CARILION
Health System

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

February 2nd, 2008

Reply to Notice of Violation:

Dear Sirs:

This letter is in response to the "Notice of Violation" related to Docket # 03034470, Radioactive Materials License # 45-25395-01, received January 17th, 2008, by Carilion Clinic, Roanoke, VA.

- **Reason for Violation:**
  The event in question has been previously documented as a Report and Notification of a Medical Event in correspondence to the NRC Operations Center on October 9th, 2007 via email to HOO1@nrc.gov., and to the Regional Administrator, USNRC, Region I, 475 Allendale Road, King of Prussia, Pa. 19406, on October 16th, 2007 describing the circumstances surrounding this event. Event # 43685 was assigned. This violation resulted from the action of a Radiation Therapy Technologist taking an inappropriate initiative to connect a MammoSite catheter to a High Dose Rate (HDR) Ir-192 treatment delivery system without appropriate training or supervision.

- **Corrective Actions:**
  In order to prevent such an incident from recurring, action was taken and the attached policy implemented. All involved radiation therapy technologists at that time were in-serviced by a representative of MammoSite and an on-site Authorized Medical Physicist (AMP). This in-service training provided a detail review of the proper method of catheter connection to the HDR treatment delivery system and discussed the consequences of improper catheter connection. This was completed by September 10th, 2006. Subsequently, prior to new personnel being assigned to this work area, it is required that this training be completed and documented on their personal Competency Document which is kept in their personnel file. Annual refresher training has become part of each involved radiation therapy technologist's in-service educational requirements.

- **Corrective steps to avoid further violations:**
  Additionally, the sequence of events that must take place in the proper use and setup of the MammoSite catheter was changed. Prior to acquisition of a CT scan of the implant treatment site the catheter transfer tube is connected only to the MammoSite catheter. This scan is conducted for verification of proper catheter inflation and treatment site symmetry by an Authorized User (AU). Final catheter connection is made to the HDR treatment delivery system by either an AU or AMP only after the AU reviews the scanned images and approves proceeding with the implant treatment.

- **Date of which full compliance will be achieved:** September 2006

Please contact us at your convenience with any further questions or concerns.

Respectfully submitted,

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Carilion Clinic

Mr. Jeffrey Messinger, M.E.
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IE07

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RGN I

Section: TECHNICAL POLICIES AND PROCEDURES				
Effective Date:	Date Revised:	Revision #:	Page:	Of:
4-19-2005	09-19-06, 01/07, 01/08	2	1	5

MammoSite Procedure

Remote High Dose Rate temporary brachytherapy implantation treatments allow for precise delivery of radiation dose to cancerous tumors. The MammoSite is a small, soft balloon attached to a thin catheter (tube) that fits inside the lumpectomy cavity. An iridium-192 (Ir-192) radioactive source is used for the MammoSite treatment. The HDR unit utilizes a computerized program, which automatically transfers the source into the patient via catheters connected to source applicators for treatment to a predetermined dwell time. HDR treatment planning allows for the ability to customize treatment doses to maximize tumor dose and minimize dose to the surrounding normal tissue, as much as possible. This type of brachytherapy treatment is performed on an outpatient basis and employs relatively short treatment times and fractionated doses. Typical treatment regimen consists of two treatment dose fractions per day with at least a six hour interval between treatments over five days for a total of ten fractionated treatments.

Quality Control is performed on the HDR unit and treatment room safety systems each day of use prior to the first patient being treated that day. This is the responsibility of the department of Physics, CRMH. Results of these operational performance safety checks are documented. Any problems identified that would affect patient or staff safety are corrected prior to releasing the HDR device for treatment usage.

The door to the CT/Simulation HDR room shall be closed and secure when either the room or console treatment area is left unattended.

Note that the number of dwell positions used for treatment will determine coding of these procedures.

Definitions:

AU – Authorized User
AMP – Authorized Medical Physicist
CC – Carilion Clinic
CRMH – Carilion Roanoke Memorial Hospital
CT – Computerized Tomography
HDR – High Dose Rate
RAM – Radioactive Materials
RT – Radiation Therapist
USNRC – United States Nuclear Regulatory Commission

Supplies needed:

Disposable gloves

HDR source applicators and transfer catheters

Patient preparation:

Prior to the patient entering the radiation department, a surgeon has placed a balloon catheter in the patient's affected breast, which is filled with saline to fill the void cavity left in the breast after surgery.

The patient should remove clothing from the waist up and be provided with a hospital gown. Patient lies supine on the CT/Simulator couch on a sheet, pillow under head, eggcrate under hips, angle sponge under knees, and arms by sides.

Procedure: Treatment Planning

1. Medical Physicist, Radiation Oncologist or Radiation Therapist unscrews a cap at the end of the balloon catheter extending from the patient's breast and removes a wire from the catheter.

2. A CT scout image is obtained to ascertain that the balloon catheter is inflated properly. Note that the unit selection switch outside the room door must be in the "CT" position. Center and align the CT Simulator's laser crosshairs to the breast nipple. "Zero" the table position and position the table through the CT gantry to "550" and "Zero". The Authorized User will review this image and make any adjustments that are deemed necessary and appropriate. If acceptable, then additional CT images are obtained around the catheter's balloon position using appropriate scanning technique parameters, e.g. 3mm. slices.

3. The CT images are provided to dosimetry for treatment planning.

Procedure: Treatment Delivery Preparation

1. After a treatment plan has been approved and signed by a Radiation Oncologist listed as an AU for HDR brachytherapy use on CC's USNRC RAM License, the treatment planning parameters and patient information are entered into the HDR unit's control console program by the AMP or AU.

2. The written directive will be defined by the Authorized User and written in the prescription section of the patient Radiotherapy chart, shall include:

    - Radionuclide, e.g. Ir-192
    - Treatment site
    - Total radiotherapy treatment dose (Gy)
    - Number of Fractions
    - Radiation dose/fraction. (Gy/fx.)
    - Number of fractions/day
    - Signature of authorized User

3. Source transfer catheter is attached to the "Red" Mammosite catheter portal. This may be performed by the AU, AMP or RT.

4. A limited range CT dataset will be obtained. Assessment for balloon integrity will be made by the AU, and signed-off on a per treatment basis.

5. After balloon integrity is approved, the transfer catheter will be connected to the HDR delivery system by either the AU or AMP.

6. Prior to commencing with treatment, the AU or AMP will perform a baseline survey of the patient with an appropriate calibrated survey meter to determine initial background radiation levels.

7. Upon the last person exiting the room, "Last Man Out" procedure will be followed, with assurance that no personnel remain in the treatment room. The door is closed to activate the door interlock system and the unit selection switch outside the room is placed in the "HDR" position.

1. The patient is alone in the room during the treatment, but is viewed continuously by a radiation oncology staff member located remotely at the control console using both video and audio communications. Also note that an AU (Radiation Oncologist) and AMP will be physically present in this control area during each treatment.

2. The treatment is automatically controlled and program-directed by the HDR unit console control for treatment dwell time and source position. Typical treatment times are on the order of three to ten minutes with the entire process taking about thirty to sixty minutes depending on the complexity of the treatment plan and radioactivity of the source.

3. Upon completion of the predetermined treatment dwell time, the source is automatically retracted back into its radiation protective safe location within the HDR device. Prior to re-entering the room, the AMP or AU will observe and assure that the independent radiation monitor visible upon entry is not activated. If either the HDR unit's control panel or the in-room radiation area monitor indicates that the source hasn't been automatically retracted, emergency procedures will be implemented by the AMP or AU. Written emergency procedures are located by the HDR unit's control panel.

4. The AMP or AU enters the treatment room with an appropriate calibrated survey meter and surveys the patient for radioactivity, as a secondary check, to ensure that the source has been removed from the patient and returned to its "safe" location within the HDR device.

5. The AU, AMP or RT may detach the HDR transfer catheter from the balloon catheter and reinsert the spacer wire into the catheter and secure the end cap.

6. The Radiation Oncology nurse will attend to the implantation site by applying bacitracin around the exposed catheter and dressing the site with drainage gauze and tape.

7. The patient is removed from the CT/Simulation room. The patient will be reminded to contact the Radiation Oncology department if they feel ill, strange, or exhibit any side effects after treatment.

Patient Education:

The physician's office placing the MammoSite will provide patient education prior to the patient coming to our department. The patient will be given a post operative instruction pamphlet and taught how to care for the MammoSite area. She will be given two prescriptions and provided a pack of sterile gauze and tape.

Upon completion of radiation, the patient will be taught how to care for the catheter site after the MammoSite is removed. She will also be given teaching materials with instructions explaining symptoms to watch for and who to call if the need should arise.