February 8, 2018

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Office of Nuclear Materials Safety and Safeguards
U. S. Nuclear Regulatory Commission
Washington, DC 20555

FEDERAL REGISTER NOTICE (82 FR 51655)-OPPORTUNITY TO COMMENT ON YTTRIUM-90 (Y–90) MICROSPHERE BRACHYTHERAPY SOURCES AND DEVICES THERASPHERE® AND SIR-SPHERES® (STC-17-078)

Dear Ms. Dimmick:

The Organization of Agreement States (OAS) Executive Board (Board) reviewed the above document and offers the following comments.

General Comments
The Board supports the elimination of the alternate pathway for authorized users; however, it should be made clear that any case performed prior to publishing this revision of Y-90 guidance may be accepted.

Due to the liberal use of "shall" and "should", the Board feels there should be a disclaimer or statement on how best to apply this guidance to the regulated community. For example, licensees may elect to commit directly to this guidance in which case the "shall" statements become binding requirements and the "should" statements are best practices that the licensee may consider implementing. If a licensee does not commit to following this Y-90 guidance, they must establish equivalent policies and procedures that will become subject to regulatory review, approval, and possibly denial.

Specific Comments

1. Page 5, Leak Test section: Replace "The small size and large number of Y-90 microspheres make leak testing, as required by 10 CFR 35.67(b), impractical. Further, if leak testing were practical, licensees would not be required to leak test individual microspheres…" with "Individual microsphere activity is below the threshold in 10 CFR 35.67(f)(3) and therefore leak testing of Y-90 microspheres is not required."
   Page 6, under "Training and Experience," For point A.1., please clarify whether a physician needs to be authorized under 35.390, or would an individual authorization

under 35.392, 35.394 or 35.396 also be an acceptable authorization. Prior version (2016) of the guidance indicated that authorization under 35.300 that included categories 1, 2, and 3 as listed in 35.390(b)(1)(ii)(G) was acceptable. If this is the intent of the wording in the draft, then the language of the 2016 version should be retained.

2. Page 7, If the intent is for documentation of the training under A.3.ii., please provide examples of acceptable documentation (e.g. copy of board certification). If it is stated in A.2. that 10 CFR 35.390 or .490 is necessary, why do we accept board certifications for .390, .392, or .394 in the footnote, recommend simplifying to exclusively .390 or possibly adding .490.

3. Page 8, A.3.iv. seems to have a typographical error. It states, "has work experience under the supervision of an AU for Y-90 microsphere brachytherapy for Y-90 microsphere brachytherapy…" One of the "for Y-90 microsphere brachytherapy" phrases should be deleted.

4. Page 9, last sentence in first paragraph: Delete "in most cases." First sentence in second paragraph: OAS recommends clarifying what "in the process" means. The Board suggests limiting continued use of the alternate pathway to physicians who have completed one in-vitro simulated case by the date when this revision to the Y-90 microsphere guidance is published.

5. Page 11, concerning "Notification," this may create an additional burden on regulatory agencies. If a licensee submits an amendment request to add an AU for Y-90 microspheres and includes a copy of the license from another facility that lists the requested individual as an AU for Y-90, how is the regulatory agency supposed to know if that individual was listed under the alternative pathway and still needs completion of three patient cases? The regulatory agency will end up having to request clarification/verification every time a request to add an AU already listed on another license is received in order to ascertain whether the requested individual will need the additional documentation, or if they are fully qualified.

Federal Register Notice (FRN) Section III Questions: The comments are numbered to correspond with the items listed in the FRN.

1. "Recommended Minimum Clinical Experience:" No comment on question of whether three patient cases provide adequate clinical training.
2. "Adding Authorization for Other Microsphere Type:" Since the NRC considers the sphere types to be so different as to warrant separate authorizations for each type, it would seem prudent that the authorized user has experience with three cases for each type. If the supervising Authorized User (AU) felt additional training was needed, they could always refrain from signing the documentation confirming that the candidate AU is adequately trained.
3. "Written Attestation from Preceptor:" Microspheres are unique in the way that they are currently being licensed under 35.1000 and until it is no longer licensed under 35.1000,

a written attestation separate from manual brachytherapy specific for each Y-90 microsphere is recommended. The attestation from an AU attesting the level of competency to function independently as an AU for each Y-90 microsphere type should be obtained to ensure the use of the delivery system for each Y-90 microsphere type.

4. "Clinical Experience Under the Supervision of a Manufacturer Representative:" It may be prudent to defer to the ACMUI's opinion for the time being, as they may have a better understanding of the difficulties physicians are having in attempting to gain the needed training. The issue can then be re-visited the next time the guidance is revised.
5. "Timeliness for Completion of In-Vivo Cases:" No comment.
6. "Medical Event Definition:" There are methods of blocking off specific artery/capillary with plugs to help direct the microspheres to where they are intended to be placed per the written directive. OAS believes there is technology to direct/control where the microspheres will be deposited, to a degree. Simply put, a medical event needs to be identified when an organ or tissue (treatment site or not) receives greater than 50 rem to AND is 20% or greater than the anticipated dose to that same site if the treatment was delivered as intended in the written directive. A written directive may be modified prior to treatment if a shunting evaluation suggests alternative dose deposition and the AU chooses to proceed, at which point a new dose calculation against the revised shunting evaluation shall be used to determine medical event classifications. Under-dosing due to stasis or emergent patient conditions, if documented, shall not trigger a medical event when more than a 20% dose deviation occurs.

We appreciate the chance to comment on this subject, and stand ready to answer any questions you may have.

Sincerely,

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