Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

Medical Use of Byproduct Material; Workshop

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of workshop.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is continuing the process of developing a proposed revision of its regulations governing the medical use of byproduct material in 10 CFR part 35, ''Medical Use of Byproduct Material.'' Throughout the development of the proposed rule the Commission solicited input from the various interests that may be affected by these proposed revisions. The proposed rule was published in the **Federal Register** on August 13, 1998 (63 FR 43516), for a 90-day comment period, which was later reopened to December 16, 1998. During the public comment period, several public meetings were held to discuss major issues, such as training and experience requirements, that are being addressed during the rulemaking. The Commission is now soliciting specific information on the implementation issues associated with the proposed revisions to the training and experience requirements. To that end, a public workshop is being convened to obtain comments and recommendations on implementation issues from affected parties. Francis X. Cameron, Special Counsel for Public Liaison, in the Commission's Office of the General Counsel, will be the convener and facilitator for the workshops.

DATES: The workshop will be held on February 17, 1999, from 9 a.m. to 4:30 p.m. and on February 18, 1999, from 9 a.m. to 12 noon.

ADDRESSES: This workshop will be held at the NRC Headquarters Office, 11555 Rockville Pike, Rockville, Maryland

Members of the public who are unable to attend the workshop can send comments to Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff.

FOR FURTHER INFORMATION CONTACT: Francis X. Cameron, Special Counsel for Public Liaison, Office of the General Counsel, U. S. Nuclear Regulatory Commission, Washington DC 20555, Telephone: 301–415–1642, e-mail fxc@nrc.gov.

SUPPLEMENTARY INFORMATION: After a comprehensive review of its medical use program, the Commission directed the staff to revise 10 CFR part 35, associated guidance documents, and, if necessary, the Commission's 1979 Medical Policy Statement (Staff Requirements Memorandum (SRM)—COMSECY–96–057, ''Materials/Medical Oversight'' (DSI–7), dated March 20, 1997). The Commission specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation by June 1999. The revision is intended to:

(1) Focus the regulations on those medical procedures that pose the highest risk, from a radiation safety aspect, with a subsequent decrease in the oversight of low-risk activities;

(2) Focus on those requirements that are essential for patient safety;

(3) Initiate improvements in NRC's medical program, by implementing recommendations from internal staff audits, other rulemaking activities, and results of analyses in medical issues papers;

(4) Incorporate regulatory requirements for new treatment modalities; and

(5) Reference, as appropriate, available industry guidance and standards.

The program for revising part 35, associated guidance documents, and the Medical Policy Statement has provided more opportunity for input from potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. Based on the worthwhile public input received earlier in the rulemaking process, the Commission is now soliciting additional comments on implementation issues associated with the proposed revisions to the training and experience requirements. The proposed training and experience requirements appear in subparts B, D–F, and H, and Appendix A of the proposed rulemaking (63 FR 43516; August 13, 1998). The Commission is specifically interested in information on the process and criteria for approving boards and examining organizations or entities. Such information includes how the boards would implement the training and experience requirements; how the boards would implement the requirements in Appendix A for examining organizations and entities; and what are the resource implications of these proposed actions? Accordingly, the Commission is convening a public workshop where representatives of the interests that may be affected by the proposed changes in the training and experience requirements will have an opportunity to discuss implementation of these requirements. Although the meeting is intended to foster a clearer understanding of the positions and concerns of the affected interests, as well as to identify areas of agreement or disagreement, it is not the intent of the meeting to develop a consensus agreement of the participants on the rulemaking issues.

To have a manageable discussion, the number of participants at the workshop will be limited. The Commission, through the facilitator for the meeting, will attempt to ensure participation by the broad spectrum of interests that may be affected by the rulemaking. Other members of the public are welcome to attend, and the public will have the opportunity to comment on the issues and the meeting discussions at periodic intervals during the workshop. Questions about participation may be directed to the facilitator, Francis X. Cameron. The agenda for the workshop will focus on:

(1) The impact, on the medical community, of the proposed revisions to the training and experience criteria; and

(2) The process and criteria used by NRC to approve certifying boards and examining organizations.

Dated at Rockville, Maryland this 28th day of January, 1999.

For the Nuclear Regulatory Commission.

Donald A. Cool,

Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards.

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