physicist (therapy technologists did not operate the controls to the HDR unit). Service, maintenance, and source exchanges were performed by the HDR device manufacturer. The department used Pd-103 for 5-10 permanent prostate implants per year. The licensee also administered 1-2 I-125 temporary ocular implants annually.

The licensee acquired a Leskell Model 24001 Type C gamma knife unit and sources on September 13, 2006. To date, the licensee had not initiated clinical use of its gamma knife unit. At the time of this inspection, the licensee and manufacturer's reps were performing acceptance testing on the unit. The licensee filed a new licensee application to list the gamma knife program on a separate license (21-01333-02 pending review and issuance) with a separate, dedicated RSO. Gamma knife activities will be reviewed and approved by the institution's RSC. The licensee anticipated treating the first patient with its new gamma knife unit in mid-December 2006.

2. INSPECTION SCOPE

INSPECTION PROCEDURE(S) USED: 87130, 87131, 87132, 87133 and 87134 Management Directive 8.10

INSPECTION FOCUS AREAS: 03.01, 03.02, 03.04, 03.05, 03.06, 03.07 and 03.08

This inspection consisted of interviews with select licensee personnel; a review of select records; tours of the new gamma knife suite, the nuclear medicine, and radiation oncology departments; and independent measurements. The inspector observed the administration of several diagnostic nuclear medicine procedures

and a 4 mCi I-131 dosage for a whole body CA follow up study. 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, HDR daily safety checks, security of byproduct material (not subject to the Order for Increased Controls), use of personnel monitoring, package receipts, and surveys.

This inspection reviewed the circumstances, causes and corrective actions pertaining to an incident initially reported to the NRC as a possible medical event on 11/08/2006. The incident involved an investigational/experimental treatment utilizing Y-90 microspheres (SIRspheres) that occurred on 11/07/2006. After further review and discussions with FSME, the discussion team concluded that the incident did not meet the criteria for a medical event. On 1/10/2007, the licensee retracted its report of the 11/7/2006 event. See section 4 below for details on this matter.

The inspection included a review of the licensee's actions in response to the Order for Increased Controls (EA-05-090), dated Nov. 14, 2005. The IC requirements only applied to the licensee's gamma knife unit. The results of the IC inspection were documented in IR 030-02006/2006004.

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: Ludlum Model 2403 GM, Tag No. 24587G , calibrated 5/24/2006.

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, (1.5 mR/hr). Radiation levels in the unrestricted areas outside the hot lab, and the imaging areas were indistinguishable from background, (<0.02 mR/hr). 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. Maximum radiation levels at contact on each HDR unit's main source safe were 1.5 mR/hr, background at 100 cm (<0.02 mR/hr at 3 feet). No violations of NRC requirements were identified.

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.)

This inspection reviewed the circumstances surrounding an incident initially reported to the NRC as a potential medical event on 11/08/2006 in accordance with 10 CFR 35.3045. The incident involved an investigational/experimental treatment utilizing Y-90 microspheres (SIRSpheres) that occurred on 11/07/2006. The

licensee submitted a written report dated 11/17/06 describing the circumstances of the event. The inspector interviewed the AU, 2 medical physicists, 2 ANPs, and the RSO with the following observations and findings:

• On the morning of 11/7/06, nuclear medicine personnel followed the manufacturer's procedures to prepare, assay and assemble the SIRTex SIRSpheres delivery system and initiate a patient treatment for metastatic colon cancer to the left lobe of the liver. The prescribed dose was 100 Gy (9.8 mCi Y-90 microspheres) to the target tumor. The licensee previously delivered a treatment to the right lobe of the liver to the same patient without incident.

• After the medical physicist and the AU set up the delivery system within the angiography suite, the physician initiated the treatment. The AU preceded to inject sterile water into the device, suspending the microspheres into a slurry and driving the microspheres into the catheter to the patient/tumor bed.

•At approximately half-way through the administration of the dosage, the AU temporarily halted the procedure in order to flush the patient catheter and to verify positioning of the microspheres within the tumor using angiography. The AU injected sterile water into the system and flushed the patient catheter. As the AU attempted to inject contrast media for the angiography, he noted resistance and "slow flow" of the microspheres from the delivery system indicating that the patient's vasculature within the tumor could not accommodate additional microspheres (the entire intended dosage of 9.8 mCi Y-90). The AU decided to abort further attempts to inject additional microspheres into the patient and revised his written directive. The AU only delivered 6.5 mCi of Y-90 microspheres which would correlate to a dose of 59 Gy to the target tumor rather than the intended dose of 100 Gy (59% of the prescribed dose). Note: according to the AU, in about 10-15% of SIRTs, it is necessary to revise the original treatment plan due to the vasculature/slow flow.

• As the AU halted the treatment he noted that the appearance of the remaining microspheres in the catheter was not as he expected. The microspheres appeared "coagulated" or "clumped" within the catheter which was contrary to the AU's experience as well as the other medical staff within the angiography suite. Refer to Attachment "A" for a photograph depicting this "clumping" phenomenon of the microspheres. Attachment "B" demonstrates the typical appearance of the microsphere slurry within the catheter tubing. According to the licensee, the coagulation of microspheres may have contributed to the slow flow encountered during the treatment, however the licensee could not accurately determine if this phenomena had any effect on the flow.

•The licensee reported the incident to the NRC Operations Office since the target tumor received only 59% of the intended dose. In addition the licensee was concerned about the physical state (coagulation) of the microspheres. At 5:39 p.m. on 11/6/2006, the licensee reported the incident as a potential medical event to the NRC Operations Center because the delivered dose differed from the prescribed dose by more than 20%.

•Upon identification of the apparent incident and the coagulation or "clumping" phenomenon of the microspheres, the licensee's staff reviewed the circumstances of the event to determine the causes and contributing factors in order to develop

corrective actions to prevent recurrence. The licensee verified that the proper priming agent (sterile water) was used in the device. The licensee believed that the three-way stopcock would prevent any contrast media using during angiography from being introduced into the delivery system tubing, which contained the microspheres, to the patient. Further examination of the device and the tubing using fluoroscopy, confirmed no contrast media was introduced into the system during treatment.

•The licensee informed the vendor, SIRTex, of this incident and "clumping" of the microspheres. According to the vendor, this "clumping" phenomenon had been reported to them once before and the cause was determined to be exposure to the microspheres to contrast media. This is contradictory to the licensee's observations and examinations of the device which confirmed an absence of contrast media. The week of 1/1/2007, licensee will sent the delivery set and the multidose vial of the remaining Y-90 to SIRTex for analysis. The licensee committed to promptly inform the Region III office of the results of the analysis.

•The circumstances of the potential medical event were discussed at length between members of the MIB staff (J. Madera, R. Gattone & D. Piskura) and members of the FSME event team (D. Howe, G. Morrell, C. Flannery, & S. Wastler) during a telecon on 1/10/2007. The consensus of the discussion group concluded that this event did not appear to meet the medical event reporting requirements in 10 CFR 35.3045. Since the AU originally halted the procedure due to the medical condition of the patient, this event did not meet the criteria for a medical event. Specifically the AU terminated the procedure due to the vasculature of the tumor and the resistance encountered during the injection of contrast media which prevented the physician from injecting the entire prescribed dosage. On 1/10/2007, the licensee subsequently retracted its event report.

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

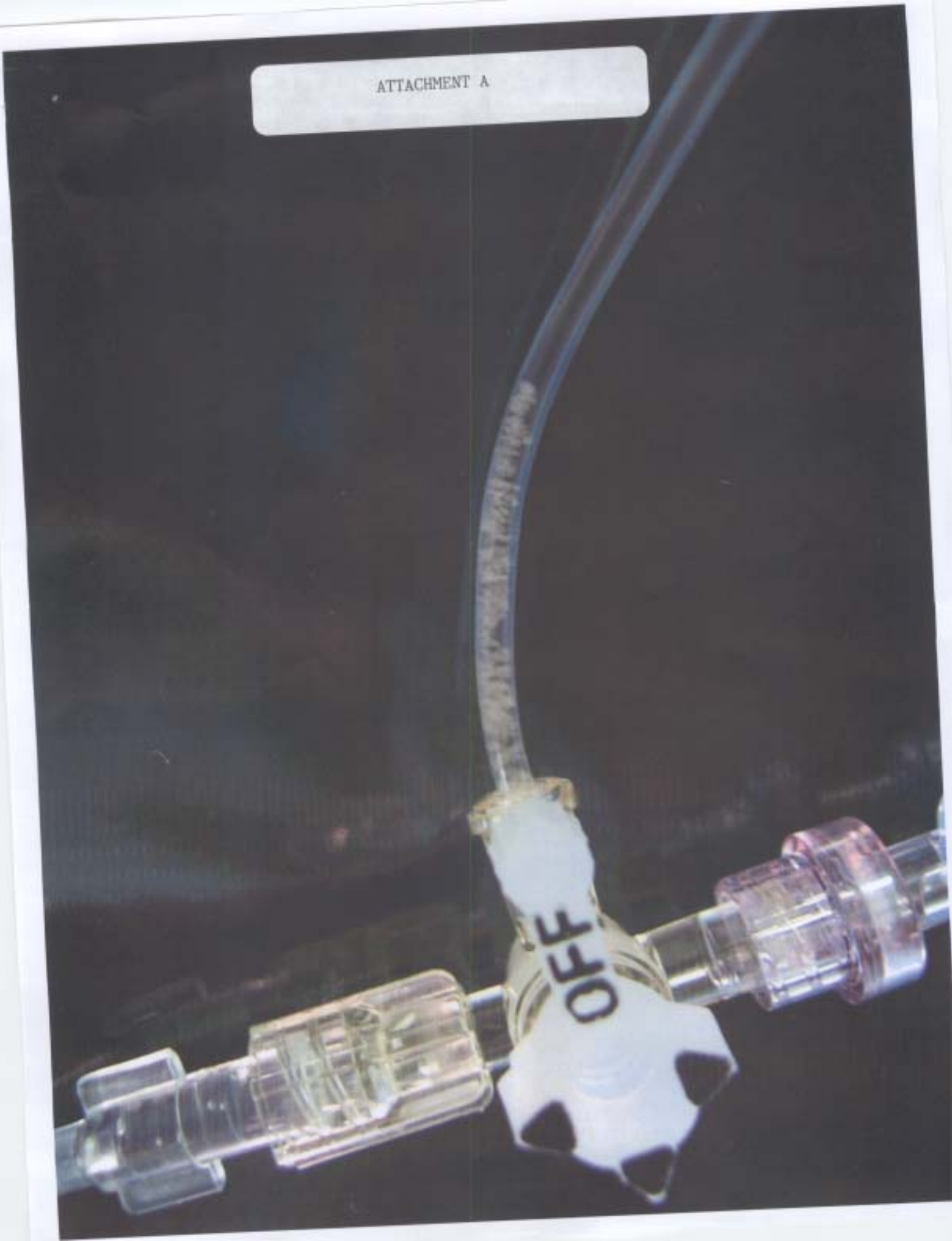
*Kay Beauregard, R.N., Administrative Director
*#Darlene Fink-Bennett, M.D., Chair, Radiation Safety Committee
*#Conrad Nagle, M.D., Corporate Medical Director
*Karen Houghton, Director (Administration)
*#+Cheryl Culver-Schultz, M.S., Radiation Safety Officer
*#+Shannon Robertson, Radiation Safety Coordinator
*#Rick Layman, M.S., RSO, William Beaumont Troy
*#Patrick McDermott, Ph.D., Gamma Knife Physicist
Michael Savin, M.D., Interventional Radiologist
Michael Garcia, M.D., Authorized User
Mihai Ghilezan, M.D., Radiation Oncologist
Peter Chen, M.D., Radiation Oncologist
Alvaro Martinez, M.D., Medical Director, Radiation Oncology
Michelle Beauvais, R.Ph., ANP
*#Wayne Melchior, Pharm.D., ANP
*#Evelyn Sebastian, B.S., Medical Physicist
Lauren Hefner, M.S., Medical Physicist
*#Janice Campbell, M.S., Medical Physicist
*Wenzheng Feng, M.S., Medical Physicist

***Steven Winokur, Chief Patient Safety Officer**
***Jim Clark, Director, Security**
***Leonard Kim, M.S., Medical Physicist**

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

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

ATTACHMENT A



ATTACHMENT B