The U.S. Nuclear Regulatory Commission's Consideration of Potential Changes to Medical Event Reporting Requirements for Permanent Implant Brachytherapy and Other Medical Issues Being Considered for Rulemaking

The U.S. Nuclear Regulatory Commission (NRC) will be holding a series of public workshops to solicit 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.

In a Staff Requirements Memoranda (SRM-SECY-10-0062), the Commission specifically directed staff to work closely with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and the broader medical and stakeholder communities to develop event definitions that will protect the interests of patients, and allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the agency to detect failures in the process, procedure, and training as well as any misapplication of byproduct materials by authorized users. In addition to the ME definition, the NRC staff believes it is beneficial to the development of the proposed rulemaking language to discuss a number of other medical issues that are currently being considered for rulemaking.

The facilitated workshops will specifically cover the following issues:

- medical event definition associated with permanent implant brachytherapy,
- relaxation of preceptor attestation requirements and extending grandfathering to certain certified individuals (Ritenour Petition),
- naming associate/assistant radiation safety officers (RSOs) on NRC medical licenses,
- additional molybdenum breakthrough testing and reporting requirements,
- additional items under consideration for rulemaking as identified in the *Federal Register* Notice (FRN).

The first workshop will be held on June 20-21, 2011, in New York, NY. The NRC also plans to hold a second meeting in August 2011 in Houston, TX. The specific dates and location will be posted at http://www.blsmeetings.net/NRCMedicalRulemakingWorkshop/ when the information becomes available. Each of the meetings will include a panel of participants, who are being selected in a convening process to represent the diversity of stakeholders. In addition to the panel, the NRC is encouraging attendance and participation by all interested individuals. The meeting agenda will specifically include opportunities for viewpoints to be expressed from individuals in attendance who are not members of the panel. The NRC plans to transcribe the meetings.

The FRN announcing the meeting is currently under development, and can be found at www.regulations.gov , when it is published. This notice will include details on the background leading to this request for comments, the issues that have been identified, and questions that have been posed by the NRC staff for consideration.

Information about the specific meeting venues, hotel accommodations, and access to public transportation is available on the Location/Lodging page, http://www.blsmeetings.net/NRCMedicalRulemakingWorkshop/location.cfm . We encourage you to keep checking the workshops' Web site, http://www.blsmeetings.net/NRCMedicalRulemakingWorkshop/ , for the most current agenda and links to subsequent documents as they become available. Documents relevant to the workshop will also be continually posted on this site.

If you need further information, please contact Mr. Varughese Kurian of the NRC staff at Varughese.Kurian@nrc.gov or 301-415-7426.