Deaconess Hospital

August 30, 2012

VIA Facsimle August 30, 2012
VIA Federal Express August 30, 2012

Mr. Robert Hayes
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Subject: 15-Day Written Report for Medical Event Discovered on August 15, 2012;
NRC License No. 13-00142-02, NRC Event Number: 48195

Dear Mr. Hayes,

In accordance with 10 CFR 35.3045, I am enclosing our 15-day report relative to the medical event discovered on August 15, 2012.

If you have any questions regarding this report, or your review of this event, you may contact me at (812) 858-0080.

Sincerely,

John Sutkowski, M.D.
Radiation Safety Officer
Deaconess Hospital

600 Mary Street Evansville, Indiana 47747 812/450-5000 www.deaconess.com

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NRC Medical Event – 15 Day Report

i. Licensee Name:

Deaconess Hospital
c/o Midwest Radiologic Imaging
4087 Gateway Boulevard
Newburgh, IN 47630

ii. NRC License Number: 13-00142-02

iii. Prescribing Physician: Jon Frazier, M.D.

iv. Brief description of the event:

Between March 5 and 9, 2012 patient received MammoSite ® treatments to the right breast, twice daily. A total dose of 34 Gy to be delivered in 10 fractions was prescribed. The patient arrived for a second follow-up appointment on June 11, 2012 where it was noted the catheter insertion site was still not healed. The patient was referred to her surgeon for antibiotics or possible surgical intervention. The patient went to a plastic surgeon and underwent excisional debridement on July 24, 2012. The surgical pathology report was received on August 10, 2012 and showed a final diagnosis of Fat Necrosis with Granulation Tissue Radiation Effect. The prescribing physician reviewed the pathology report on August 12, 2012 and requested a complete internal review of her treatment record the following day. The review was immediately initiated with findings reported to him on August 15, 2012. The result of the review demonstrated an unintended dose to the right breast was introduced by the incorrect digitization of the treatment device. This led to a 42 mm offset of all dwell positions, for all treatments.

v. Why the event occurred:

The event occurred because there was unfamiliarity and/or inadequate training with Nucletron Oncentra Masterplan treatment planning system when planning a procedure utilizing a MammoSite ® device. A contributing factor was an ineffective treatment plan second check.

The Oncentra planning system allows the user to draw in the delivery catheter with a setting of "Tip End" or "Catheter End." This is analogous to specifying if the reference origin for the dwell time for the radiation delivery is the tip (distal point) or end (proximal point) of the catheter. The plan was calculated using a "Catheter End" as a reference and produced a dose distribution that satisfactorily covered the Planning Target Volume (PTV). The patient was treated with a reference of "Tip End" resulting in a displacement of the dose distribution by almost 4 cm.

The qualified medical physicist received formal training for the Oncentra planning system in April 2010; however he had not used this system for planning until January 2012.

vi. The effect, if any, on the individual(s) who received the administration:

The effects were confined to the breast tissue itself as well as surrounding skin. She experienced toxicity of the skin in the region of the administration, with a central area 1cm in size of ulceration which was draining serous fluid and a surrounding 4 cm area of discoloration and dry desquamation. In addition, she developed necrotic breast tissue over a 4 cm region deep to the affected skin. This area was non-tender but firm. No other short term effects were noted. After conservative management failed to heal this area, she had full excision by a plastic surgeon of the necrotic tissue and skin, with full closure of the wound, with good cosmetic

result. The surgical wound appears to be healing well at this point. Both by report of the plastic surgeon, and evaluation of the pathology report, the entire skin and breast tissue area affected by the administration was excised. Only normal healthy tissue appears to remain.

The possibility of long term effects are low, but nonetheless additional skin ulceration and breast tissue necrosis could occur. This may require additional surgery, or possible mastectomy, but this is unlikely. In addition, slow and poor healing of her most recent surgery could occur resulting in pain and discomfort, as well as poor cosmetic result which may require additional surgery or mastectomy. This again is unlikely, especially as she is healing well to date. In addition, scar or seroma formation could occur in the breast, or breast infection could develop, leaving overall a poor cosmetic outcome.

There is a low risk of breast cancer recurrence in this patient. The patient has an early stage breast cancer with a low risk of recurrence. The patient had a large excision of the breast, including the area that would have been irradiated. There was no tumor in the surgical specimen. The patient is on Tamoxifen to decrease her risk of recurrence. She could have a completion mastectomy now or if she had a recurrence in the future. She will routinely have follow up visits and mammograms to evaluate her for recurrence.

vii. <u>What actions, if any, have been taken or are planned to prevent recurrence</u>:

1. The RSO and referring physician were notified of the probable medical event on August 15, 2012 at approximately 3:30 pm. After review, the RSO issued an order temporarily suspending the HDR Program until an external investigation could be completed.

2. Reportable medical event was reported to NRC on August 16, 2012, at 9:55 AM CST. The NRC Event Number is 48195.

3. A qualified consultant was retained to investigate this event. The investigation determined the root cause leading to the medical event and provided recommendations for the corrective action and resumption of the HDR program.

4. HDR treatment plans will be independently reviewed prior to delivery by a qualified third party for the first five plans provided by each physician or physicist. For any physician or physicist with more than one year since last planning or treatment was performed, the first two plans will be independently reviewed. These actions are in addition to training requirements listed below in item 6. c.

5. An additional independent check that can verify the physical orientation of any channel (catheter) used in an HDR procedure is now required. This check would consist of the treatment planner identifying the deep (distal to treatment unit) dwell position and labeling this point with name and coordinates. The same process would then be completed for the superficial (proximal to the treatment unit) dwell position. This will be completed for each channel (catheter) used in procedure.

   These deep and superficial points will be identified and visualized on the master treatment plan printout and have their respective x, y, z coordinates compared to the deep and superficial dwell positions. The process would be completed for all channels (catheters) in use.

   This will be documented in a customized independent check and the physician will be able to readily verify the treatment plan orientation. This process will be included in our quality control procedures to address the geographic component for radiation therapy planning errors.

6. Implement appropriate training and CME programs for all staff participating in HDR procedures.
   a) At least one Physician and one Physicist will complete the Oncentra Brachytherapy Training Course no later than October 31, 2012. The Oncentra Brachytherapy Training is a four-day course taught by Certified Clinical Applications Specialists.

      Upon successful completion, these individuals will be the Authorized User and Qualified Medical Physicist responsible for HDR treatment upon resumption of the HDR program.
   b) Before a Physician or Physicist can provide HDR planning or treatments at the center, they will be required to provide documentation of training completed within the last year either by the appropriate Qualified Physician or Physicist or by completion of the Manufacturer's training course.
   c) Physician or Physicist who has not performed any HDR planning or treatments in the most recent 12 months will be required to complete a training course prior to planning or treating the patient.
   d) The Physicians, Physicist, Dosimetrist, Therapists, and Nurse will complete training provided by Certified Applications Specialists for all aspects of the HDR program including the use of MammoSite ® and other applicators in use at the center, certain features of Oncentra treatment planning, treatment plans interpretation and treatment delivery.
   e) Implementing Continuing Medical Education (CME) program consisting of:
      - Refresher courses annually for those receiving initial training by an on-site Clinical Trainer. *This may consist of treatment planning, treatment delivery, emergency response and /or physics calibrations depending on the individual's role in the HDR program.*
      - Presentations and visits by Qualified HDR Specialists at least semi-annually to reinforce education. These Qualified HDR Specialists will also be responsible for training of any staff new to the HDR program prior to their participation in the program.
      - Attendance of specialized HDR meetings will be implemented to ensure that all Center HDR staff maintain their qualifications and credentials in using this special procedure. *These may be off-site or via webinar.*

viii. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not why not:

The patient was informed of the medical event on August 16, 2012 at approximately 9:30 AM CST via telephone because she was out-of-state. The telephone note is documented in the patient's chart. A copy of this 15 day written report is also being sent to the patient via Federal Express.

Respectfully submitted: John Sutkowski, M.D.
Radiation Safety Officer
Deaconess Hospital c/o Midwest Radiologic Imaging

Dated: August 30, 2012

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