Meeting Summary: Medical Rulemaking Workshop for Discussion of Topics Related to Medical Part 35 Regulations

The second of two facilitated public medical rulemaking workshops was held on August 11-12, 2011, in Houston, TX. The purpose of the workshop was to solicit key stakeholder input on topics associated with the medical event (ME) definition, including sections involving reporting and notifications of MEs for permanent implant brachytherapy, and other medical issues that are currently being considered for rulemaking. These workshops were initiated as a result of the Commission's direction to staff to work closely with the Nuclear Regulatory Commission's (NRC's) Advisory Committee on the Medical Uses of Isotopes (ACMUI) and the medical community to develop event definitions that would protect the interests of patients. The Commission also directed that these definitions should also allow physicians the flexibility to take actions that they deem medically necessary, while preserving the NRC's ability to detect misapplications of radioactive material and failures in process, procedure and training.

The workshop began with opening remarks from Michael Weber, NRC's Deputy Executive Director for Materials, Waste, Research, State, Tribal and Compliance Programs. He welcomed the distinguished panelists and explained the purpose of the meeting. He also encouraged active participation and highlighted the NRC staff and Commission's interest in better understanding the views and perspectives of the medical and broader stakeholder community on the issues that are under consideration for medical rulemaking.

The workshop featured two separate panels of participants representing the diversity of stakeholders for these issues and was dedicated to panel presentations and discussions. The panelists included representation from the NRC's ACMUI, the Organization of Agreement States (OAS), professional societies, and a patients' rights advocate. Following Mr. Weber's opening remarks, each panelist gave a presentation on their perspectives on the following topics delineated in the May 20, 2011, *Federal Register Notice* (76 FR 29171): ME definition association with permanent implant brachytherapy, amending preceptor attestation requirements, extending grandfathering to certified individuals, naming associate/assistant radiation safety officers (RSOs) on an NRC medical-use license, additional molybdenum breakthrough testing and reporting requirements, and additional 10 CFR 35 items under consideration for rulemaking. The presentations were followed by discussions of the topics amongst the panelists, after which, audience members including those present via webinar/teleconference, were given the opportunity to make comments, offer input on each topic item, and ask questions of the panelists.

The first day of the workshop was devoted to panel presentations and a panel discussion on the medical event definition as it relates to permanent implant brachytherapy. A wide variety of perspectives and views were expressed. The following key messages or themes were conveyed during the discussions:

- Among the States, there are fairly consistent regulations, but there can be wide variance among a few States in the interpretation and implementation of those regulations. This may warrant the need for training of licensees as well as regulators. Also, it was noted that none of the States that had recently responded to an OAS questionnaire advocated for a ME definition based upon total source strength (or activity).

- All of the panelists, except for the OAS representative, recommended that the definition of medical events as it relates to permanent implant brachytherapy needs to be revised,

and it should be based upon total source strength (activity) and not absorbed dose. If the definition is based upon total source strength, then a tolerance of ± 20% is reasonable. Contrary to the comments received at the New York workshop, participants were not in support of an absorbed dose criterion being appropriate for defining a ME for unintended organs and tissue. In fact some of the participants stated that the dose to unintended organs and tissue should not be under the purview of the regulators, and that the related section in 10 CFR Part 35.3045 should be eliminated.

- Several of the panelists stated that, for prostate implants in particular, absorbed dose is very difficult to quantify and is a very subjective value.

- Many of the panelists agreed that the "D-90" value poorly predicts clinical outcomes, lacks precision, and should not be used for regulatory purposes.

- The term "Medical Event" should be reserved for those instances where there is real harm to the patient or a potential for same (clinically significant). If the regulators need to capture less serious events, then there should be more than one category so that serious events can be distinguished from "near misses."

- Licensee staff should be trained in the policies and procedures for identifying MEs.

- The patients' rights advocate panelist stated that the patient/doctor relationship is changing, and that many patients today view themselves as "medical service consumers." This change in attitudes suggests that more and more individuals wish to share in the decision-making process when their personal medical care is being discussed and considered. Therefore, more information, not less, should be shared.

- The Authorized User (AU) should be required to attest in writing that the distribution of seeds within the target volume was implanted as intended. Participants were in support of requiring post implant imaging.

The second day of the workshop was devoted to panel presentations and a panel discussion on preceptor attestation requirements and extending grandfathering to certified individuals, as well as NRC staff presentations on other medical rulemaking topics including – naming associate/assistant RSOs, and molybdenum breakthrough requirements. Additionally, the 10 CFR 35 preliminary draft proposed rule language that was made publicly available at the beginning of the workshop was discussed. The following key messages or themes were conveyed during the discussions:

- NRC should remove the requirement for attestation for board certified AUs, Authorized Medical Physicists, RSOs, and Authorized Nuclear Pharmacists (ANPs). Board Certification coupled with the "recentness of training" requirement should be sufficient for the regulator's needs. Also, the elimination of attestation for Board certified individuals does not eliminate the issues surrounding the need to extend grandfathering to certain certified individuals.

- There should be no requirement for attesting to someone's competency, but rather preceptors should be attesting to someone's training and experience necessary to carry out one's responsibilities independently. The general consensus was that maintenance

of board certification is important for all medical professionals as it covers activity of the licensee, training, and recentness in the field, and it demonstrates competency.

- NRC should allow for the naming of associate/assistant RSOs on an NRC medical-use license. There should be no arbitrary limit placed on the number that can be so named. Also, what the additional individuals are called matters because certain terms have particular meaning, so some care needs to be exercised here.

- There should be a new requirement for testing each Mo-99/Tc-99m generator elution (not just the first elution), but there should not be a requirement for NRC licensees to be required to report failures to NRC. Also, the rules in this area should be generic, and not reference particular radiopharmaceuticals.

During the final session on the second day, an NRC staff person from the Division of Intergovernmental Liaison and Rulemaking (DILR), led the participants through a review of the 10 CFR Part 35 preliminary draft proposed rule language. The following were key points of discussion for the language in specific sections:

- 35.13(h) regarding access to the sealed source and device (SS&D) registry;
- 35.14(b)(6) regarding the need to identify the activity of each source or maximum activity that is not to be exceeded;
- 35.65 regarding the removal of transmission sources and including it in 35.500;
- 35.65 regarding the need for bundling and aggregation of single sources defined with respect to risk;
- In 35.290, consider the removal of training requirements that AUs must be required to elute generators;
- In 35.390, consider a separate category for parenteral administrations, but not specify a separate provision for alpha emitters;

The NRC staff considers the workshop to have been very successful in soliciting key stakeholder input on a variety of Part 35 topics. NRC staff received substantive and useful comments and suggestions from key stakeholders representing the broad range of medical licensees, the ACMUI, the States, and other stakeholders.

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Documents relevant to the workshop, including transcripts, are posted on the following web-site: http://www.blsmeetings.net/NRCMedicalRulemakingWorkshop/.