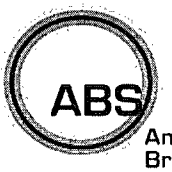
PR 35
(73FR45635)

Annette L. Vietti-Cook
Secretary of the Commission
Mail Stop O-16G4
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001
ATTN: Rulemakings and Adjudications Staff

DOCKETED
USNRC

October 14, 2008 (4:38pm)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF



American
Brachytherapy
Society

5

Subject: RIN 3150–AI26:

14 October 2008

Dear Ms. Vietti-Cook,

The American Brachytherapy Society (ABS) is a clinically-oriented society of over 2,000 radiation oncologists and medical physicists intimately familiar with using radionuclides for cancer therapy. We have reviewed the proposed NRC rule on medical use of byproduct material for permanent implants published in the Federal Register Vol. 73. No. 152 issued on 6 August 2008, and would like to offer our comments preceding the 20 October 2008 comment period deadline.

We agree with many of the proposed rules for permanent brachytherapy drafted by the NRC, which are in accordance with the recommendations of the ACMUI. We wish to reiterate that while these rules were developed with prostate brachytherapy in mind, the rules will apply to all types of permanent brachytherapy in any organ. The precision of source implantation in other organs as determined from post-implant or intraoperative imaging may be limited, due either to image artifacts or operator variability in defining the treatment site. For some treatment sites, such as postoperative brachytherapy of a tumor bed, there is no well-encapsulated or radiographically visible target volume that can be used to precisely determine target volume. NRC enforcement policy must be based upon realistic expectations of the precision that can be achieved in medical event (ME) determination in different clinical settings. We are concerned that the proposed language in some parts of § 35.3045(a)(2) could result in inadvertently and inappropriately categorizing some clinically appropriate and acceptable implants as "medical events" including the following:

1. The proposed language for § 35.3045(a)(2) (i) on page 45643, column 3 currently reads: [A licensee shall report as a medical event any administration requiring a written directive if a written directive was not prepared or any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material for permanent implant brachytherapy (excluding sources that were implanted in the correct site but migrated outside the treatment site) results in] The total source strength administered differing by 20 percent or more from the total source strength documented in the preimplantation written directive. Further in page 45637 column 3 it is noted: *G. Can the AU Modify the Preimplantation WD During the Administration of Brachytherapy?*

Regarding the question for section G – we believe the answer should be "no". Making changes to the preimplantation written directive (WD) would constitute revising the WD. As is also provided by the current regulations, revisions to the WD must be made before implantation begins. The reason the preimplantation WD cannot be changed is that the preimplantation WD serves as the basis for determining if an ME has occurred.

The ABS wishes to clarify that many authorized users (AU) perform real-time adaptive interactive planning whereby the WD and source strength to be implanted is based on the actual volume dynamically determined during the procedure rather than being based on the preimplant volume.

Template = SECY-067

SECY-02

Real-time planning takes into account alterations in the prostate volume and shape that occur between the time of preplan and the implant procedure, and therefore represents the actual implant situation. Hence, for those performing real-time adaptive planning implantation, the WD refers to final WD after administration, but before the patient leaves the post-treatment recovery area, and not to an arbitrary preimplant WD. Further, even those performing permanent brachytherapy using preplanned techniques will often modify their plan if intraoperatively they find discrepancies in the gland volume from the volumes determined during the preplan. Therefore, the WD in this section should refer to the total source strength implanted *after* administration but *before* the patient leaves the post-treatment recovery area *rather than* an arbitrary preimplantation WD.

The ABS suggests that: § 35.3045 (a)(2)(i) should be modified to:

"The administration of byproduct material or radiation from byproduct material for permanent implant brachytherapy (excluding sources that were implanted in the correct site but migrated outside the treatment site) results in the total source strength administered differing by 20 percent or more from the total source strength documented in the written directive."

Delete "preimplantation". It should be clarified that the source strength implanted in the WD refers to the source strength implanted *after* administration but *before* the patient leaves the post-treatment recovery area. This wording would therefore apply both to those using the preplanned technique and those using real time adaptive technique.

The ABS wishes to clarify that the definition of treatment site as described in § CFR35.2 as "the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive" leads to some ambiguity regarding the exact volume the treatment site refers to. There are various standard volumes already defined in radiation oncology. This includes the gross tumor volume which is the volume that contains tumor. Then there are two margins added to the gross tumor volume during the brachytherapy planning process. There is a margin added to account for the subclinical spread of tumor, which is termed the "clinical target volume". There is an additional margin added to account for uncertainties in source positioning, tumor boundaries, isodose constrictions etc. which is termed the "planning target volume". These expansion margins are not constant but are different for different clinical situations. Radiation oncologists use a larger margin if there is high degree of uncertainty and/or if there are no adjacent critical structures. Conversely, the margins are smaller if the boundary is distinct and/or if there are adjacent critical structures. The question of margins and the source strength to be placed in the margin is a clinical decision. The NRC will be interfering into medical judgment if it dictates the amount of source strength the AU can place in the margins. Using § 35.2 definition of treatment site as "the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive" leads to ambiguity since it is unclear whether the "treatment site" refers to the gross tumor volume or includes the margins as in the clinical target volume or include the margin as in the planning target volume.

The ABS suggests that: to be considered a medical event, the sentence "The total source strength implanted outside the treatment site and within 3 cm (1.2 in) of the boundary of the treatment site exceeding 20 percent of the total source strength documented in the preimplantation written directive" be replaced by "The total source strength implanted outside the treatment site (including the gross tumor, the clinical target volume plus a variable planning margin as defined by the AU) exceeding 20 percent of the total source strength documented in the written directive". With this definition, the NRC will not interfere with clinical judgment, but may assist prevention of poor implants.

2. The proposed language for § 35.3045 (a)(2)(iii) on page 45643, column 3 currently reads: [A licensee shall report as a medical event any administration requiring a written directive if a written directive was not prepared or any event, except for an event that results from

patient intervention, in which the administration of byproduct material or radiation from byproduct material for permanent implant brachytherapy (excluding sources that were implanted in the correct site but migrated outside the treatment site) results in] Brachytherapy source(s) implanted beyond 3 cm (1.2 in) from the outside boundary of the treatment site, except for brachytherapy source(s) at other sites noted in the preimplantation written directive. Further in page 45638 column 2 it is noted: *I. Would One Sealed Source Implanted Beyond the 3 cm Boundary Constitute an ME?*

Regarding the question for section I – we believe the answer should be "yes", with the exception of sealed sources that migrate after implantation. A single brachytherapy source implanted beyond 3 cm from the outside boundary of the treatment site would constitute an ME.

The ABS wishes to clarify that in the normal course of some brachytherapy implants, a few seeds can end up beyond 3 cm from the outside boundary of the treatment site due to a number of factors.

a. Seeds can be deposited into the periprostatic blood vessels and then travel to distant organs like the lung. This is correctly recognized by the NRC which excludes sources that were implanted in the correct site but migrated outside the treatment site from medical event. However, the deposited seeds could also travel to the adjacent pelvic area and be more than 3 cm away from the prostate via the pelvic vessels. In this case, it could be determined to be a medical event as it would be impossible to distinguish whether it was wrongly deposited there or was correctly placed but migrated there.
b. Some seeds are dragged along the needle track while the needle is being retracted and may end up more than 3 cm inferior to the prostate.
c. Patients sometimes inadvertently cough or otherwise move during the needle retraction causing some seeds to be deposited more than 3 cm from the treatment site.
d. Sometimes a few seeds are implanted into the urethra or adjacent bladder. Most of these seeds normally are eliminated in the urine. However, sometimes they move within the bladder or urethra and lodge more than 3 cm from the prostate.
e. While most permanent brachytherapy procedures are performed for the prostate, these Rules will apply to other sites of permanent implant. At other sites, for example the tumor beds after resection, and deep seated liver tumors, the margins are indistinct and there are greater uncertainties. Therefore, clinicians routinely implant beyond the tumor or tumor bed,if there are no critical structures in that area. Further, sometimes (especially after tumor resection) there may be no tissues to anchor the seeds to and so they are placed in gelfoam or vicryl mesh. Some of these seeds may become dislodged and travel more than 3 cm away in a free cavity (e.g., the abdominal, pelvic, or lung cavities). It would be virtually impossible to determine whether they were deposited there or were dislodged and migrated there (and therefore could be deemed a medical event).

The above events sometimes happen in the normal course of some brachytherapy implants, are beyond the control of the AU, and there is no evidence that there is harm from these infrequent occurrences. We are concerned that with the proposed rule, the above situations may be deemed to be MEs, and further, that some practitioners will simply abandon the permanent brachytherapy procedure rather than risk having MEs. This will be detrimental to patient care.

It is to be noted that section § 35.3045 (a)(2)(iii) will become superfluous and therefore could be eliminated when § 35.3045(a)(2) (ii) is modified per the ABS suggestions above to "The total source strength implanted outside the treatment site (including the gross tumor, the clinical target volume plus a variable planning margin as defined by the AU) exceeding 20 percent of the total source strength documented in the written directive". This would take into account source migrations, seeds being dislodged, dragged out, etc., but would still hold accountable cases where the target organ was

grossly misidentified and the wrong area was implanted. We feel this better follows the spirit of the proposed rules.

We thank you for affording us this opportunity to provide comments on the NRC's preliminary draft rule changes to 10 CFR 35.40 and 35.3045 related to MEs in brachytherapy.

Sincerely yours,

Brian Davis

Brian J. Davis, M.D., Ph.D.
President
American Brachytherapy Society

Rulemaking Comments

From: Rivard, Mark PhD [MRivard@tufts-nemc.org]
Sent: Monday, October 13, 2008 8:24 PM
To: Rulemaking Comments
Cc: davis.brian@mayo.edu; eric.horwitz@fccc.edu; rguggolz@drohanmgmt.com
Subject: American Brachytherapy Society response to NRC's Proposed Rules for Permanent Implant Brachytherapy (RIN 3150-AI26)
Attachments: ABS final letter to NRC regarding medevent.doc

Dear Ms. Vietti-Cook,

Please find attached a letter from the American Brachytherapy Society commenting on proposed NRC rule RIN 3150–AI26. As the focus of our society is brachytherapy, we hope you will strongly consider our proposed changes. Please note that I am submitting this letter on behalf of our President, Dr. Brian Davis.

Yours Truly,
Mark J. Rivard, Ph.D.
ABS Board Member-at-Large

Received: from mail1.nrc.gov (148.184.176.41) by OWMS01.nrc.gov
(148.184.100.43) with Microsoft SMTP Server id 8.1.291.1; Mon, 13 Oct 2008
20:29:15 -0400
X-Ironport-ID: mail1
X-SBRS: 5.4
X-MID: 31560851
X-IronPort-Anti-Spam-Filtered: true
X-IronPort-Anti-Spam-Result:
AjkBAIuD80hAEgMjmmdsb2JhbACBclcqj0GBKAEBAQEBCAsKBxEFnTkZBQYCBwoUDQmKZ
oFs
X-IronPort-AV: E=Sophos;i="4.33,405,1220241600";
d="doc'32?scan'32,208,217,32";a="31560851"
Received: from exprod8ob118.obsmtp.com (HELO psmtp.com) ([64.18.3.35]) by
mail1.nrc.gov with ESMTP; 13 Oct 2008 20:28:54 -0400
Received: from source ([160.109.101.129]) by exprod8ob118.postini.com
([64.18.7.12]) with SMTP; Mon, 13 Oct 2008 17:28:45 PDT
Received: from neexchange05.tufts-nemc.org ([10.138.50.24]) by
NeExchange51.tufts-nemc.org with Microsoft SMTPSVC(6.0.3790.1830); Mon, 13
Oct 2008 20:26:01 -0400
x-mimeole: Produced By Microsoft Exchange V6.5
Content-Class: urn:content-classes:message
MIME-Version: 1.0
Content-Type: multipart/mixed;
boundary="----_=_NextPart_001_01C92D93.34C066F2"
Subject: American Brachytherapy Society response to NRC's Proposed Rules for Permanent
Implant Brachytherapy (RIN 3150-AI26)
Date: Mon, 13 Oct 2008 20:24:22 -0400
Message-ID:
<139AED815E1711468BFC306008A708BF014C7BD8@neexchange05.tufts-nemc.org>
X-MS-Has-Attach: yes
X-MS-TNEF-Correlator:
Thread-Topic: American Brachytherapy Society response to NRC's Proposed Rules for
Permanent Implant Brachytherapy (RIN 3150-AI26)
Thread-Index:
AckO7mwJ7IFZGoSYQumZLmICDntPaAAAI8KGABmx6oAFZzEz3AAf35ywAGURDbEA/bpZcA
AAFzEgAKR8V6A=
References:
<C3FDDFE5E604634A9EC23CE6C377BC0D013E81BD@exchange2k3.DROHAN.LOCAL>
From: "Rivard, Mark PhD" <MRivard@tufts-nemc.org>
To: <Rulemaking.Comments@nrc.gov>
CC: <davis.brian@mayo.edu>,
<eric.horwitz@fccc.edu>,
<rguggolz@drohanmgmt.com>
Return-Path: MRivard@tufts-nemc.org
X-OriginalArrivalTime: 14 Oct 2008 00:26:01.0622 (UTC) FILETIME=[6FD19B60:01C92D93]