

July 21, 2011

EA-11-163
NMED No. 110193 (CLOSED)

Ms. Kay Beauregard, R.N., M.S.A.
Vice President
William Beaumont Hospital
3801 West 13 Mile Road
Royal Oak, MI 48073-6769

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002006/2011001(DNMS)
WILLIAM BEAUMONT HOSPITAL

Dear Ms. Beauregard:

On May 2 through 5, 2011, U.S. Nuclear Regulatory Commission (NRC) inspectors conducted a reactive inspection at the William Beaumont Hospital with continued NRC in-office review through July 7, 2011. The in-office review included a review of your staff's written report dated May 9, 2011, with a revised report dated June 8, 2011. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for a medical event that occurred on April 27, 2011. The enclosed report presents the results of this inspection.

Based on the results of this inspection, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://pbadupws.nrc.gov/docs/ML0934/ML093480037.pdf>. The apparent violation involves the failure to develop adequate procedures to provide high confidence that a yttrium-90 microsphere therapy was performed in accordance with the written directive, as required by Title 10 of the Code of Federal Regulations (CFR) Section 35.41(a). The circumstances surrounding the apparent violation, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and members of your staff at the preliminary exit meeting on May 5, 2011, and during the final telephone exit meeting with members of your staff on July 7, 2011. As a result, it may not be necessary to conduct a Predecisional Enforcement Conference (PEC) in order to enable the NRC to make an enforcement decision.

In addition, since your facility has not been the subject of escalated enforcement actions within the last two inspections, and based on our understanding of your corrective actions, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter; or (2) request a PEC. If a PEC is held it will be open for public observation and the

NRC will issue a press release to announce the time and date of the conference. Please contact Tamara E. Bloomer at (630) 829-9627 within ten days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to the Apparent Violation in Inspection Report No. 03002006/2011001(DNMS); EA-11-163" and should include, for the apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the information notice on the NRC website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation.

In addition, please be advised that the number and characterization of any apparent violations may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

K. Beauregard

-3-

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-02006
License No. 21-01333-01

Enclosure:
Inspection Report No. 03002006/2011001(DNMS)

cc w/encl: State of Michigan

K. Beauregard

-3-

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-02006
License No. 21-01333-01

Enclosure:
Inspection Report No. 03002006/2011001(DNMS)

cc w/encl: State of Michigan

DISTRIBUTION:

RidsSecyMailCenter.Reso
urce
OCADistribution
Bill Borchardt
Michael Weber
Roy Zimmerman
Andy Campbell
Nick Hilton
Kerstun Day
Mark Satorius
Cynthia Pederson
Marvin Itzkowitz
Catherine Scott
Cynthia Carpenter

Terrence Reis
Michele Burgess
Duane White
Daniel Holody
Scott Sparks
Heather Gepford
Holly Harrington
Hubert Bell
Cheryl McCrary
Mona Williams
Anne Boland
Patrick Louden
Tamara Bloomer
Steven Orth
Jared Heck

Allan Barker
Harral Logaras
James Lynch
Viktoria Mitlyng
Prema Chandrathil
Patricia Lougheed
Paul Pelke
Magdalena Gryglak
Patricia Buckley
Tammy Tomczak
MIB Inspectors
OEMAIL
OEWEB

*See previous concurrence

DOCUMENT NAME: G:\DNMS\Work in progress\IR- Wm Beaumont Report 2011001.docx

Publicly Available Non-Publicly Available Sensitive Non-Sensitive

To receive a copy of this document, indicate in the concurrence box "C" = Copy without attach/encl "E" = Copy with attach/encl "N" = No copy

OFFICE	RIII DNMS *	RIII DNMS *	RIII DNMS *	RIII EICS *
NAME	DAPiskura: jm *	BCLin: *DAP for	TEBloomer: *	SKOrth: *
DATE	07/15/11	07/15/11	07/18/11	07/20/11
OFFICE	RIII DNMS	RIII	RIII	RIII
NAME	ATBoland			
DATE	07/21/11			

OFFICIAL RECORD COPY

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No. 030-02006

License No. 21-01333-01

Report No. 03002006/2011001(DNMS)

EA No. EA-11-163

Licensee: William Beaumont Hospital

Locations: Main Hospital
3601 W. 13 Mile Road
Royal Oak, Michigan

William Beaumont Hospital-West Bloomfield
6900 Orchard Lake Road
West Bloomfield, Michigan

Beaumont Hospital, Grosse Pointe
468 Cadieux Road
Grosse Pointe, Michigan

Dates: May 2-5, 2011, with continued in-office
review through July 7, 2011

Final Exit Meeting: July 7, 2011 (Telephone)

Inspectors: Deborah A. Piskura, Senior Health Physicist
Bill C. Lin, Health Physicist

Reviewed By: Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

**William Beaumont Hospital
Royal Oak, Michigan
Inspection Report No. 03002006/2011001(DNMS)**

The U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection on May 2-5, 2011, to review the events and circumstances associated with a medical event that William Beaumont Hospital (the licensee) reported to the NRC on April 27, 2011. The inspection included a review of other routine aspects of the licensee's radiation safety program.

During a palliative treatment of a liver tumor from metastatic colorectal cancer on April 27, 2011, the licensee underdosed the treatment site using yttrium-90 microspheres within the Sirtex SIR-Spheres® delivery set. The authorized user noted difficulty during the administration of the microspheres and terminated the treatment, having only administered approximately 20 percent of the prescribed dose of 63 Gray. The root cause of the medical event was the licensee's failure to recognize the potential for the microcatheter to become blocked as a result of such a high concentrate and an inability to add enough water to suspend the microspheres in a dilute enough concentration to permit flow of the microspheres through the microcatheter. Specifically, the licensee did not account for the amount of water required to be added to the dose vial in order to effectively drive the microspheres into the patient. The licensee concluded that the medical event would not result in adverse health consequences for the patient. The inspectors observed the licensee administer a compensating dose of microspheres to the patient on May 4, 2011.

The licensee contacted the device manufacturer for assistance; the manufacturer advised the licensee to send the delivery system to their headquarters for analysis. In addition, the licensee contacted other institutions that administered microsphere treatment to compare practices on administering large doses. The licensee adopted advice from an institution to divide large doses into two smaller dosages to ensure the entire intended dose is provided to the patient. The licensee also revised its policies for microspheres by implementing a procedure limiting the catheter size to be used in these treatments. In addition, the licensee revised its procedures for yttrium-90 administrations directing the authorized user to consider dividing any dose in excess of 2GBq by half to ensure that the suspension is dilute enough to pass through the microcatheter. During a teleconference on June 27, 2011, the licensee committed to incorporate a "time out" process in their procedures when encountering difficulties during microspheres administrations.

The inspectors identified an apparent violation of Title 10 of the Code of Federal Regulations (CFR) 35.41(a)(2) involving the licensee's failure to develop, implement and maintain written procedures to provide high confidence that administrations requiring a written directive, were performed in accordance with the written directive. Specifically, the licensee's written procedures for yttrium-90 treatments did not specify how personnel should administer a dose of microspheres using a fine bore catheter and a high concentration of microspheres in order to prevent blockage within the catheter. This resulted in an administration of a dose on April 27, 2011, not in accordance with the written directive of 63 Gray to left lobe of the liver using 3 gigabecquerels (81 millicuries) of yttrium-90 microspheres. Specifically, the patient received a dose of approximately 14.8 Gray rather than the prescribed dose of 63 Gray because the microspheres became occluded within the microcatheter, and prevented the authorized user from administering the entire intended dose to the patient.

Report Details

1 Program Scope and Inspection History

This licensee was a large medical institution and conducted licensed activities at eight locations in the suburban Detroit area. This licensee operated as a Type A medical broadscope program and is authorized to use licensed material with atomic numbers 3-83, iridium-192 in two high-dose rate brachytherapy units and yttrium-90 microspheres. In addition, the licensee was authorized to conduct laboratory and human research studies; no human research protocols were conducted at the time of this inspection. The licensee established a radiation safety committee to review and approve users, uses, and facilities as required for a medical broadscope licensee. All human research protocols were reviewed by the licensee's Institutional Review Board. The daily radiation safety activities were managed by the corporate radiation safety officer (RSO), an assistant RSO, RSO delegates at each 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 radiopharmacy staff prepared all dosages for the main hospital and the other satellite locations. Typically in a year, the licensee administered 250+ whole body thyroid carcinoma follow up studies and treated 300+ cases of hyperthyroidism and 100+ cases of thyroid carcinoma. Radioiodine dosages were prepared on site from stock solution by the radiopharmacy staff.

The department administered approximately 70-80 yttrium-90 microsphere treatments annually using the MDS Nordion TheraSphere® or the Sirtex SIR-Spheres® brachytherapy systems. The licensee typically administered an average prescribed dosage of approximately one gigabecquerel (GBq) (with a range of 0.1 to 3.3 GBq). The licensee instituted a multi-departmental approach for the use of yttrium-90 microspheres. The team consisted of an interventional radiologist/authorized user, a nurse, a nuclear pharmacist or technician, and a medical physicist. The licensee received bulk quantities of the yttrium-90 microspheres from the vendor from which it assayed and stored the prepared dosages within the main radiopharmacy. The team administered all microspheres treatments in the interventional radiology suite.

The radiation therapy activities under this license were performed at the main hospital in Royal Oak. The department possessed two high dose rate (HDR) remote afterloading 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.

One violation of the NRC requirements was identified as a result of the last routine safety inspection conducted on November 3-6, 2008 (EA-08-327). The inspection included a review of the licensee's reported loss of an iodine-125 seed which occurred on September 8, 2008. No violations were identified during the previous routine inspection conducted on November 2 - 4, 2006. The inspection included a review of a potential medical event

involving an yttrium-90 SIR-Spheres® treatment which the NRC later determined was not a reportable medical event due to patient stasis.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspectors reviewed the licensee's investigation of the medical event. The inspectors also interviewed selected licensee personnel, and observed related equipment and facilities.

2.2 Observations and Findings

On the morning of April 27, 2011, the nuclear pharmacy personnel prepared, assayed and assembled the Sirtex SIR-Spheres® delivery system and initiated a patient treatment for metastatic colorectal cancer to the left lobe of the liver. The authorized user prescribed a dose of 63 Gray (Gy), equivalent to 63 Sievert (Sv), to the tumor. The medical physics staff planned the treatment according to the physician's prescribed dose and calculated a dosage of yttrium-90 microspheres at three gigabecquerels (GBq) (81 millicuries). After the medical physicist and the authorized user set up the delivery system within the interventional suite, the physician initiated the treatment. The authorized user utilized fluoroscopy to position a 2.8 french (Fr) microcatheter threaded within a 5 Fr catheter in order to reach the tumor vasculature. The authorized user injected contrast media, followed by sterile water into the catheter system to verify the positioning within the tumor and to ensure the microcatheter was free of any occlusions, kinks, etc. The authorized user proceeded with the treatment/implant by injecting (or "pulsing") sterile water into the device, suspending the microspheres into a slurry and driving the microspheres into the catheter to the tumor.

According to the authorized user, after the initial pulses, he experienced difficulty in injecting the water into the device. The authorized user checked various components of the delivery set and suspected the microspheres may have formed an occlusion within the microcatheter. He attempted to introduce additional pressure within the catheter by using a smaller syringe in an effort to release the suspected blockage. Attempts to release the blockage were unsuccessful and the authorized user terminated the procedure. The authorized user requested an additional medical physicist to assist him in the interventional suite. Additional drapes were placed on the patient. As the physician withdrew the microcatheter from the patient, an unknown quantity of microspheres, forming a cohesive mass exited from the microcatheter and spilled onto the surgical drape. The licensee successfully contained the spill and photographed the spill and the delivery set. Based on the licensee's surveys and calculations, the patient only received approximately 14 Gy (14 Sv) or 20 percent of the prescribed dose.

The direct cause of the medical event was attributed to the concentration of the microspheres in the dose vial. In order to deliver the physician's prescribed dose, a relatively large dosage was required. Such a dosage is accomplished in a large volume and the void within the dose vial would be minimal and directly affect the ability to add water to the system in order to push out the dosage into the patient. In addition, the device manufacturer cautions the use of a microcatheter in combination with excessive

concentration suspensions of microspheres that may cause clogging in the fine catheter as the licensee experienced.

Title 10 CFR 35.41(a) states that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b). Section VI.E. "Y-90 Microsphere Therapy," of the licensee's Quality Management Program, dated March 23, 2009, for yttrium-90 treatments did not specify how personnel should administer a dose of microspheres using a fine bore catheter and a high concentration of microspheres in order to prevent blockage within the catheter. Further, the manufacturer specifically cautioned the user about these specific conditions in the written training program (instructions) for physicians and institutions. The licensee's failure to develop, implement, and maintain procedures to provide high confidence that each yttrium-90 microsphere administration was in accordance with the written directive is an apparent violation of 10 CFR 35.41(a)(2).

The root cause of the medical event was the licensee's failure to recognize the potential for the microcatheter to become blocked when using such a high concentrate and an inability to add enough water to suspend the microspheres in a dilute enough concentration to permit flow of the microspheres through the microcatheter. Specifically, the licensee did not account for the amount of water required to be added to the dose vial in order to effectively drive the microspheres into the patient. The authorized user attempted to compensate for this volume by adding smaller pulses of water in order to maintain the liquid level within the vial and to avoid contact of the microspheres with the rubber septum. The licensee's limited experience administering such high doses and high concentrations of microspheres contributed to the medical event. Subsequent to the event, the licensee contacted another institution which advised the licensee on its protocol for administering large doses of microspheres.

Based on discussions with the vendor of the treatment system (Sirtex), the inspectors determined that the licensee most likely insufficiently suspended the microspheres and created a clog within the microcatheter. In addition, when the authorized user attempted to introduce additional pressure within the catheter by using a smaller syringe in effort to release the suspected blockage he may have intensified the occlusion. Since the licensee's procedures failed to address how personnel should administer a high dose of microspheres using a fine bore catheter in order to prevent blockage within the catheter, the Region determined that the apparent violation demonstrated a programmatic weakness in implementation. The inspectors also noted that the licensee's procedures focused on preparation of the dosage, emergency procedures (which did not include circumstances associated with this medical event), and revisions to the written directive. In addition, the licensee's procedures referenced another manufacturer's (Therasphere®) device components not applicable to the Sirtex delivery set.

The licensee reported the event as a medical event because the dose to the treatment site differed from the prescribed dose by more than 0.05 Sievert (5 rem) effective dose equivalent and the total dose delivered differed from the prescribed dose by 20 percent or more.

The licensee's medical staff evaluated the potential adverse effects on the patient and concluded that the underdose to the patient would not cause any adverse health effects. On May 4, 2011, the licensee administered a compensating dose of SIR-Spheres® to the patient.

2.3 Conclusions

A medical event occurred because the licensee failed to recognize the potential for the microcatheter to become blocked with using such a high concentrate and an inability to add enough water to suspend the microspheres in a dilute enough concentration to permit flow of the microspheres through the microcatheter. The licensee's limited experience administering such high doses and high concentrations of microspheres contributed to the medical event. The inspectors identified an apparent violation of 10 CFR 35.41(a) involving the licensee's failure to develop, implement and maintain written procedures to provide high confidence that administrations requiring a written directive, were performed in accordance with the written directive.

3 Licensee Corrective Actions

3.1 Inspection Scope

The inspectors reviewed the licensee's proposed corrective actions to prevent similar events. The inspectors also interviewed selected licensee personnel.

3.2 Observations and Findings

The licensee took immediate corrective actions which included administering a compensating dose of microspheres to the patient. In addition the licensee photographed the delivery set as well as the spill. The licensee contacted the device manufacturer for assistance; the manufacturer advised the licensee to send the delivery system to their headquarters for analysis. The licensee intended to send the delivery system and all materials contained in the waste container to the manufacturer after decay. The licensee committed to provide these results to NRC.

The licensee contacted other institutions which administered microsphere treatment to compare practices on administering large doses. The licensee adopted advice from an institution to divide large doses into two smaller doses to ensure the entire intended dose is provided to the patient. A smaller dose also ensures that the concentration of microspheres would be dilute enough to pass through the microcatheter and into the tumor bed. Through approval by the radiation safety committee, the licensee also revised its policies for microspheres by implementing a procedure limiting the catheter size to be used in these treatments. In addition, the licensee revised its procedures for yttrium-90 administrations directing the authorized user to consider dividing any dose in excess of two GBq by half to ensure that the suspension is dilute enough to pass through the microcatheter. During a teleconference on June 27, 2011, the licensee committed to incorporate a "time out" process in their procedures when encountering difficulties during microspheres administrations.

3.3 Conclusions

The inspectors identified that the licensee implemented immediate adequate corrective actions and discussed long-term corrective actions to address the root cause of the medical event.

4 Notifications and Reports

4.1 Inspection Scope

The inspectors reviewed the licensee's notifications to the NRC Operations Center, the referring physician, and the patient. In addition, the inspectors reviewed the licensee's written report describing the medical event.

4.2 Observations and Findings

On April 27, 2011, the day of the microspheres administration, the licensee notified the NRC Operations Center of the medical event (Event Number 46791). The licensee notified the patient and the patient's referring physician. In addition, the licensee provided the referring physician and the patient a copy of its written report on the medical event. The licensee provided its written report of the medical event to the NRC in a report dated May 9, 2011, with a revised report dated June 13, 2011, detailing its corrective actions. The report and the revision included the information required by 10 CFR 35.3045(d)(1).

4.3 Conclusions

The licensee made all of the notifications and reports as required by 10 CFR 35.3045 within the specified time period. The licensee's written report included all of the required information.

5 Other Areas Inspected

5.1 Inspection Scope

The inspectors reviewed other aspects of the licensee's radiation protection program which included high dose rate brachytherapy activities, security of licensed material, personnel monitoring, training, physical inventory and leak testing of sealed sources, labeling of containers, and postings. The inspectors interviewed selected individuals, toured the licensee's facilities, examined the licensee's containers and reviewed selected records.

5.2 Observations and Findings

The inspectors reviewed selected radiation safety committee meeting minutes and documentation of training for selected authorized users. The radiation safety committee established a quorum for its meetings held at least quarterly to review events, program audit results, and approve uses, facilities and users. Audits of the radiation safety program were discussed in the meeting minutes.

The inspectors observed the administration of several diagnostic nuclear medicine procedures. The inspectors observed the administration of two dosages of yttrium-90 SIR-Spheres® for a patient treatment. The inspectors also observed the licensee staff administer two patient treatments utilizing its HDR units. The inspection included observations of dose calibrator checks, security of byproduct material, use of personnel monitoring, package receipts, and patient surveys.

The inspectors examined a sampling of sealed sources in the licensee's possession. Each source container was noted to bear a clearly visible label identifying the radionuclides and source activities.

The inspectors observed that the licensee posted a copy of NRC Form 3. The inspectors also observed that the areas where licensed material was used and stored were appropriately posted with "CAUTION-RADIOACTIVE MATERIALS" signs. The radiopharmacy was also posted with emergency/decontamination procedures and an approved "dosage chart."

5.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspectors determined that no violations of NRC requirements were identified.

6 **Exit Meetings**

The inspectors discussed the sequence of events that led to the medical event, the root and contributing causes of the medical event, and the licensee's proposed corrective actions. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature. The final exit meeting was subsequently conducted via telephone on July 7, 2011, and included a discussion of the apparent violations and the licensee's corrective actions.

Partial List of Persons Contacted

Licensee

*Kay Beauregard, R.N., Administrative Director
Michelle Beauvais, R.Ph., Authorized Nuclear Pharmacist
Donald Brabbins, M.D., Radiation Oncologist
*#Janice Campbell, Ph.D., Assistant RSO, Medical Physicist
*+Cheryl Culver-Schultz, M.S., Radiation Safety Officer
* Scott Emerson, M.S. Medical Physicist
*# Darlene Fink-Bennett, M.D., Chair, Radiation Safety Committee
Matthew Kirsch, M.D., Director, Interventional Radiology
* Conrad Nagle, M.D., Corporate Medical Director
* Shannon Robertson, Radiation Safety Coordinator
* Michael Savin, M.D., Interventional Radiologist
Evelyn Sebastian, M.S., Medical Physicist
Steve Snyder, Pharmacy Technician

Several Nuclear Medicine Technologists were also contacted.

Sirtex Medical, Inc.

Terry Hendricks, Service Rep
Linda Teigland, Director of Operations
Heather Winslade, Global Head of Regulatory Affairs and Quality Assurance

*Individuals who participated in the onsite preliminary exit meeting on May 5, 2011.

*#Denotes individuals who participated in the final exit meeting conducted via telephone on July 7, 2011.