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Ms. Penny Lanzisera
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U.S. NRC Region I
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Reference: NRC License #29-01862-02, Virtua-West Jersey Hospitals
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Dear Ms. Lanzisera:

Responding to your question regarding two additional LDR Prostate Brachytherapy implant cases performed by Dr. Nachman at our Marlton Division on 4/10/08 and 10/23/08, we believe neither of these cases based on their post-operative dosimetry estimates to meet the definition of "Medical Event", and have not classified them as such.

We base our conclusions on the activity-based definition of Medical Event. Our Written Directive prescription process designates a specific number of seeds, per seed activity and total activity delivered as the basis for treatment. The prescribed activity is determined by setting a "target dose" in Gy to the Planning Target Volume (PTV) and then calculating the necessary activity and placement of seeds to achieve that target dose. The seed activity can be directly measured and controlled, and we believe the written directive and quality control procedures directly reflect control of the licensed material in assessing the correct type, isotope, activity and number of sources, and identifying the location of placement (target organ = prostate). In both these cases, the correct seeds and activities are documents by independent review, and all seeds were placed within the PTV as confirmed by ultrasound and CT imaging.

Furthermore we feel that characterization of a Medical Event based on estimated absorbed dose to the target organ is not a good indicator of successful treatment. There are several sources of error associated with assessing the absorbed dose, including accurate delineation of the target volume on US and CT and then co-registering the two, inaccuracies of identifying all radioactive sources in the correct orientation on the CT images, the inability of the treatment planning computer to account for alignment differences in sources and their resulting dose profiles (not all the seeds align themselves along the theoretical patient Z-axis), and because of natural changes in patient anatomy, such as due to edema and seed migration, which may occur during the period between implant and post-operative imaging and dosimetry. Thus although we set a "quality indicator" of 90% dose to the prostate ("D90") being +/- 20% of the target dose (145 Gy I-125, 125 Gy Pd-103, etc.) as a means to achieve consistent treatments among all patients, this target is experimentally driven and revised based on current literature, thus not making it a definitive quality control indicator for successful treatment.

Should you need any other information prior to our final written report please do not hesitate to contact me.

Sincerely,

Daniel J. Januseski, MS
Radiation Safety Officer

Cc Dr. Ariyaratnam, Dr. Horowitz, Dr. Nachman