August 28, 2009

Mr. Peter Crane
6545 27th Ave., NW
Seattle, WA 98117

Dear Mr. Crane:

This letter is in response to your July 28, 2009, letter to Chairman Gregory B. Jaczko and the Commissioners of the U.S. Nuclear Regulatory Commission (NRC), regarding the Agency's response to the events at the Philadelphia Veterans Affairs Medical Center (VAMC).

The NRC shares your concern about the events that occurred at the Philadelphia VAMC. In May 2008, after the NRC was notified by the licensee of the apparent events involving prostate cancer treatments at the Philadelphia VAMC, the NRC began increasingly intensive inspections of the brachytherapy program at the Philadelphia VAMC and 12 other VA facilities that conduct this medical procedure. The VA has suspended this procedure at five sites until the NRC is satisfied that the problems have been addressed.

As you have stated, additional questions remain to be answered, and the NRC is aggressively continuing its efforts to resolve remaining issues. Our inspections are continuing. Once they are complete, the NRC will make its final determinations regarding the events at the Philadelphia VAMC. These conclusions will be considered in developing any proposed regulatory changes and changes to improve our inspection and licensing programs.

With regard to your perception that NRC's interpretation of the regulations changed over time, it has been the Office of the General Counsel's (OGC) interpretation that, in accordance with the plain language of section 35.40, a preimplantation written directive (WD) must contain, before implantation, treatment site, radionuclide, and dose (see section 35.40(b)(6)(i)). The preimplantation WD may not be revised after administration of the dose (see section 35.40(c)). Certain information, including the radionuclide, treatment site, number of sources and total source strength must be entered into the WD after implantation but before completion of the procedure, to more accurately reflect what actually took place (see section 35.40(b)(6)(ii)). Therefore, under the current regulations (which were in effect at the time that the incidents at VAMC occurred), if an Authorized User revised the WD after implantation but before the patient left the operating room to reflect the number of seeds that were actually implanted into the target organ, this would not constitute a reportable medical event.

The VA events were determined to be reportable not because of any change in the above interpretation, but because based upon an external review conducted for patients receiving prostate brachytherapy implants, the licensee subsequently determined that the two incidents at VAMC involved doses that met the criteria for reporting under 10 CFR 35.3045. Specifically, the determination was made that one patient received a dose that exceeded 0.50 Sievert and 50 percent more than the expected dose to an organ or tissue, while the second patient received an administered prostate dose that was less than 80 percent of the prescribed dose. See NRC Special Inspection Report No. 030-34325/2008-029 (March 30, 2009). Therefore, these

incidents were considered to be potentially reportable medical events; however, not because there was any change to the position taken by OGC attorneys that under section 35.40 as it is currently written, certain information may be added to a written directive after implantation but before completion of the procedure.

Events involving therapeutic use of byproduct material, including the incidents at VAMC, as well as advice from ACMUI, prompted the NRC to reconsider the appropriateness and adequacy of the regulations for medical events and WDs, and a proposed rule has been published in the *Federal Register* that would amend the regulations regarding reporting of medical events involving permanent implant brachytherapy. 73 FR 45635 (August 6, 2008). Development of the final rule is in progress and will consider the results of our inspections and any issues raised as a result of the public comments, including any input received from ACMUI and Agreement States.

In your letter you stated that questions remain regarding the notification of the 92 patients involved in the medical events. The NRC has confirmed that the Philadelphia VAMC sent a letter of notification on July 2, 2008, to all of the patients treated with permanent prostate seed implants. The NRC has also confirmed that the latest updated report in Nuclear Material Events Database reflects that all patients and referring physicians have been notified.

The NRC takes these medical events very seriously and will continue efforts to improve the regulatory framework and effectiveness of our regulatory program.

Sincerely,

/RA/

Charles L. Miller, Director
Office of Federal and State Materials
and Environmental Management Programs

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