Presentation of Chris Timmerman, OAS
NRC Commission Meeting on April 24, 2012

Good morning Chairman Jaczko and Commissioners, I am pleased to be here today representing the Organization of Agreement States and briefing you on the Organization's position on the Part 35 Medical Definition as it pertains to permanent implant manual bracytherapy.

There are three primary areas that I will be focusing my time on today. First, I will describe the Organization of Agreement States position on the recently submitted SECY paper 12-0053 on the Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs. Next, I will discuss what some of the Agreement States have done in the interim awaiting guidance from the NRC concerning these types of implants since the inspection of the VA Hospital. Finally, I will cover the work completed by a joint NRC/OAS Working Group tasked to create a supplement to the Inspection Manual Chapter 2800 "Material Inspection Program" and the Inspection Procedure 87132 "Brachytherapy Programs" as based on current Part 35.

The Organization of Agreement States Executive Board has reviewed the SECY paper 12-0053 and supports the stated goal of the Commission (SRM-SECY paper 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. However, the Board does not support using only activity based medical event criteria as recommended in the SECY paper 12-0053. All other therapy treatments utilize dose based criteria, thus, it is inconsistent to have one radioactive material therapy treatment that does not utilize dose based criteria. OAS recommends retention of dose based criteria. If dose based criteria is not retained, OAS requests that the Agreement States be allowed the flexibility to utilize dose based criteria for these types of implants.

The OAS also performed a survey of the Agreement States concerning medical event criteria for prostate brachytherapy implants and 14 states responded. The

results of the survey were briefed at the stake-holder workshops held in New York City and Houston last year as well as at the OAS Annual meeting. All of the 14 states that responded have the same "current" medical event definition as the NRC or a definition that is more restrictive than the NRC's.

Now I will discuss what Wisconsin has done. Wisconsin has inspected the majority of their medical licensees that perform manual brachytherapy implants and all of the licensees have established dose based criteria. These inspections were conducted utilizing the Wisconsin's Information Notice, issued July 21, 2010 which reminded licensees that they are required to have written procedures to verify that each administration is performed in accordance with the provisions of the written directive, and a Regulatory Information Summary, issued February 18, 2011 which detailed additional guidance, requested licensees to respond with the criteria currently used and provided some lessons learned from previous inspections. Additionally, during this time frame Wisconsin completed 29 inspections and compiled the number of implants performed and the number of medical events reported. A retrospective review was conducted by the licensees to determine if any process improvements could be made by the licensees concerning their prostate manual brachytherapy programs. Out of 1970 prostate implants performed (since 2003) there have been only 35 reported medical events, which is 1.78%. Many of the reported medical events could have easily been prevented (i.e. planning errors, not documenting the correct number of seeds, etc.). Therefore, as seen in Wisconsin, if licensees use a dose based medical event definition, there will not be a huge surge of medical events, as some people have projected.

Now moving on to the Joint NRC/OAS working group, it was assembled in August 2011. The working group was comprised of personnel from the Office of Federal and State Materials and Environmental Managements Programs, 2 Agreement States, all NRC Regions, Office of General Counsel, Office of Enforcement and the Division of Intergovernmental Liaison and Rulemaking. As

you may know the Inspection Procedure 87132 is in the final steps of the approval process and the training will be conducted for all NRC Regions and all Agreement States this Thursday April 26, 2012 via webcast and webinar. This training will go over the changes made to the Inspection Procedure based on the "current" 10 CFR 35.40, "Written Directives" and 10 CFR 35.3045, "Report and Notification of Medical Events". This Inspection Procedure will be used until the new Part 35 is finalized.

As the co-chair of the Working Group, the group worked hard to find common ground that would benefit not only the NRC Regions but also the Agreement States as pertaining to inspection guidance for manual brachytherapy programs. In the NRC Regions as well as the Agreement States there is a big difference when it comes to licensees using dose based criteria or activity based criteria or even how licensees are performing these implants. In providing interim guidance for inspectors, we had to work within the constraints of the current rule. We identified some areas that can be improved. The revised rule should define key terms (e.g., Completion of procedure, Prescribed Dose, Administered Dose, Absorbed Dose, etc.) and, unlike the current Part 35, it should use the defined terms consistently throughout the revised rule and associated guidance.

One consistent message from the Working Group is that training and guidance needs to be given to the licensees and the inspectors on the current and new medical event definition.

In closing the OAS would also like to submit the following recommendations concerning the new Part 35 rulemaking process:

- Consider listing Authorized Medical Physicist (AMP) on the license for Manual Brachytherapy based on the Medical Physicist 's involvement with treatment plans and post treatment plans. Similar to the requirement for SR-90 eye applicators;
- Incorporate treatment planning;

- Incorporate post treatment evaluation steps (most licensees do a 30 day follow-up); and
- Do not remove the „total dose" as an option for completion of the Written Directive or at a minimum allow Agreement States flexibility in this area.

Thank you again for allowing me to talk with you today. This concludes my remarks.