U.S. Nuclear Regulatory Commission Public Meeting Summary

October 8, 2014

Title: Part 35 Proposed Rule

Meeting Identifier: 20141609

Date of Meeting: Wednesday, October 8, 2014

Location: NRC Complex, 3WFN-1C05, Rockville, Md.

Type of Meeting: Category 3

Purpose of the Meeting:

The purpose of the meeting was to promote understanding of the NRC's proposed rule amending the regulations related to the medical use of byproduct material in 10 CFR Parts 30, 32 and 35. The NRC published the proposed rule in the *Federal Register* (79 FR 42410) on July 21, 2014 for a 120 day comment period. The purpose of the meeting was also to discuss the associated draft guidance and the NRC's process for submitting public comments.

General Details:

The NRC staff conducted a public meeting/webinar beginning at 10:00 a.m. eastern standard time (EST) to discuss the Part 35 proposed rule and the associated guidance documents. The meeting was webcasted, and recorded. The meeting was scheduled from 10:00 a.m. - 5:00 p.m. EST, but was over at about 4 p.m.

Mr. Lance Rakovan, who is an NRC in-house facilitator, facilitated the meeting. Mr. James Danna, NRC, in the opening remarks stated that there has been a considerable outreach with the medical community in developing the proposed amendments which included: interactions with the Advisory Committee for the Medical Uses of Isotopes, the Agreement States, public workshops, and posting of some preliminary rule text to develop this rulemaking. Mr. Danna also stated that the proposed amendments are consistent with the Commission's Medical Use Policy Statement, published in August 2000. In that, the rule balances the interests of the patient with the flexibility needed by the authorized physicians to take the actions that he or she deems medically necessary, while continuing to enable the NRC to detect deficiencies in processes, procedures, and any misapplication of byproduct material.

Mr. Rakovan provided the meeting logistics and the ground rules. After that, the NRC staff made presentations on the various amendments proposed in the proposed rule. Meeting participants were encouraged to ask questions at the end of each presentation.

There were approximately 60 attendees at the meeting; 39 remotely on the webinar/webcast and 22 physically located in the room. The attendees included: radiation safety officers,

medical physicists, representatives of the American Association of Physicists in Medicine, American Society of Therapeutic Radiology, Agreement States, and NRC staff.

Summary of Presentations:

The NRC is considering amendments to the regulations related to the medical use of byproduct material. On July 21, 2014, the NRC published a proposed rule in the Federal Register (79 FR 42410) for public comments. The website to access the proposed rule and to submit comments is http://www.regulations.gov (Docket ID NRC-2008-0175). Send comments by email to: rulemaking.comments@nrc.gov. Comments on the proposed rule and the guidance documents should be submitted by November 18, 2014.

The presentations provided an overview of all the 3 rulemaking projects that are included in the proposed rule. These are:

1. Proposed changes for permanent implant brachytherapy;
2. The expanded rulemaking(e.g., preceptor attestations, Associate Radiation Safety Officers, reporting of failed generators, and several clarifications); and
3. The issues raised in the Ritenour petition (PRM-35-20).

The presentations also included the background, and the history of the rule development. One presentation discussed the Agreement State Compatibility for medical event reporting. In addition, the meeting had a presentation dedicated to the conforming guidance documents. The last presentation focused on the specific issues that NRC is requesting comments on, and how to submit comments. The presentations are located in the Agencywide Documents Access and Management System (ADAMS), Accession No. ML14279A058.

Public Participation Themes:

Members of the public were encouraged to ask questions throughout the presentations. Here are some examples of the questions asked at the meeting:

- Will the proposed changes for permanent brachytherapy apply to yttrium-90 microspheres treatments – they will not apply;
- How should a licensee perform the assessment within 60 days after source implantation – the NRC does not have prescriptive requirements for the assessment;
- Does patient unavailability require written notification to the NRC - documentation of patient unavailability should be maintained at the licensee's site for review during the next inspection;
- Does the NRC have a definition for "treatment site" – this term is defined in 10 CFR 35.2;
- Confusion about the use of the term "contiguous" in the phrase "absorbed dose to the maximally exposed 5 contiguous cubic centimeters;" does this mean normal tissue directly adjacent to the treatment site – contiguous refers to a single, connected mass of normal tissue; and

- Confusion about use of the term “modalities” in the request for specific comments on whether the application of the proposed medical event definition for normal tissue during permanent brachytherapy is appropriate for all modalities – staff believes the Commission’s intent was to ask if the definition is appropriate for all treatment sites;

NRC staff encouraged meeting participants to submit the same questions and comments in writing during the public comment period for the proposed rule.

The meeting was recorded. The recording is being converted to a written transcript and will be posted at the federal rulemaking website, http://www.regulations.gov (Docket ID NRC-2008-0175).

Action Items/Next Steps:

After the public comment period closes on November 18, 2014, the NRC staff will begin work on the final rule package.

Attachments:

- Meeting agenda - ADAMS Accession No. ML14254A343
- NRC staff presentations - ADAMS Accession No. ML14279A058