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January 6, 2004

George Pangburn, Director Division of Nuclear Materials Safety Nuclear Regulatory Commission – Region 1 475 Allendale Road King of Prussia, PA 19405-1405

Docket No. 03003013 CAL No. 1-03-003

Dear Mr. Pangburn:

I am writing to you in follow-up to the request of attorney Karl Farrar, legal counsel for the NRC-Region 7, for additional specific information related to our belief as to the cause of any alleged misadministrations that may have occurred between 1993, the inception of the program, and August 2003, when this investigation commenced.

As we know, the recommendation by the American Brachytherapy Society in 2000 for the use of CT for post-implant dosimetry, created a qualitative difference in the medical direction of the previous seed implant program as compared to the current seed implant program, hence, explaining an element in variation in the outcomes of patients treated between 1993 and 1999, and the current program initiated in January 2000, when CT became the standard for checking post-implant seed placement.

An additional finding questioned technique of the radiation oncologist. While all other members of the treatment team (urologist, dosimetrist, and medical physicist) varied over the duration of the previous program, one radiation oncologist remained constant until early January 2002. It appears that the process for locating the target organ was consistently executed in an appropriate manner. It has been noted that the majority of the alleged misadministrations had an inferior placement, which, according to the experts with whom we consulted, could result from technique of needle retraction. These experts have advised us that since January 2002 this problem appears to have been corrected. We feel it is important that we clarify this point regarding seed placement to note that we do not mean to suggest, nor do we, nor do our consultants uphold the notion that placement of seeds outside the intended target, in and of itself, constitutes professional negligence.

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At this time we believe that these two findings represent the cause of any alleged misadministrations which may have occurred. Should you require any additional information, please do not hesitate to contact me.

Sincerely,

Mary N. Mannix, FACHE Chief Operating Officer

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MNM:dl

cc: Mr. William Vanaskie

Ralph D. Zehr, M.D.

Gary Proulx, M.D.

Ms. Bonnie Onofre

Ms. Sandra Gabriel