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 Nuclear Regulatory Commission has initiated a rulemaking for a comprehensive revision to its regulations governing the medical use of byproduct material in 10 CFR part 35. As part of this rulemaking, the Commission intends to solicit the active input of the various interests that may be affected by the rulemaking early in the rulemaking process. One of the mechanisms that will be used to obtain the comments and recommendations from affected interests will be the convening of workshops to discuss the fundamental approaches and issues that must be addressed in the revision of 10 CFR part 35. A workshop on NRC's medical rulemaking initiative will be held during the Organization of Agreement States' All Agreement States Meeting in Los Angeles, California.

DATE: The workshop will be held on October 18, 1997, from 8:30 a.m. to 2:15 p.m.

ADDRESS: The Westin LAX Hotel, 5400 W. Century Blvd., Los Angeles, CA 90045.

FOR FURTHER INFORMATION CONTACT: Cathy Haney, U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, telephone (301) 415–6825, e-mail cxh@nrc.gov.

SUPPLEMENTARY INFORMATION: The NRC has examined the issues surrounding its medical use program in great detail during the last four years. This process started with NRC's 1993 internal senior management review report; continued with the 1996 independent external review report by the National Academy of Sciences, Institute of Medicine; and culminated in NRC's Strategic Assessment and Rebaselining Project (SA). In particular, medical oversight was addressed in the SA Direction-Setting Issue Paper Number 7 (DSI 7) (released September 16, 1996). In its ''Staff Requirements Memorandum (SRM)—COMSECY–96–057, Materials/Medical Oversight (DSI 7),'' dated March 20, 1997, the Commission directed the NRC staff to revise Part 35, associated guidance documents, and, if necessary, the Commission's 1979 ''Medical Policy Statement.'' The Commission SRM specifically directed the restructuring of part 35 into a risk-informed, more performance-based regulation.

A June 30, 1997, SRM informed the NRC staff of the Commission's approval, with comments, of the NRC staff's proposed program in SECY–97–131, Supplemental Information on SECY–97–115, Program for Revision of 10 CFR part 35, ''Medical Uses of Byproduct Material,'' and Associated **Federal Register** Notice,'' dated June 20, 1997.

After Commission approval of the NRC staff's program to revise 10 CFR part 35 and associated guidance documents, the NRC staff initiated the rulemaking process, as announced in 62 FR 42219 (August 6, 1997). The rulemaking is being conducted using a group approach. A Working Group and Steering Group consisting of representatives of NRC, Organization of Agreement States(OAS), and Conference of Radiation Control Program Directors have been established to develop rule text alternatives, rule language, and associated guidance documents. State participation in the process is intended to enhance development of corresponding rules in State regulations, to provide an opportunity for early State input, and to allow State staff to assess potential impacts of NRC draft language on the regulation of non-Atomic Energy Act materials used in medical diagnosis, treatment, or research, in the States.

As directed by the Commission, the NRC staff has developed alternatives, with draft regulatory text, for the more significant issues associated with the regulation of the medical use of byproduct material. These alternatives to regulation in specific areas are intended to help focus the discussion during workshops and meetings during the Fall of 1997 and to assist the NRC staff in developing the text of the proposed rule. Alternative regulatory text has been developed for: (a) The quality management program; (b) training and experience for authorized users, radiation safety officers, and medical physicists; (c) radiation safety committee; (d) patient notification of reportable events; and (e) the threshold for reportable events. The alternatives represent a broad range of possibilities and are being provided to stimulate input from members of the public in an effort to encourage all interested parties to provide input into the development of the revised regulation. The staff has not selected any alternatives at this time and is open to additional alternatives that might be proposed, which are consistent with the guidance provided by the Commission.

The OAS workshop will be open to the public, on a space available basis. The agenda for the workshop will focus on discussion of the above regulatory issues, but will also provide enough flexibility for the public to have an opportunity to comment on related rulemaking issues. Members of the public who are unable to attend the workshop can obtain copies of the papers developed by the staff through NRC's Public Document Room (U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555–0001) or on the Internet via NRC's Technical Conference Forum (http://techconf.llnl.gov/noframe.html).

Dated at Rockville, Maryland this 2nd day of October, 1997.

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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