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

The first of two facilitated public medical rulemaking workshops was held on June 20-21, 2011, in New York, NY. 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 U.S. 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 the Office of Federal and State Materials and Environmental Management Programs (FSME) Acting Office Director, Cynthia Carpenter. She welcomed the distinguished panelists and explained the purpose of the meeting. She 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, Agreement States, professional societies, and a patients' rights advocate. Following Ms. Carpenter'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.

- 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 $\pm$ 20% is reasonable, albeit arbitrary. Participants were in support of an absorbed dose criterion being appropriate for defining a ME for unintended organs and tissue.

- Only one participant during the first day of the workshop expressed support for the medical event definition based on both activity and absorbed dose. This participant also supported reporting of minimum and maximum activity of individual seeds.

- 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." NRC needs to consider either using another term instead of ME or having different categories of MEs that separate the near miss events from the egregious events. Licensee staff should be trained in the policies and procedures for identifying MEs. There was no support for this type of training to be a new regulatory requirement.

- The patients' rights advocate panelist stated that patients need to be aware of anything that could impact their health, their chances of cure, and their chances of side effects. It is critically important that the interests of the patient are always put first. Also, regardless of what criteria are ultimately decided upon for reporting a ME, the patient should be informed of the ME.

- 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. There was less consensus about when this imaging should be required. A panel member said that the post implant evaluation timeline should be based on the edema half-life, which is typically within a 60-day limit. Another panelist said that violations involving requirements for post implant dosimetry should be minor violations and not medical events.

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 in advance 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.

- 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.

- AUs and ANPs should be allowed to become RSO for small licensees (e.g. private practices).

- 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. The stakeholders were fairly unanimous in stating that any licensee that identified a problem would immediately notify the generator vendor/manufacturer, and the manufacturers are regulated by the FDA and NRC. They identified that the manufacturer and the licensee have a reliable and efficient process currently in place to respond to events, and there is no need for a reporting requirement to the NRC or any regulatory oversight in this area. There was a question raised regarding the change in the definition of byproduct material and the effect on other types of generators like Actinium generators.

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) with respect to the need to identify the activity of each source or maximum activity that is not to be exceeded;
- 35.50 and other relevant sections with respect to a re-write if attestation is removed;
- 35.65 with respect to 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 addition, the differences in training requirements if 35.200 users are included in 35.500;
- In 35.290, consider the removal of training requirements for professionals using eluding generators;
- In 35.390, specify the basis to include a separate provision for alpha emitters;
- If 35.500 is changed to include transmission sources, a change will also need to be made in 35.590 and 35.290, with respect to additional education requirements that apply only to transmission sources.

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. The second workshop will be held at the Houston Marriott at the Texas Medical Center, August 11-12, 2011.

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