

Community Medical Center
License No. 37-11507-01
Mail Control No. 136702
Docket No. 030-03142

MS16
L-2

August 22, 2005

1. Novoste Beta-Cath Intravascular Brachytherapy (IVB), We confirm:
 - Authorized users meet the training and experience requirements in either 10CFR35.690, "Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units" or until October 25, 2005, 10CFR35.940, "Training for use of brachytherapy sources"
 - The authorized user, interventional cardiologist/physician, and authorized medical physicist shall receive vendor training for use of the device.
 - Procedures shall be conducted under the supervision of the authorized user, who shall consult with the interventional cardiologist/physician and authorized medical physicist before initiating treatment. The procedures shall be conducted in the physical presence of the authorized user or the authorized medical physicist.
 - Written directive shall, before treatment, specify treatment site, the radionuclide, and dose.
 - The authorized medical physicist shall perform independent measurement of source output, before the first patient treatment, using a dosimetry system that meets the requirements of 10CFR35.630(a).
 - The licensee shall develop, implement, and maintain written emergency procedures for both stuck and detached sources, including provision of appropriate emergency response equipment and any appropriate surgical procedures.
 - The licensee shall survey the patient and IVB treatment catheter immediately following source retraction or removal to confirm complete retraction of the source(s) as specified in 10CFR35.404.
 - In order to protect the radiation safety of patients and to reduce the risk of a medical event, an introducer sheath shall be used unless such use is contraindicated for an individual patient.
 - In order to protect the radiation safety of patients and to reduce the risk of a medical event, a dual syringe system shall be used.
 - "Source stepping" is permitted, if the licensee establishes appropriate procedures in writing.
 - The licensee shall commit to locked storage of the storage container in a secure location.
 - The device should be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed only by the manufacturer or persons specifically licensed by NRC or an Agreement State to perform such services.

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2. Please add Will Chen as an authorized medical physicist. Reference 37-01374-03.

Thank you.

for



David Sabbar, M.D.
Radiation Safety Officer