



Terry Derstine, Chair, Pennsylvania
David Crowley, Chair-Elect, North Carolina
Jennifer Opila, Past-Chair, Colorado
Beth Shelton, Treasurer, Tennessee
Keisha Cornelius, Secretary, Oklahoma
Sherrie Flaherty, Director, Minnesota
Jenny Goodman, Director, New Jersey
W. Lee Cox, III, Champion, North Carolina

February 26, 2020

US NRC Chairman and Commissioners
U.S. Nuclear Regulatory Commission
Mail Stop O-16 B33
Washington, DC 20555-0001

Dear Chairman Svinicki, Commissioners Baran, Caputo and Wright:

Thank you for the opportunity to present the Organization of Agreement State (OAS) positions at the January 28, 2020 Commission meeting: Discussion on Medical Uses of Radioactive Materials. The OAS Board (Board) hopes this letter will clarify our position and better address some of the questions and topics covered during that meeting. We have separated these into four categories that include: I. Training and Experience (T&E), II. Medical Events (ME) and Abnormal Occurrences (AO), III. Patient Release Criteria, and IV. Organizational Positions.

I. TRAINING AND EXPERIENCE

1. The Board believes there is no data that suggests a shortage of authorized users (AU). This belief is built on the feedback of our members, interactions with licensees, and work by NRC staff and the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Additionally, the National Materials Program (NMP) would provide for one less barrier to new AUs by moving away from evaluation of T&E.

2. The Board fully supports the NRC staff's position as presented in SECY-20-0005, "Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material", specifically that NMP-approved specialty boards are best suited to determine qualifications and competencies of medical personnel. Specialty board requirements and examinations should reinforce knowledge and practices that provide for safety of the patient, workers and the public. Part of the approval for these boards could be verifying a competency-based focus on radiation safety aspects (i.e. dose planning and verification, written directive requirements, medical event criteria, emergency procedures and decontamination, supervised users and roles, reporting, patient release criteria, etc.).

3. When formulating our position, we asked ourselves is there an analogous regulatory body that has such oversight to approve or deny whether a physician can perform a medical function? We are unaware of any and assert the NMP's regulations for authorized users appear unique. This seems to fall under the practice of medicine and is a primary reason for the Board to support changing the T&E regulations.

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, Vermont, Virginia, Washington, Wisconsin, Wyoming

4. The basis for current T&E hours is absent and the required hours are arbitrary. An unintended consequence of these arbitrary requirements was that some specialty boards adopted that criteria into their certification steps. Whether the NMP establishes these criteria or not, those specialty boards must evaluate their own board requirements necessary to train competent medical professionals. If the NRC staff recommendations are followed, then any recognized specialty boards will include strong radiation safety elements.

5. The NMP should be risk informed and consider value added by regulations. Less than 5% of medical events in 2017 and 2018 mention training as a potential related cause. Countless hours are spent by license reviewers to add AUs that are often not physically present during radiopharmaceutical administration. A better approach would be for the NMP to focus on overseeing those individuals actually handling materials, medical devices and the procedures governing administrations.

6. The Board does not advocate for verifying AU credentials during inspections in lieu of adding them through licensing. This would transfer the problem from licensing staff to inspectors and could extend the time needed for medical inspections by several factors. Licensing staff will attest that it is rare when a licensee provides all required credentialing documentation correctly the first time. Reviewing this information during an inspection is not only impractical but may leave facilities with AUs who lack appropriate T&E. The Board believes this would be a step backwards and we maintain that NMP recognized specialty boards are the best option for determining AU qualifications and competency.

7. Evaluating T&E as proposed is truly a rare opportunity, a chance for transformation and evaluation of decades' old practices. We need to consider the idea of making a shift to better align our regulation with the medical policy statement, increase safety focus elsewhere, save limited NMP staff time, and remove a regulatory barrier for new users and materials.

II. MEDICAL EVENTS AND ABNORMAL OCCURRENCES

1. The Board supports maintaining the current ME thresholds. It is understood that many of these do not cause serious health consequences; however, MEs are almost always the result of some error. These errors may be of a human nature, engineering design, or procedural failing. The reporting criteria assists the NMP in evaluating common causes and possible corrective actions. NMP staff can share these lessons with industry and fellow regulators to reduce unintended future events.

2. When actual detriment is caused and the errors require medical attention, those MEs should remain categorized as an AO. The Board recognizes the necessity for distinction between MEs and AOs. MEs are there so that we can fulfill our roles as regulators, but AO criteria exists to highlight hazards to the Commission and Congress over what is causing actual and immediate harm to the public.

3. The Board is happy to hear the Commission has directed an independent review of extravasations. We support the ACMUI's dissenting opinion in their final report, dated October

23, 2019, that MEs are possible by the injection of a radiopharmaceutical into an unintended tissue and should be reported upon occurrence. Whether there is immediate harm or not has no bearing on the reporting criteria; it is only a matter of dose with the current ME rule.

III. PATIENT RELEASE CRITERIA

1. The NMP places a large amount of responsibility on patients to avoid dosing members of the public, but it is up to the AU to determine if those patients will be able to follow those protective instructions. The Board generally agrees with NRC staff, our current regulations adequately protect the population while affording flexibility and discretion to physicians.
2. Where the Board disagrees with NRC staff is in context to the draft Regulatory Guide 8.39 (DG-8057), we believe the 5 mSv limit should be considered for all doses received from a patient over the course of a year, not on a per treatment basis. This would require facilities to evaluate past and future treatments in their release criteria.
3. Prescriptive limits for certain treatments should only be established when there are known thresholds for safety concerns; the questions about insurance and reimbursement are beyond the scope of the NMP.

IV. ORGANIZATIONAL POSITIONS

1. OAS and Conference of Radiation Control Program Directors (CRCPD) sometime differ in their perspective and opinions. This is most likely due to their differing memberships and focus. OAS is comprised of state staff that work on inspecting and licensing radioactive materials; our members make up a large portion of the NMP. The CRCPD is comprised of state staff beyond those who regulate radioactive materials, such as machine sources of radiation, non-ionizing radiation, and nuclear emergency responders. CRCPD also allows affiliate members to join who may be individuals from industry or other non-regulatory organizations.
2. The Board is elected by the Agreement States to represent the majority view of the states. Comments are solicited from all members when crafting a comment letter. If there are disagreements or differing views received, the Board tries to reconcile the differences or encompass those views in comment letters whenever practical.

Please let us know if you have any further questions and we will be happy to provide explanation.

Sincerely,



Terry Derstine, Chair
OAS Board