HEALTH PHYSICS SOCIETY

"Specialists in Radiation Safety"

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RE: Docket ID NRC-2008-0175
Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments

To whom it may concern:

The Health Physics Society[1] (HPS) is a professional organization whose mission is to promote excellence in the science and practice of radiation safety. The HPS appreciates the opportunity to provide comments in response to the proposed rule published July 21, 2014 relating to potential changes to 10 CFR 35.

The following comments were prepared by the HPS Medical Health Physics (MHP) Section (note there are also more detailed comments included in an attachment):

1. ***Proposed Amendment:*** Adding Written Directive requirements, procedure requirements and separate medical event (ME) definitions for permanent implant brachytherapy.

    a. ***General Comment:*** In general, the MHP Section agrees that changes to the existing ME definitions are needed for permanent implant brachytherapy. However, the proposed ME definitions may not fit certain currently available and utilized radiotherapy products, and may be difficult to apply.

    For example, Y-90 Selective Internal Radiation (SIR-) Spheres and TheraSpheres are currently licensed under the manual brachytherapy requirements and meet the category of "permanent implant brachytherapy." However, the implanting of spheres is much less precise than implanting sealed sources, and they would never pass the leak test requirements. We

[1] The Health Physics Society is a non-profit scientific professional organization whose mission is to promote the practice of radiation safety. Since its formation in 1956, the Society has grown to include over 4,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the department of defense, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society.

are sure the NRC did not intend the ME definitions to apply to Y-90 therapies, but the proposed amendment does not specifically exclude them. It may be clearer to the licensed community if the NRC were to include a definition of the types of sources to which the "permanent implant brachytherapy" ME definitions apply.

b. **General Comment:** The complexity of the medical event reporting requirements as currently proposed may create confusion for the regulated community and for regulators when applied to permanent prostate implant procedures.

c. **General Comment:** The identification of "treatment site" ("intended treatment site", "wrong treatment site") is not well defined. Some facilities identify the prostate gland only as the treatment site and plan a dose margin around the prostate. Other facilities include a PTV structure around the prostate as the treatment site and target coverage to that structure.

d. **General Comment:** The proposed amendment also specifies performing a post plan assessment to ensure the goals of the written directive have been met. Our interpretation of the proposed amendment is that a single seed in the incorrect location, out of many implanted, would constitute a ME. We believe that a reasonable *de minimus* threshold should be established. A post implant assessment may also be difficult to evaluate for compliance with the ME definitions for Y-90 therapies discussed above. See further detailed discussion under 10 CFR 35.3045(a)(2)(v)(C) concerning negative impact on permanent prostate implants.

e. **General Comment:** The volume for determining an absorbed dose to normal tissue for ME's for compliance with the reporting requirements in 10 CFR 35.3045 is not clearly defined. The volume of a maximally exposed 5 contiguous cubic centimeters of normal tissue appears reasonable in theory. However, it will be difficult to determine in practice with current technology. Planning systems typically report dose-volume histograms to structures, but they do not identify contiguous volumes.

f. **General Comment:** The proposed implementation period of 180 days is too short. An implementation period of 365 days or longer is needed to implement the significant changes in dose evaluation technology that will be required if this current proposed rule is implemented as published.

g. **General Comment:** The majority of the MHP Section supports designating the compatibility for reporting MEs for the Agreement States as Compatibility Category B. The MHP Section agrees with the opinion of the ACMUI that criteria defining a medical event relating to a permanent implant brachytherapy procedure be designated as Compatibility Category B for all the reasons stated in the proposed rule. The ACMUI has consistently approached this subject with thorough knowledge and understanding. Knowing the details and clinical implications of the prostate implant procedure, it only makes sense to have activity-based criteria for a medical event. The MHP Section also believes there is merit in consistent rules for subjects that have significant implications such as criteria for a medical event. Standardization removes uncertainty and confusion.

h. **General Comment:** In this proposed revision of section 10 CFR 35.3045(a), the exclusion for migration of seeds from original correct site is no longer included. This means that for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site will be a reportable medical event. The migration of seeds from a prostate treatment site is a potential expected clinical event, and therefore does not meet the ACMUI's principal that "a Medical Event should be potentially of true medical significance to a patient." The MHP Section recommends that the migration of seeds from an intended site be added back into the proposed regulations as an exclusion from an ME.

2. ***Proposed Amendment:*** Amending preceptor attestation requirements.

Response: We have no objections to this proposed amendment.

3. ***Proposed Amendment:*** Grandfathering certain board-certified individuals.

Response: We agree in general with the proposed amendment; however, we request clarification on the type and extent of documentation that will be required for the individual to demonstrate that he or she was practicing certain modalities prior to 2005.

4. ***Proposed Amendment:*** Requiring increased frequency of testing to measure Mo-99 breakthrough.

Response: We have no objection to this amendment.

5. ***Proposed Amendment:*** Requiring reporting and notification of failed Mo-99/Tc-99m and Sr082/Rb-82 generators.

Response: We agree with the proposed amendment. However, we believe that the proposed reporting requirement of within 30 days should be shortened to more effectively address patient safety concerns.

6. ***Proposed Amendment:*** Allowing Associate Radiation Safety Officers (ARSOs) to be named on a medical use license.

Response: We agree with the proposed amendment.

7. ***Proposed Amendment:*** Additional issues and clarifications - Extend the 5-year full inspection servicing frequency for a gamma stereotactic radiosurgery unit to 7 years, and to make several clarifying amendments.

Response: MHP Section members stated that a full inspection is only possible when the sources in a gamma stereotactic radiosurgery unit are replaced. We request that the full inspection frequency be revised to occur upon source exchange.

If you require clarification on any of our responses, please feel free to contact me at bhamrick@uci.edu, or by phone at 714-356-5607.

Sincerely,

Barbara L Hamrick

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ATTACHMENT

See the detailed discussion of each proposed section pertaining to permanent implant brachytherapy, specifically as it relates to prostate procedures below:

35.40(b)(6)(i)
In general, the specification for a “before implantation” and an “after implantation” assessment is an excellent improvement from the current regulations. However, one concern is how to define the “treatment site” for a prostate procedure. Prior to the surgery, the physician will prepare a prescription that defines the goals for absorbed dose to 100% of the prostate plus a specified margin, and limits for absorbed dose to critical structures, such as the bladder, rectum, and urethra. Once the patient is in the operating room (OR), the ultrasound image is used to plan needle placement to best achieve the prescription goals. At this time the margins may increase and the number of seeds used may change from the prescription based on the actual prostate volume and shape viewed in the OR. To ensure the prostate tissue is adequately dosed, some seeds may be placed in interstitial tissue since it is not a critical structure. The physician will balance the benefits of thorough dosing of prostate tissue against the limits for critical structures, based on conditions in the OR. Ultimately, the before implantation dose to the urethra (normal tissue within the treatment site) may change after implantation. Therefore, evaluation for a Medical Event for absorbed dose to normal tissue will be based on a condition that changed during the procedure.

35.40(b)(6)(ii)
Positive impact. This requirement is consistent with clinically relevant circumstances. However, since this is post implantation, it would be appropriate to list the number of seeds purposely implanted outside the prostate plus margin specified in the prescription. This information will be needed when determining a Medical Event.

35.41(b)(6)(i)
Negative Impact. It is not clear how and when this comparison should be made. There is no requirement in the post implant Written Directive to determine the number of sources outside the treatment site. In fact, there will be sources placed outside the treatment site as defined in the pre-implant Written Directive. The important question is how many seeds were placed in unintended locations after the procedure is completed. Comparing to the total seeds implanted is not reasonable since it will include seeds outside the treatment site as defined in the pre-implant portion of the Written Directive. Therefore, this part should be rewritten to clearly specify that sources put in unintended locations, i.e., errors in placement, are the concern and not sources outside the treatment area.

35.41(b)(6)(ii)
Negative Impact. The volume of a maximally exposed 5 contiguous cubic centimeters of normal tissue appears reasonable in theory. However, it will be difficult to determine in practice with current technology. Planning systems typically report dose-volume histograms to structures, but they do not identify contiguous volumes.

35.41(b)(6)(iii)
Negative Impact. The volume of a maximally exposed 5 contiguous cubic centimeters of normal tissue appears reasonable in theory. However, it will be difficult to determine in

practice with current technology. Planning systems typically report dose-volume histograms to structures, but they do not identify contiguous volumes.

35.3045 (a)(2)(i)
Positive impact. This criterion is consistent with clinically relevant circumstances. The one concern with this requirement is that it seems to be exactly the same requirement as 10 CFR 35.3045(a)(2)(v)(E). The rationale for subsection (a)(2)(i) for comparing against the post-implantation source strength versus in subsection (a)(2)(v)(E) comparing against the pre-implantation source strength is not understood. Current practice is to assay a portion of the seeds to ensure the total source strength is as ordered, which would prevent both of these MEs from occurring.

35.3045 (a)(2)(ii)
This would have positive impact if the definition of treatment site is clarified to include implantation of seeds in interstitial tissue, and not critical structures. This criterion is consistent with clinically relevant circumstances when several seeds are accidently placed in critical organs to the extent that they could cause a medically significant event to the patient.

35.3045 (a)(2)(iii)
Negative impact. This will be difficult to implement. Planning systems typically report dose-volume histograms to structures, but they do not identify contiguous volumes. Also, the identification of the “treatment site” is not well defined. Some sites identify the prostate gland only as the treatment site and plan a dose margin around the prostate. Other sites include a PTV structure around the prostate as the treatment site and target coverage to that structure. And again, seeds may be placed in interstitial tissue outside the prostate to ensure adequate dosing. In the discussion portion of the Federal Register, it is stated that this requirement is to identify when ‘bunching’ of sources causes an increased dose to contiguous volume of ‘normal tissue’. If the normal tissue involved interstitial tissue, it would not cause a medically significant event to the patient.

35.3045 (a)(2)(iv)
Negative impact. Identification of normal tissue in the treatment volume (urethra) is difficult if not impossible with a CT scan. Also, due to the variability of the radiation dose distribution in the treatment volume, the determination of the pre-implantation absorbed dose to normal tissue is ambiguous. The only way to clearly define the urethra during the post Dosimetry CT scan would be to catheterize the patient, which would cause significant pain to the patient, and therefore is not performed.

35.3045 (a)(2)(v)(C)
Negative impact. Since ninety to one hundred seeds are routinely implanted, it occurs with some frequency that a seed is implanted in a location different than the intended location. A seed could end up in tissue surrounding the prostate, in the bladder, or in the rectum. The overall impact would be numerous medical events of no clinical significance reported. I do not believe a single seed out of place warrants a medical event since there would be no clinical relevance. Also, this is in direct conflict with 10 CFR 35.3045 (a)(2)(ii) which allows 20% of the implanted source activity outside of the intended treatment site. Since the seeds are ordered with the same activity, essentially 20% of the total seeds located outside of the treatment site would not satisfy the criteria for a medical event according to 10 CFR 35.3045 (a)(2)(ii). Why include another criterion for a medical event that allows for zero seeds to be outside of the treatment

site? The ACMUI recommendation states: “3.d. A treatment is delivered directly to the wrong site or body part.” It does not follow that one source would constitute a treatment to the wrong site or body part. It is recommended that this requirement be rewritten to reflect the intent of the ACMUI recommendation.

35.3045(a)(2)(v)(E)
Negative impact. It is not clear why this medical event criterion was proposed by the ACMUI. The exact wording in the ACMUI proposal is: “Using the wrong activity or source strength (+/- 20%) as specified in the Written Directive.” The ACMUI did not specify whether it is “wrong” pursuant to the pre or post-implantation portion of the WD. This requirement appears to be a duplication of the intent of 10 CFR 35.3045(a)(2)(i). Our recommendation is to delete this requirement.