Beaumont

Beaumont Hospital, Farmington Hills
28050 Grand River Ave.
Farmington Hills, MI 48336

November 10, 2016

VIA FEDERAL EXPRESS OVERNIGHT DELIVERY

John B. Giessner, Director
Division of Nuclear Materials Safety
Nuclear Regulatory Commission
Region III
2443 Warrenville Rd. Suite 210
Lisle, IL 60532-4352

Re: Response to the Apparent Violation in Inspection Report No. 03002077/2014001(DNMS); EA-16-066

Dear Mr. Giessner:

In response to the letter from NRC dated October 12, 2016, the following shall serve as Botsford General Hospital's ("Botsford") written response. We appreciate the opportunity to provide the NRC with additional information and clarification of certain information contained in the NRC Executive Summary and Report Details.

Reason for disputing the Apparent Violation:
At the time of the incident, the then current HDR GYN Policy (see Attachment A -- Botsford's Cancer Center Policy No: BCC 060036, effective November 2012) in item #26 explicitly required two (2) person verification of the HDR treatment plan against the HDR treatment unit pre-treatment report. The treatment plan error would have been identified prior to administration had the Physicist A, who was performing the procedure on July 10, 2014, followed this step as expected. We believe that the requirement to carefully check the HDR pre-treatment report against the printed HDR plan report, if properly followed, is sufficient to ensure that the proper plans have been loaded for execution. We believe that the cause of the medical event was the failure of the Physicist A to follow the policy.

At the time of administration, Botsford's Cancer Center was following the appropriate workflow instituted and configured by Elekta, the HDR vendor. According to that workflow, all treatment plans were exported using Elekta pre-configured filters in to the location designated by Elekta to be manually imported into the treatment unit. Elekta still recommends this workflow.

Additional corrective steps described below were designed and implemented by Botsford's Cancer Center to enhance and supplement the workflow offered by Elekta, which we believe further strengthens the program. These corrective steps are more advanced and not obvious to an average licensee. Botsford's Cancer Center brought these process/system improvement ideas to Elekta's attention in order to assist Elekta with improving the safety of its clinical workflow that can have impact on a national level. This included the recommendation to completely transfer the plan name from the treatment planning system to the treatment unit, which at this time has to be manually corrected by the user at the time of import. See the corrective action for the uniform naming convention described below.

Corrective actions implemented after the incident:

1. Data transfer protocol instituted by Elekta was supplemented to address the retention of the old treatment plan files in the designated network location.
    a. The plan is exported from the planning system into the designated network location and imported into the HDR treatment console system (TCS). Since Elekta does not offer a mechanism to automatically purge this file after the import into the TCS, the next step was introduced.
    b. The second check software RadCalc (Lifeline Software Inc.) was implemented to verify the treatment plan as an independent calculation. The plan file is first imported into the TCS. Due to the step in a. above, it remains there and is secondly imported into RadCalc for independent calculation verification. Once imported from the designated network location into RadCalc, the file is automatically deleted from that location. This is done within minutes in this specific sequential manner so that there is full assurance that the plan reviewed by the physician is exported to the TCS where it is retrieved for import and then imported into Radcalc (i.e., removing the file for further import into the TCS). This also assures that the old treatment plans are no longer residing in the network location. When a patient returns for a fractionated treatment where a new plan is necessary due to a different needle loading pattern and/or treatment volume, a new plan is done and the above steps are repeated. This process reduces the risk of incorrectly loading the wrong plan as only one available plan can be imported into the TCS at a given time. Additionally, we get a second verification of the treatment plan for correctness of calculation.

2. The HDR GYN Policy was modified to further expand on the previous requirement to check the treatment plan against the pre-treatment report to determine that the characteristics of the implant are unique to the plan being treated.
    a. Checking that the product of the planned source activity (mCi) with the planned time (s) from the treatment plan matches the product of the source activity at the time of the implant with the re-calculated time from the HDR unit brachytherapy pre-treatment report.
    b. Checking the number of catheters and visually verifying dwell positions in each catheter displayed on the treatment unit display or listed in the brachytherapy pre-treatment report against the treatment plan report.

c. Authorized User and Authorized Physicist review/approve and co-sign electronically in Mosiaq record and verify system 1) the treatment plan exported by the dosimetrist; 2) the brachytherapy pre-treatment report; and 3) the Radcalc report.

3. Upon plan import into the Treatment Unit the plan name is manually changed from the default "Brachy plan" to match the plan name from the treatment plan report. This assures the uniformity of the plan naming in the two (2) systems.

Future corrective actions:
After carefully reviewing the current program, we only have one outstanding item which is not within control. Currently, we are waiting for Elekta to modify its software in a manner that would allow seamless transfer of the treatment plans from the Oncentra (Elekta treatment planning system) to their Nucletron HDR afterloader. At the current stage, some information that is available in the Oncentra is not imported into Nucletron afterloader and requires manual modification by the end user. We have implemented sufficient checks on the policy level to address this; however, we look forward to a permanent solution (i.e., hard-wired solution) from Elekta in the future.

Date the full compliance was achieved:
Full compliance was achieved immediately after the incident was discovered by reviewing the existing policy with the employees. Additional advanced safeguards were introduced before the initial inspection by Mr. Geoffrey Warren and Mr. Ryan Craffey on August 29, 2014. RadCalc for HDR use was officially commissioned on August 13, 2015 and has been used in Botsford's Cancer Center since that time.

Should you have any questions or require additional information, please do not hesitate to contact me.

Sincerely,

David J. Gaffney, MBA, FACHE
Administrator, Imaging & Lab Service

Enclosure

cc: Timothy Allen McKnight, D.O.
Radiation Safety Officer
Bethany Parish, BSBT(T)
Director, Cancer Center
State of Michigan

Attachment A

BOTSFORD
HOSPITAL

CANCER CENTER

Title: **HDR GYN POLICY** Policy No: **BCC 090036**
Effective Date: November 2012
Reviewed Date: November 2012
Written By: Nicholle Mehr, Candace Mozak & Karen Milosevski
(Director, Oncology Nursing)
Approved By: *Nicholle Mehr*
(*Director*, Cancer Center)

PURPOSE

To establish procedures and staff responsibilities within the Botsford Cancer Center with the purpose of insuring patient and personal safety; and that all equipment is in safe working condition prior to and at the end of the procedure.

To establish a process for Gynecologic HDR Procedures at the Botsford Cancer Center.

POLICY

These policies and procedures are written guidelines for the setup, treatment, and patient care before, during and after the GYN HDR Implant procedure at the Botsford Cancer.

1. Daily HDR QA to be performed according to HDR QA Policy 090042;
2. All HDR personnel to wear a radiation monitoring badge per BCC Policy 090022;
3. Patient has been prequalified for implant procedure with following methods:
   A. Diagnostic pretests
   B. Radiation Oncology consult
   C. Volume study to determine anatomic eligibility
4. HDR coordinator to board patient and notify CEMS of implant date
5. Surgical Evaluation Department is to contact the patient prior to implant for pre-screening. Appropriate pre-tests are ordered according to anesthesia protocol;
6. Patient is contacted by nursing at least two days prior to procedure to review prep instructions – to be documented in Navigator.
7. The patient arrives 60 minutes prior to scheduled procedure time;
8. The patient undresses completely and changes into a gown. He is given a personal belongings bag to hold clothes and personal items;
9. Fleets enemas are done in bathroom prior to procedure. Nursing assistance as needed, until clear;

10. Confirm that the patient has been NPO since Midnight and completed bowel prep;
11. The HDR suite is set up for the procedure;
    A. Mayo stands and the O.R. tables are set up with all necessary disposable and reusable equipment;
    B. The ultrasound system and planning system are prepared;
    C. The procedure table is prepared for the patient with appropriate linens.
12. Nursing is to begin an IV, per policy, if unsuccessful CRNA to insert.
13. Confirm consent has been signed and that the anesthesia team has met with the patient.
14. Confirm H&P has been completed by Radiation Oncologist or Urologist, and signed off on within 24 hours of the procedure;
15. The patient is led into the HDR suite;
16. Time out: Urologist or Radiation Oncologist must verify patient identification prior to initiation of invasive procedures;
10. Anesthesia is administered by anesthesiologist and CRNA;
11. The patient is prepared for the implant procedure;
    A. A Foley catheter is inserted by nursing in a sterile manner. Bladder is filled with 150cc sterile water. Balloon is filled with 7cc sterile water or air according to physician preference;
    B. Sequential Ted hose are placed on the patient's legs;
    C. Patient is positioned for implant with legs placed in stirrups and raised into lithotomy position;
    D. The perineum is shaved for the implant, disinfected, and draped with sterile draping.
12. The implant equipment is attached to the table and the disinfected stepper unit and probe are attached to the support equipment and draped with sterile draping by a physics team member;
13. The ultrasound cart and planning system are placed in position;
14. An ultrasound acquisition is obtained for planning purposes;
15. The attending physician places the sterile implant catheters into the perineum utilizing a sterilized template and tool set; utilizing ultrasound guidance.
16. The needles are advanced to the base of the prostate, again under ultrasound guidance.
17. When the needles are all in place, the Foley is drained and pulled by the nurse and a cystoscopy is performed by a Urologist to ensure the needles are in the correct position; tenting of the bladder by the needles but with no needles in the urethra or through the bladder
18. A Foley is replaced into the bladder and the bladder is instilled with 45cc Cystografin and 105cc sterile water; balloon is inflated with a solution of 3cc Renografin and 4cc sterile water; nursing injects a mixture of sterile water, Lidocaine, and air into the Foley catheter for the purpose of visualizing the urethra under ultrasound;
19. A new ultrasound acquisition is obtained for planning purposes;
20. The treatment is planned intra-operatively, reviewed, and approved by the attending physician;

21. A treatment plan, DVHs, and isodoses are generated;
22. A C-arm film of the implant is obtained and approved by the attending for documentation;
23. The HDR Afterloader is withdrawn from storage cabinet and moved to treatment position at foot of treatment table only by physicist or designated physics team member [1]

The wheels of the afterloader are locked once position is established by designated physics team member;

24. The head is raised to the appropriate height by designated physics team member;
25. The transfer tubes are connected to the implant by an HDR staff team member and double checked by a member of the physics or treatment planning team;
26. The plan and pretreatment report is carefully checked and signed by a physicist and a physician;
27. A verbal announcement will be made by the physicist (or designated radiation therapy professional delivering the treatment) prior to leaving the room that all personnel should exit the treatment room;
28. The room is cleared of all personnel. The physicist (or designated radiation therapy professional delivering the treatment) will physically check the room to ensure that all personnel have vacated the treatment room;
29. The door will be closed by the physicist (or designated radiation therapy professional delivering the treatment) only;
30. The anesthesiologist and radiation oncologist will be directly notified that the treatment is about to begin;
31. Anesthesia will monitor the patient from the control area and a Radiation Oncologist and physicist will be physically present at the HDR treatment area;
32. All employees, not specified in #32, to remain silent and vacate the inner HDR control area;
33. Time out: Physicist or physics staff member to verbally:
    a. announce patient's name to be treated;
    b. verify that plan and patient entered in TCS match;
    c. ask anesthesia if the patient is ready;
    d. verify that all personnel are accounted for.
34. The physicist or physics team member will verbally announce over the speaker that the treatment is starting;
35. The door is closed to the treatment room. In the event of a door malfunction there are two methods to manually open the door:
    a. The magnetic lock disable switch located in the communications room. This will allow for disengagement of the magnetic lock.
    b. The circuit breaker in the maintenance room next to the dock. This will allow for power to the door to be disabled. Box LA, #4.
36. When treatment is complete, the patient/room are surveyed for any radiation; the room is cleared for physics staff to enter;
37. Anesthesia and cancer center personnel enter to begin preparing the patient for template removal and transport to hospital;
    a. The transfer tubes are disconnected from the implant.

[1] Physics team member defined as a physicist, dosimetrist or brachytherapy treatment planning specialist.

b. The afterloader is moved back to the storage cabinet by physics or a designated individual only (dosimetrist or treatment planning specialist) as follows:
    i. The head of the afterloader is lowered as far as allowed;
    ii. The afterloader is unlocked and the designated employee carefully drives the unit into the storage cabinet;
    iii. The wheels of the afterloader are locked;
    iv. The cabinet is closed and locked.
c. The patient drapes are removed;
d. The probe and stepper unit are removed from the table and set aside for cleaning;
e. The table mount and stabilizer are removed and put back on the stand. This is rolled out of the way for later cleaning;
f. Nursing sets up for the removal of the implant per physician preference
g. The attending removes the implant and applies pressure to the area until bleeding has stopped;
h. The perineum is cleaned with water and a dry dressing with Bacitracin ointment is applied;
i. The Foley is unclamped and the bladder is drained;
j. A stretcher is brought into the room and positioned along side the treatment table;
k. The table extension is put back on the end of the table;
l. The patient is taken out of stirrups and stirrups are removed.

38. Patient is transferred to a stretcher;
39. Nursing to ensure report sent to PACU prior to patient departure, and chart prepared and travels with patient
40. Table extension is removed and stretcher is rolled out of room;
41. When the room has been cleared of patient, anesthesia, and ancillary staff;
    a. Room is cleaned. Dirty linen and garbage are bagged and removed;
    b. Ultrasound probe, stepper unit, table arms, and stabilizer bar are cleaned in the appropriate manner;
    c. Cystoscope is prepared for sterilization;
    d. Reusable implant instruments (i.e. template, obturators, basic set, forceps) are prepared for sterilization;
    e. Ultrasound system, planning system (we keep this power per Nucletron), cystoscopy equipment, and C-arm are powered down.