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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

February 26, 2008

Subject: RIN 3150-AI26

(6)

The following comments are submitted in response to NRC's Part 35 Draft Preliminary Language, dated February 7, 2008, and Revision 1, dated February 21, 2008. They represent a preliminary review by the Department of Veterans Affairs, Veterans Health Administration National Health Physics Program.

1. 35.3045 (a)

a. We oppose this new definition of a medical event, which would now include the failure to prepare a written directive - for all such administrations, not just permanent implant brachytherapy, the stated aim of the revision - as a medical event. We believe that existing regulations, under which failure to prepare a written directive is a violation, but not a medical event, provide adequate protection. One interpretation could be that the failure to fully complete a written directive, e.g., an authorized user physician fails to sign a written directive or put units on the prescribed dose or dosage, is a medical event. It further seems inappropriate to put such events in the same class as "true" medical events, i.e., those in which a significant dose other than intended was delivered. This would also require a reactive inspection under current NRC policy, an unnecessary usage of resources.

2. 30.3045 (a) (2) (i)

a. We oppose the provision of 35.3045 (a) (2) (i) that defines as a medical event "The total source strength implanted in the treatment site differing from the preimplantation written directive by 20 percent or more." In permanent implant brachytherapy, the authorized user physician is typically present and either performing the implantation or directing it. It is common for additional seeds to be implanted, per the judgment of the authorized user physician. The clinical goal is to obtain an optimal dose distribution, not a total source strength matching the preimplantation written directive. Instead, the criteria for a medical event should be based on the total source strength differing from the postimplantation written directive. For example, at one facility known for its expertise in permanent implant prostate brachytherapy, which achieves excellent dosimetric results (nearly all implants achieve V100s exceeding 90%, with acceptable R100s), in nearly 20% of cases the implanted activity differs by more than 20% from that in the preimplantation part of the written directive. Indeed, it is the freedom to implant fewer or more seeds than stated in the preimplantation written directive that permits these excellent dosimetric results.

b. Section 30.3045 (a) (2) (i) uses the word "preimplantation" whereas Section 35.40 (b)(6)(i) and elsewhere use the phase "before implantation." A common terminology should be used in these sections.

3. 30.3045 (a) (2) (i) – (v): It is not clear if each of these items is separated by an "or", although it appears so. If so, then (iii) would require that a single seed outside the boundary (also ill-defined) (an insignificant activity/dose) would be defined as a medical event.

4. 35.40 (b) (6) (i) -- the term "other sites as applicable" is too vague and is undefined.

5. 35.40 (b) (7) (i) -- this definition is not now consistent with the new (b) (6) (i), i.e., similar requirements should be in place for all modalities.

6. 35.40 (c) (1) -- It is not clear how this requirement relates to or addresses 35.40 (b) (6) (i). In permanent implant prostate brachytherapy in particular, it would appear that this would not allow revisions to a written directive after the implantation had begun. However, clinicians must be allowed to adjust, during the procedure, the activity that is implanted.

Template = SECY-067

SECY-02

7. 35.3045 (a) (3)

a. We oppose the provision of 35.3045 (a) (3) that defines as a medical event "An error in calculating the total source strength for permanent implant brachytherapy documented in the preimplantation written directive that resulted in a total source strength that delivered a dose that differed by more than 20 percent from the intended dose to the treatment site." What constitutes an "error in calculating the total source strength"? In permanent implant prostate brachytherapy, the total source strength documented in the preimplantation written directive is merely an estimate of the source strength needed to obtain an optimal dose distribution. At many institutions, it is based upon a volume imaging study performed two or more weeks before the procedure.

b. The term "dose to the treatment site" is not defined. In permanent implant prostate brachytherapy, the dose varies greatly from point to point within the treatment volume and various dose indices such as V100 and D90 are used to assess the dose distribution.

c. The inclusion of dose appears to be contrary to the original intent of this rulemaking, which was to, for permanent implant brachytherapy, define a medical event based upon the total source strength or apparent activity implanted, instead basing it on dosimetric parameters.

8. We believe that the response date of February 26, 2007, does not provide sufficient time for response, particularly in view that Revision 1 to the draft preliminary language was released by NRC on February 22, 2007. We request that the response date for comments be extended so we may solicit comments from VA impacted parties on this important issue for provision of veteran patient care.

Secy

From: Emile Julian
Sent: Wednesday, February 27, 2008 3:37 PM
To: Secy
Subject: FW: RIN 3150-AI26
Attachments: VA Comments for NRC.doc

From: Leidholdt, Ed [mailto:Edwin.Leidholdt@va.gov]
Sent: Tuesday, February 26, 2008 4:47 PM
To: Emile Julian
Cc: Rulemaking Comments
Subject: FW: RIN 3150-AI26

From: Leidholdt, Ed
Sent: Tuesday, February 26, 2008 1:41 PM
To: 'Rulemaking.Comments@nrc.gov'
Cc: McGuire, Lynn (VACO); Williams, Gary E
Subject: RIN 3150-AI26

Dear Sir or Madam:

Attached are comments submitted in response to NRC's Part 35 Draft Preliminary Language, dated February 7, 2008, and Revision 1, dated February 21, 2008. They represent a preliminary review by the Department of Veterans Affairs, Veterans Health Administration National Health Physics Program.

Thank you for the opportunity to comment on the draft preliminary language.

Questions regarding these comments may be sent to me or to:

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Received: from HQCLSTR01.nrc.gov ([148.184.44.79]) by OWMS01.nrc.gov
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From: Emile Julian <Emile.Julian@nrc.gov>
To: Secy <SECY@nrc.gov>
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