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January 15, 2020

Duncan White  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

RE: OAS Board Y-90 comments

Dear Mr. White:

As you know, the Executive Board (Board) of the Organization of Agreement States (OAS) is disappointed with the response to comments document outlining the resolution to a Board comment letter dated June 24, 2019 on the Draft Yttrium-90 Microsphere Brachytherapy Licensing Guidance. There are several issues that the Board felt strongly about that were not addressed. Moreover, we were told that since the guidance was Compatibility D, the NRC was satisfied with their responses and revisions, causing the Board to relax its resistance. Subsequently, the Board learned that the guidance was finalized and that it is in fact Compatibility C, requiring Agreement States to use this guidance as written.

Specifically, the NRC is aware of the Board's aversion to complex licensing requirements in not only this guidance, but broadly for all Training and Education (T&E) requirements. In this guidance document, the main concern was the justification for treating the Y-90 modality differently than other modalities, especially since it has been in use for more than 10 years. The response from the working group was that public comments provided enough justification and that the NRC and OAS did not have data to dispute the claim that there are not enough Authorized Users (AUs). Providing the ML number to those public comments or summarizing them might have helped the Board's understanding. Maybe then the Board would have agreed that these claims were different than the claim that T&E needed to be tailored for certain modalities.<sup>1</sup>

Beyond that, the Board's comments on the Y-90 guidance gave the NRC several compromises to avoid complex licensing actions including: limiting conditionally approved AUs to one per license per microsphere product; exploring other 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; or limiting this alternate pathway to two years after publication of the guidance. Instead, the NRC did not address any of these suggestions; thus, leading to the natural supposition of the Board that the NRC does not value OAS as an equal partner in the National Materials Program. A lot of state personnel time and effort is expended to review these

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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, Vermont*

documents and provide comments; that time may be better spent if their words are so easily discarded.

As the NRC Co-Champion, the Board is confident you understand our frustration. Please allow this letter to serve not only as documentation of disappointment in this case but as a reminder of what might be avoided in future revisions for licensing guidance.

Sincerely,

*Terry W. Derstine*

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<sup>i</sup> The NRC did a comprehensive study on these claims and did not concur.