Penn
University of Pennsylvania
Environmental Health & Radiation Safety

TO: Frank Costello
Radiation Health Physicist
PA Department of Environmental Protection

FROM: Robert Forrest, CHP
Director of Radiation Safety

DATE: July 27, 2009

RE: Prostate Brachytherapy Review

As requested, we again reviewed the prostate brachytherapy cases performed at the Hospital of the University of Pennsylvania from 2005 through 2008. Our conclusion was that there was no reportable medical event relating to any of the cases.

The current definition of a reportable medical event is set forth in 10 C.F.R. § 35.3045, which provides that a licensee must report as a medical event any procedure in which the "total dose differs from the prescribed dose by 20 percent or more" (assuming the dose exceeds a *de minimis* amount set forth in the preceding paragraph).[1] "Prescribed dose" for manual brachytherapy, however, is defined as "either the total source strength and exposure time or the total dose, as documented in the written directive."[2] The definition makes clear that prescribed dose, along with total dose (which is not separately defined), and the difference between the two, may be measured in terms of activity, i.e. source strength and exposure time.

Moreover, the alternative – measuring the difference between prescribed dose and total dose by referring to a dose-based metric – has been deemed unworkable by experts and practitioners. As noted in the Federal Register, Vol. 73, No. 152 (August 6, 2008), the NRC's Advisory Committee for Medical Uses of Isotopes (ACMUI) recommended that the criteria for defining most Medical Events (MEs) for permanent implant brachytherapy be based on activity because, in the words of the ACMUI, "there is no suitable clinically used dose metric available for judging the occurrence of MEs."[3] The NRC staff agreed "that, for permanent implant brachytherapy, total source strength (activity-based) is an acceptable alternative to total dose (dose-based) for the purpose of determining the occurrence of most MEs."[4]

---

1 10 C.F.R. § 35.3045 (a)(1)(i).

2 10 C.F.R. § 35.2.

3 73 FR 45636

4 *Id.*

Suite 400 3160 Chestnut Street Philadelphia, PA 19104-6287
Tel 215 898 4453 Fax 215 898.0140 http://www.ehrs.upenn.edu

Finally, the use of activity allows the treatment team to determine whether a medical event has occurred before the end of the procedure. If 20% or more of the seeds implanted were placed outside the treatment site (the prostate plus whatever margin deemed appropriate by the physician), there is a reportable medical event. The alternative – a dose-based metric – would require a number of arbitrary decisions: Dose delivered to what volume of the prostate? Measured at what time? The regulation offers no guidance, and practitioners do not conduct post-implant dosimetry in a uniform fashion.[5] Moreover, there is significant variability in prostate contouring,[6] as well as the possibilities that the prostate size can change or seeds could migrate after the implant, thereby changing the calculated dose.

The thirty day post-implant CT scan and subsequent post-treatment plan calculation is a clinical tool to help the physician evaluate the patient, not an evaluation for regulatory reporting purposes. Indeed, although it is recommended by relevant practice guidelines, it is not required by NRC regulations.

In accordance with the ACMUI and NRC recommendations, the University has used activity-based criteria for determining the occurrence of medical events in prostate brachytherapy. The Radiation Safety Office staff periodically audit the written directives for prostate brachytherapy as part of routine regulatory audits of Department of Radiation Oncology records. The Department prepares a written directive in accordance with each treatment plan, as required by 10 CFR 35.41. Our audits compare the prescribed activity with the implanted activity as documented on the written directive. Our focus on the written directive is consistent with the NRC's statement, in the Federal Register, Vol. 67, No. 79 (April 24, 2002), regarding the purposes of retaining written directives, inasmuch as they "provide documentation that the actual administrations were according to the written directives prepared before the administrations."[7]

Our audits have not uncovered any case in which the seeds were not implanted under imaging guidance by the authorized user in accordance with the written directive. Please let me know if you have any additional questions.

---

5 See ACR Practice Guideline, "Practice Guideline for the Transperineal Permanent Brachytherapy of Prostate Cancer" (2006), available online at http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/ro/brachy_prostate_cancer.aspx, at 964 (noting that "optimal timing for obtaining the post-implant CT . . . is not known")

6 *Id.* (noting that "[s]ignificant intraobserver variability in the contouring of prostate volumes can be noted on post-implant CT scans.").

7 73 FR 20287.