

Washington Hospital Center

MedStar Health

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January 6, 2010

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

Sub: Written Directive for Novoste Procedure at the Washington Hospital Center

Dear Ms. Lanzisera:

In reference to your email to Dr. Mohapatra on January 6th, we are providing you with the following information after consultation with our Radiation Oncologists, Medical Physicists and Radiation Safety Officer.

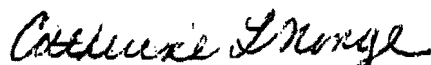
At Washington Hospital Center (WHC), Intravascular Brachytherapy treatment (IVBT) is always performed under sterile conditions. Patient consultation done by the Interventional Cardiologist prior to starting the angiogram may include a possible IVBT treatment based on the history of the patient. IVBT can only be confirmed after patient is under anesthesia and angioplasty has been performed.

Once confirmed, the Radiation team is called to the cardiology 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, the Radiation Oncologist is gowned and gloved immediately upon arrival to prepare the source for treatment. 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 repeated by the Physicist to the Radiation Oncologist and Cardiologist. The Radiation Safety staff documents all the information into the hospital approved Brachytherapy treatment record form prior to delivery which includes all information pertinent to the 10 CRF 40 requirements. In addition, it is also documented in the patient's electronic chart. The written directive is immediately signed by the Radiation Oncologist upon completion of treatment and filed in the patient's medical record.

Due to the emergent & sterile nature of our procedure we had adopted 10 CFR 35.40 (1)
"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."

If you need any additional information, please contact me at 202-877-2876 or Dr. Mohapatra at 202-877-2906.

Sincerely,



Catherine Monge
Senior Vice President, Operations

cc: Michael Porrazzo, M.D.
Radiation Oncologist/Chairman, Radiation Safety Committee

Rosanna Chan, Ph.D.
Chief Medical Physicist

Shashadhar Mohapatra, Ph.D.
Radiation Safety Officer