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June 24, 2019

Katherine Tapp  
US Nuclear Regulatory Commission  
Washington, DC 20555-0001

Dear Ms. Tapp:

The Organization of Agreement States (OAS) Executive Board (Board) reviewed the Draft Yttrium-90 Microsphere Brachytherapy Licensing Guidance (RCPD-19-006). Fundamentally, the Board believes that there are sufficient Authorized Users (AUs) available to eliminate the alternate pathway. The Board offers the following comments, including comments on the alternate pathway if it is decided to be retained.

1. Page 5, 2. Licensing Guidance: The last sentence states, “If an applicant commits to following the guidance provided below, this applicant shall follow commitments described with the use of the word ‘should’”. If applicants that commit to following the guidance are required to interpret the word “should” as “shall”, it would be clearer if the word “should” be replaced with the word “shall”. For states that require spelling out what they are committing to, the guidance needs to be clearer about what the licensee needs to submit and what is more for informational purposes.
2. Page 7-9, A.1.3. Training and Experience: The draft version requires work experience on how to calculate and measure activity and how to prepare and administer patient dosages but does not require work experience on determining patient dosage. This section no longer includes the sentence “Evaluation of each patient or human research subject for the dose and activity of Y-90 microspheres to be administered to each treatment site” that was formerly listed as A.3.iii.c. in revision 9. Determining the proper patient dosage is one of the AU’s most important responsibilities. The Board believes this sentence should be retained.
3. Page 9, footnotes 4 and 5: Footnotes are the same. Delete 5 and change footnote 6 to 5.
4. Page 9, 4.1 B Training and Experience: Conditional approval for AUs makes licensing very complicated. The Board believes that to the extent possible, the guidance should be written to discourage conditional approval. Limiting conditionally approved AUs to one per license per microsphere product may provide a needed disincentive. If the alternate pathway is retained, the Board believes the NRC should explore other

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*Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin, Wyoming*

mechanisms for AU trainees to get clinical case studies without needing to list the dates on the license of when these cases should be completed, perhaps not listing trainees at all.

5. In the Board's letter of February 8, 2018, comment #5 concerned being able to tell when an Authorized User (AU) completed the 3 patient cases. The Board was concerned that it placed the burden of determining this on the regulator. However, instead of making licensing for Y-90 easier, this revision places even more of a burden on the regulator by 1) listing the date when an AU should complete their patient case work on the license, 2) amending the license when documentation is received that the cases have been completed, 3) amending the license to remove the AU if the cases are not completed in a year, and 4) evaluating documentation if an extension is requested.

The Board concurs with the language in the previous revision: "After more than 10 years of licensing Y-90 microsphere brachytherapy, the NRC has determined that there is a sufficient number of AUs available to supervise physicians who wish to gain AU status for microsphere brachytherapy." The alternate pathway, with its complicated path to AU status, or a simpler method should only be applied within 2 years of the date of the issuance of the licensing guidance.

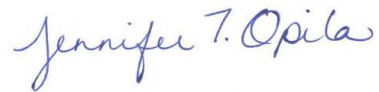
6. Page 9, 4.1.B. Training and Experience: The last sentence in the second paragraph seems to have a typographical error. It states, "Mock simulated cases ... for new or an AU who is authorized for the type of Y-90 microsphere for which the individual is seeking authorization. The word "users" should be inserted between the word "new" and "or".
7. Page 11, 4.3 Training and Experience: "For individuals completing the patient cases following the license amendment, this documentation shall include documentation from the supervising physician of the 3 mock simulated cases..." Should this be changed to reflect the fact that the 3 mock simulated cases can be supervised by a manufacturer representative or a physician (if this pathway is retained)?

There appears to be a typographical error- "Office" should be changed to "Officer" in Radiation Safety Officer.

8. Page 15, 5.3 Medical Event Reporting: This section exempts the licensee from reporting events resulting from shunting when shunting was evaluated prior to treatment. This should be clarified that this only applies to the specific shunting (such as lung shunting) that was identified and evaluated prior to treatment and the AU chose to proceed. This exemption should not apply when the unexpected shunting, not identified during the pre-treatment mapping procedure was present.
9. Page 17, 5.8 Surveys: Please add "of sufficient energy range to detect Y-90 and expected impurities" after "should commit to survey with a radiation detection survey instrument."

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

Sincerely,

A handwritten signature in blue ink that reads "Jennifer T. Opila". The signature is written in a cursive style.

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