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February 27, 2012

Ronald E. Zelac, PhD.  
U. S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Subject: Pre-decisional Draft of Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs

Dear Dr. Zelac,

The Organization of Agreement States (OAS) Executive Board (Board) has reviewed the above document and offers the following comments for review by the Nuclear Regulatory Commission (NRC).

1. The OAS Board supports the stated goal of the Commission (SRM-SECY-10-0062) to clarify the medical event definition to protect the interests of the patient, allow physicians to take actions that they deem medically necessary, while continuing to enable the NRC and agreement states to detect failures in process, procedure, and training. The Board does not support using only activity based medical event criteria. It is inconsistent to have one radioactive material therapy treatment that does not utilize dose based criteria. The Board recommends retention of dose based criteria.
2. The Board believes that it is inappropriate for the regulatory agency to define a threshold dose for the adjacent organs such as the bladder, rectum and urethra. The authorized users (AUs) must decide what is acceptable in terms of dose to the other organs. For example, some AUs believe it is acceptable for the urethra to receive up to 400 Rem. Furthermore, if the post implant imaging is not done the same day when there is the ability to visualize the urethra (via catheter), then a dose cannot be calculated. The Board recommends that this criteria be established by the AU and documented in the written directive procedures.

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

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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*

Sincerely,

A handwritten signature in cursive script that reads "Cheryl K Rogers".

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