Washington
Hospital Center

MedStar Health

To:

January 7, 2010

Ms. Penny Lanzisera
Senior Health Physicist
US NRC, Region 1
478 Allendale Road
King of Prussia, PA 19406

Sub: Written Directive for the Novoste IVBT Procedure

Dear Ms. Lanzisera:

In response to your question in Item 1, we have taken the following immediate corrective actions.

1. To be in full compliance with the10 CFR 35 (40)(a) requirement, our Radiation Oncologists have agreed to sign the Written Directive before they are gowned and gloved for the sterile procedure to make the device ready and before the treatment begins. Please note that in complying with this regulation there may be delays in performing the IVBT procedure which may not be in the best interest of the patient.

2. We have redesigned our Brachytherapy Written Directive form (Attachment -A) to include a separate signature line for the Radiation Oncologist. This form is more concise for recording the treatment with the Novoste source. Implementation is immediate upon approval by the Radiation Safety Committee.

If you need any additional information, please contact Dr. Rosanna Chan at 202-877-3950 or Dr. Shashadhar Mohapatra at 202-877-2906.

Sincerely,
Catherine Monge
Catherine Monge

Nuclear Regulatory Commission Response

Item 1. With regard to the issue of the authorized user signing the written directive at the completion of Novoste Sr-90 IVB treatments from inception of the program until December 2009, please document WHC's basis for not signing the written directive prior to the initiation of the treatment. Additionally, please include a time sequence of events for the conduct of these treatments (i.e. when does the patient initially come in to see the cardiologist, length of time between the cardiologist's visit and the cardiac catheterization procedure, how the IVB treatment is decided, list of personnel contacted and timing of this contact, list of who responds to the procedure room and timing of response, etc.). If any corrective actions or program changes have been implemented following the inspection, please document these actions along with the date of implementation for each action. Finally, please prepare a letter signed by senior-level management to document the information requested above.

Response:

The rationale behind the fact that authorized user signature was done immediately after Novoste IVB treatment instead of before is that it is a timely procedure. The Radiation Oncologist is put into a sterile environment as soon as he gets to the lab before evaluating the final IVUS result for dose prescription. 10 CFR35.(40) (1) states that " ***If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive."*** Based on our interpretation, we opt to do an oral directive which is immediately written onto the prescription form by the Radiation Safety staff and signed off by the Radiation Oncologist at the completion of treatment. This way the Radiation Oncologist does not have to break sterility and prolong the time the delivery catheter has to stay inside the patient. Since both the prescription dose and dwell time are verbally confirmed and verified by all parties involved before treatment starts, there is very minimal chance of misadministration.

At Washington Hospital Center (WHC), Intravascular Brachytherapy Treatment (IVBT) is always performed under sterile conditions. Patient consultation done by the Interventional Cardiologist prior to starting the angiogram may include a **possible** IVBT treatment based on the history of the patient. IVBT can only be confirmed after patient is under anesthesia and angioplasty has been completed by the Cardiologist. Once confirmed the Radiation team is called to the Cardiology lab. The team includes a Radiation Oncologist, a Medical Physicist and a Radiation Safety staff. Normally it takes 15 -20 minutes for the team to get all the equipment and get to the lab. The procedure is usually an urgent one requiring immediate preparation of the equipment and delivery of treatment in a timely manner to minimize the time that the patient is under anesthesia and to reduce the amount of time that the radiation treatment catheter is in place. The latter can result in cardiac ischemia and potentially severe chest pain for the patient. Due to this being a sterile procedure, Radiation Oncologist is gowned and gloved immediately

upon arrival to prepare the source for treatment. Majority of the time, the Cardiologist is on his or her last angioplasty. A final ultrasound (IVUS) is performed prior to treatment to determine treatment depth and length for radiation prescription. The Radiation Oncologist will verbally communicate the prescription to the medical physicist for calculating the treatment time. After calculation, the dose and the treatment time are reported by the Physicist to the Radiation Oncologist and Cardiologist and verified by the Radiation Oncologist. The Radiation Safety staff documents all the information into the hospital approved Brachytherapy treatment record form (Written Directive) prior to delivery which includes all information pertinent to the 10 CRF 40 requirements. In addition, the medical transcriber in the lab also documents that (dose, dwell time, source etc.) into the patient's electronic chart immediately. Once the radioactive source is in position, as verified by cine, medical physicist starts time. Normal treatment time is 3 to 4 minutes per step depending on the prescribed dose and activity of source at the time of treatment. A minute by minute count down is done by the physicist throughout treatment. Upon completion of treatment the source is removed, the written directive is immediately signed by the Radiation Oncologist and filed in the patient's medical record.

Procedural Change

To be in full compliance with 10 CFR 35 (40)(a), we redesigned our Brachytherapy form (Attachment- A) to include a separate signature line for the Radiation Oncologist. The Radiation Oncologist is to sign the written directive before gowning up for the sterile procedure. In addition, the form is streamlined to be more concise for recording treatment with the Novoste source. Implementation is immediate upon approval by the Radiation Safety Committee.

Attachment - A

MRN | Patient Sequence Number: | Date of Procedure: dd / mmm / yy

Novoste IVBT Prescription

Patient Name: _____

Site (Artery) _____ Vessel Length: _____cm Diameter: _____cm

Treatment Device: Novoste _____seeds Total Activity: _____ mCi (Sr/Y-90)

Prescribed Dose: _____ Gy to 2mm point from source center No. of steps: _____

Dwell Time: _____' _____" per step

Radiation Oncologist Signature : _____ Date:_____

Treatment Record

Patient ID Method : ☐ Photo ☐ Name ☐ ID Bracelet Cath Lab # : _____

Treatment Device : Novoste _____seeds Total Activity: _____ mCi (Sr/Y-90)

S/N : _____ Calculated Treatment Time : _____' _____" for ____Gy

Artery: _____ No. of Steps: _____

Step:	1	2	3	*Position notation:*
Position:				*P = proximal*
Start Time:				*M = middle*
End Time:				*D = Distal*
Dwell Time:				*nA if only one step*
Dose delivered:				

Patient Survey in mR/hr with Ludlum3, S/N _____ Calibration Date: _____

Before Tx.				@ patient surface
During Tx.				@ patient surface
During Tx.				@ 1 m
After Tx.				@ patient surface

Source Removed: ☐ Y ☐ N Room Survey : ☐ Y ☐ N

Comment: _____

_____
Medical Physicist Signature

_____
Radiation Oncologist Signature

Place Patient ID Label here

Corrective Actions Taken:

1. The Oncologist now signs the Written Directive before the treatment begins.
2. A new form for the written directive has been developed that includes a separate signature line for the Oncologist before the treatment.