Ronald Zelac

From: Ronald Zelac
Sent: Monday, April 13, 2009 3:25 PM
To: 'Michael Hagan'
Cc: Cindy Flannery; Christian Einberg
Subject: RE: VA clinical guidelines
Attachments: Ronald E Zelac Ph D CHP CMP.vcf

See the following excerpts from the responses that I received to my request for comments from NRC staff on the VA clinical guidelines that you supplied. There are repetitions (multiple comments) on the specific issue/section dealing with medical event recognition and reporting, which I understand from you will be addressed in a separate document.

1. The underlined sentence in their guidelines seems conflicting with the current 10 CFR 35.3045 (a)(1)(i), "The total dose delivered differs from the prescribed dose by 20 percent or more."

"v. Because higher prostate doses are associated with higher cancer control rates, there is no clinically defined upper dose limit, as long as urethral and rectal dose tolerances are respected. However, it is recommended that an effort be made to keep the final D90 < 130% of the prescription dose. An implant resulting in D90 < 85% should be considered for a supplementary procedure. In the absence of contra-indications, supplementation is required for an implant resulting in D90 < 80%. Medical Event reporting will conform to federal statutory requirements."

2. Please describe what constitutes a medical event or provide the link to the medical event definition (http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3045.html.

3. It is unclear whether an overdose as documented in the current medical event reporting requirements would be reported since the document states "there is no clinically defined upper dose limit.....However, it is recommended that an effort be made to keep the final D90<130%." This statement should be clarified to ensure that a medical event is reported when required.

4. The document appears to imply that 10% of all sources will be calibrated by the permittee. It is unclear whether the permittees will be allowed to rely on the manufacturer's measurements. The 10% verification would be difficult to perform for preloaded needles or stranded sources, unless the permittees are required to order loose seeds to meet the 10% confirmatory measurement requirement.

5. For such detailed procedures, certain topics like the conduct of a cystoscopy at the end of the implant are not addressed. For example, is a cystoscopy required and what action is taken if sources are found in the bladder? Are removed seeds re-implanted (hopefully not, since they may be damaged)?

6. The procedure fail to address a bounding upper limit dose for the prostate. If the bounding dose involves another organ or tissue, like dose to the rectum, that should be included in their procedures. We find it difficult to understand why there is no upper limit bounding dose for trans-perineal (prostate) brachytherapy implants proposed by the VA.

7. The procedure does not address Cs-131 sources (we know VA Pugent Sound uses Cs-131) This source is not exactly common but since certain sites use Cs-131, the VA's procedure should make mention of Cs-131, the approved prescriptions for doses with Cs-131, etc.

8. What really stands out is the lack of an upper dose limit (D- 90) for the prostate. Item b. v. of their procedure: "However, it is recommended that an effort be made to keep the final D90 $\leq$ 130% of the prescription dose" should be revised in keeping with part 35. They should keep the final D-90 within +/- 20% until further word from NRC.

9. For Item B.a.i., "Treatment Volumes", we wonder if there is an acceptable time limit between the volume study and the implant? Since the prostate can change over time, would the VA have considerations/reimaging if a certain amount of time passed between the initial volume study and the implant?

We hope that you find to be useful these regulatory-compliance-related comments on the VA's clinical guidelines for trans-perineal permanent implant brachytherapy, which you supplied for informal review.

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From: Michael Hagan [mailto:MHagan@mcvh-vcu.edu]
Sent: Wednesday, February 11, 2009 3:07 PM
To: Ronald Zelac
Subject: VA clinical guidelines

Dr. Zelac,

Here are the clinical guidlines we spoke of earlier.

As you see, my preference is to ascribe to the ACR guidleines, modifying them to fit my preferences for these practices within the VAMCs.

I've tried to make these procedures clear and appropriately constraining with room for individual physician variation.

Thanks for taking a look.

Mike Hagan