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November 17, 2014

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555
By Fax: 301 415 1101

RE: ABS feedback on the NRC Proposed Rules for permanent brachytherapy.

The American Brachytherapy Society (ABS) wishes to comment on the proposed rules for Medical Event Definition for permanent brachytherapy published in the Federal Register Vol. 79, No. 139, July 21, 2014.

Founded in 1978, the American Brachytherapy Society (ABS) is a nonprofit organization that seeks to provide insight and research into the use of brachytherapy in malignant and benign conditions. The mission of the ABS is to benefit patients by providing information directly to the consumer, by promoting the highest possible standards of practice of brachytherapy, and to benefit health care professionals by encouraging improved and continuing education for radiation oncologists and other health care professionals involved in the treatment of cancer. Additionally, the ABS seeks to promote clinical and laboratory research into the frontiers of knowledge of the specialty and to study the socioeconomic aspects of the practice of brachytherapy. The organization consists of approximately 1,500 physicians, medical physicists, and other health-care providers interested in brachytherapy.

The ABS is pleased to note that the NRC has incorporated a source strength based definition for the written directive as recommended by the ACMUI and the scientific societies. It is also helpful to have a two part written directive for permanent brachytherapy before and after implant in § 35.40(b)(6). Likewise, § 35.41(b)(6) will help improve the quality of permanent brachytherapy by requiring all permanent brachytherapy licensees to perform a dosimetric evaluation of each implant within 60 days unless the patient was demonstrably unavailable. The ABS also supports that these issues be deemed compatibility B (rather than compatibility C) such that the rules are uniform from one state to another for minimizing confusion. Over 90% of medical licensees are under Agreement State authority, hence anything less than compatibility B makes these changes an over-regulation of the minority.

The ABS has the following concerns and recommendations regarding the proposed new rules:

1. The proposed permanent implant ME definition is a hybrid based on source strength and absorbed dose. The WD has no absorbed dose specification. Regulatory inspectors do not have nor can they be expected to have the expertise to assess a permanent seed implant and determine if any 5 contiguous centimeters have exceeded an expected absorbed dose by 50%. Different licensees use different absorbed dose metrics to determine a successful implant. The dose to 5 cc introduced by the NRC is totally arbitrary and not based on any clinical data. The ACMUI in 2008 recommended a source strength ME definition for permanent implants and explicitly stated it should not include an absorbed dose criteria. Subsequently, this was sent to the Commissioners with absorbed dose component added by NRC staff to the ME definition. To the wisdom of the Commissioners, this was rejected. The NRC held national stakeholder workshops in 2011 on Part 35 revisions including the ME permanent implant definition. The overwhelming consensus at each workshop attended by professional organizations and radiological professionals was to have a source-strength ME definition rather than an absorbed dose based definition. The ACMUI presentations at these workshops also stated a source-strength definition was preferable. In spite of this, the NRC staff is persisting to establish its own metric which is the practice of medicine and not within the scope of the NRC. The ABS recommends that any medical event reporting for permanent implant brachytherapy must be based solely on a source strength based definition for the written directive as recommended originally by the ACMUI and the radiological societies rather than the proposed hybrid definition based on source strength and absorbed dose.

2 The proposed ME definition is based on the PRE-implantation written directive for absorbed dose which is inappropriate and contrary to the criteria for source-strength WD The ABS recommends that any medical event reporting for permanent implant brachytherapy must be based on the POST- implantation source strength written directive as described in §35.40(b)(6)(ii) rather than the criteria established in the proposed §35.3045 which specify the pre-implantation written directive approved by the authorized user.

3 The new proposed Rule 3c now states (§ 35.3045(a)(2)(v)(C), page 42415,) that a ME has occurred if a treatment involves: (c) source(s) implanted directly into the wrong site or body part, i.e., not in the treatment site identified in the WD; This requires that even a single sealed source directly delivered to the wrong treatment site would constitute an ME that must be reported. This rule requires to be modified If, for example, the RIGHT breast was implanted when the LEFT breast was intended to be implanted, then it would definitely be a wrong site ME. However, it has to be recognized that in the course of a normal implant procedure, sources can occasionally be deposited outside the treatment site due to various factors such as uncertainties in intraoperative imaging, patient motion, suction of seeds due to needle withdrawal, or seed migration. It is well known, for example, in implanting the prostate, a few seed may be lodged in the bladder wall or the penile bulb or even migrate distally to the lung. These events should not be deemed a wrong site ME. The proposed definition of ME (ME is if 20 percent or more of the implanted sources are located outside the intended implant location) correctly accounts for the fact that a few (<20%) of sources being outside the treatment site is not considered a ME.

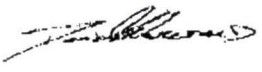
4. Previous 10 CFR part 35.3045 (a) (3) had correctly noted that migrated sources were not ME by noting "excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site". Hence the ABS recommends that the statement "even a single sealed source directly delivered to the wrong treatment site would constitute an ME that must be reported" be modified to state "even a single sealed source directly delivered to a **non-contiguous** wrong treatment site would constitute an ME that must be reported" and the previous exclusion of "seeds that were implanted in the correct site but migrated outside the treatment site are not considered to be ME" be reintroduced for clarification. If these changes are not done, there will be numerous spurious ME reported that will be unnecessarily burdensome and time consuming to the NRC and the licensee without increasing the patient safety.

In conclusion, ABS thanks the NRC for making the new proposed rules on Medical Event Definition for permanent brachytherapy and requests that the NRC modify the proposed regulations as follows:

1. Medical event reporting for permanent implant brachytherapy must be based solely on a source strength based definition for the written directive as recommended originally by the ACMUI and the radiological societies rather than the proposed hybrid definition based on source strength and absorbed dose.
2. Medical event reporting for permanent implant brachytherapy must be based on the POST-implantation source strength written directive as described in §35.40(b)(6)(ii) rather than the pre-implantation written directive.
3. The statement; "Even a single sealed source directly delivered to a wrong treatment site would constitute a ME that must be reported" be modified to state "Even a single sealed source directly delivered to a **non-contiguous** wrong treatment site would constitute an ME that must be reported".
4. Reinstate the statement, "seeds implanted in the correct treatment site but migrated outside the treatment site are not considered a ME".

Thank you for affording the ABS this opportunity to provide comments on the NRC's proposed rules for Medical Event Definition for permanent brachytherapy. Please contact Mr. Rick Guggolz at 703-234-4078 if you have any questions.

Sincerely,



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