St. Mary Medical Center

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November 22, 2004

Ms. Sandra Gabriel, Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

NRC License No. 37-15400 -01
Control No. 135131

Dear Ms. Gabriel:

As you have requested, we will individually confirm each statement in item 4 of your October 25, 2004 letter.

4.a. We confirm that each authorized user, interventional cardiologist/physician, and authorized medical physicist will receive the vendor training for use of the device prior to first clinical use.

4.b. We confirm that procedures will be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and authorized medical physicist prior to initiating treatment. The procedures will be conducted in the physical presence of the authorized user or the authorized medical physicist.

4.c. We confirm that the written directive will, prior to treatment, specify the treatment site, the radionuclide, and dose.

4.d. We confirm that the authorized medical physicist will perform independent measurement of source output, prior to the first patient treatment with each new source train, using a dosimetry system that meets the requirements of 10 CFR 35.630 (a).

4.e. We confirm that we will survey the patient and IVB treatment catheter immediately following source retraction or removal to confirm complete retraction of the source(s) as specified in 10 CFR 35.404.

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4.f. We confirm, in order to protect the radiation safety of patients and to reduce the risk of a medical event, an introducer sheath will be used unless such use is contraindicated for an individual patient.

4.g. We confirm that in order to protect the radiation safety of patients and to reduce the risk of a medical event a dual syringe system will be used.

4.h. We confirm that "source stepping" is permitted, if we establish appropriate procedures in writing. We understand that source stepping procedures are not covered by the manufacturers' instructions.

4.i. We confirm that the device will be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair will be performed only by the manufacturer or persons specifically licensed by NRC or an Agreement State to perform such services.

4.j. We confirm that source separations during treatment will be evaluated as possible medical events.

As always, if you require additional information please contact me at your earliest convenience.

Sincerely,

Edward Maher
Vice President of Finance