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VIA U.S. MAIL AND VIA FACSIMILE
(610) 337-5269

Mr. Randolph C. Ragland, Jr.
Senior Health Physicist
NRC Region I
475 Allendale Road
King of Prussia, PA 19406

Re: Response to your fax of December 8, 2005

Dear Mr. Ragland:

This letter responds to your request for comments on an apparent discrepancy between my correspondence with the NRC dated September 23, 2005 and a notation made by Dr. Rosanna Chan on or about April 9, 2003.

Before addressing this issue, please let me reiterate that it remains Washington Hospital Center's (WHC) strong contention that this occurrence was the exclusive result of patient intervention and that WHC made an entirely reasonable interpretation of NRC regulations when determining this was not a reportable event under 10 CFR § 35.3045(a). This position is clearly supported by the NRC's own retained expert. WHC's clinical experts further determined that there was no clinical significance to this occurrence and contends that it otherwise complied with NRC regulations.

Nonetheless, notwithstanding these facts, WHC also maintains that this occurrence may not have even been a medical event fitting reportable criteria under NRC regulations. As discussed in WHC's correspondence with the NRC, WHC trained clinicians reasonably concluded that this occurrence was not clinically significant. This was determined at the time of the occurrence as well as confirmed by WHC's Radiation Safety Committee at its June 17, 2003 meeting and was based on four primary factors: 1) the location of the final shot; 2) the dose delivered during the final shot; and 3) the duration of the final shot; and 4) the occurrence and timing of the patient intervention.

While the focus of WHC's analysis was on the potential impact to the patient please let me offer the following to help clarify WHC's analysis at the time of the occurrence. WHC first attempted to calculate whether this shot would result in any unintended permanent functional damage to any organ or system. Based on the location of the shot being either on the tumor or potentially in the auditory canal, the dose delivered during the final shot, and the potential duration that it was off its intended focus, the trained clinical staff concluded there was no clinical significance. Second, WHC attempted to determine the impact that this shot may have on diminishing the

tumor volume. In evaluating the location and dose, it concluded that hypothetically even if the entire shot missed to tumor, coverage would be reduced by only 4%.

In addition, and notwithstanding WHC's contention that patient intervention obviates the reporting requirement, because of the potential location of the shot after patient movement being either on the tumor or in the internal auditory canal, WHC further believed the shot did not reach any unintended skin, organ or tissue that exceeded regulatory thresholds.

As mentioned in my September 23, 2005 correspondence, the left anterior pin shift at skull level was approximately 6mm. While its difficult to precisely calculate the focus location of the final shot after patient movement, it is reasonable to conclude that a 6mm shift at skull level would result in potentially a 3mm shift at the tumor level assuming, as in the present case, the tumor was at a midpoint in the skull and that there was no posterior pin shift. As a result, it is very likely that even with the 6mm pin shift at skull level the final shot was much closer to, and perhaps did not even move off tumor. At this location, even if the cough/sneeze occurred at the defocus position (and therefore for the duration of the final shot), WHC would calculate that the dose delivered was not to an organ or tissue resulting in 50% or more than the dose expected.

However, as previously discussed, recollection of WHC's staff is that the cough/sneeze occurred at a point approximately ½ way though the final shot. As a result, and again assuming a 3mm shift at tumor level, again the resulting dose would not exceed 50% of the expected dose to that location.

Notwithstanding WHC's reasonable positional analysis, as discussed in my September 23, 2005 correspondence, even with a 6mm shift at the tumor level, a cough/sneeze occurring midway through the final shot would not give rise to a medical event under NRC regulations by our calculations.

As I indicated when we initially discussed the matter by phone, my independent interviews with Dr. Larry White, Radiation Oncologist, Dr. Rosanna Chan, Radiation Physicist, as well as with Dr. Shashi Mohapatra, Radiation Safety Officer and my predecessor who was handling this matter uniformly reported that the cough/sneeze occurred at some point approximately mid-way through the final shot.

Upon receipt of your recent fax requesting comment, and without describing the basis for my request, I again independently queried the above individuals who again uniformly reported their belief that the cough/sneeze occurred at some point mid-way through the final shot. Dr. Chan reports she is unable to explain why this event was initially noted to be at the defocus position as this is clearly not what she reported in her materials to the NRC dated March 31, 2005 nor her August 4, 2005 supplemental report to the NRC.

Dr. White on the other hand, maintains that he was in the best position to visualize the patient while the patient was undergoing treatment, that he was the person who personally spoke to the patient immediately after the occurrence, that he is ultimately responsible for the care of the patient while receiving treatment, that he is the person responsible for making the determination

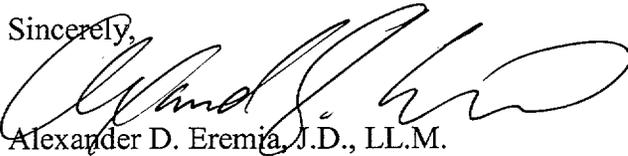
of whether to cease treatment, and that he recollects the cough/sneeze occurring a point approximately mid-way through the final shot.

While we recognize that records made contemporaneously with the occurrence may carry some weight with the NRC, I would also point out that the Patient/Visitor Incident Report, previously provided to the NRC, contemporaneously indicates that the cough/sneeze occurred during the final shot and not at the beginning or prior to the final shot. I would also point you to the enclosed Radiation Operative Note dictated by Dr. White on April 9, 2003 which describes "...during the last minute of treatment, the patient had a significant cough which may have loosened the frame."

As a result, we hope that regardless of patient intervention, for the foregoing reasons the NRC will similarly conclude that this occurrence was not a reportable medical event.

Please feel free to contact me at 202.444.3553 if you have any questions.

Sincerely,



Alexander D. Eremia, J.D., LL.M.
Associate General Counsel

Enclosures

Cc: Shashadhar M. Mohapatra, Ph.D., Radiation Safety Officer
Robert L. White, M.D., Radiation Oncologist
Jeffrey Jacobson, M.D., Neurosurgeon
Rosanna Chan, Ph.D., Chief Medical Physicist
Jeffrey Matton, Vice President, Professional Services