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; Workshops

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of workshops.

SUMMARY: The Nuclear Regulatory Commission has initiated a rulemaking for a comprehensive revision of 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 part 35. The first NRC public workshop will be held in Philadelphia, Pennsylvania on October 28, 29, and 30, 1997. The second NRC public workshop will be held in Chicago, Illinois on November 12, 13, and 14, 1997. Both workshops will be open to the public. 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 first workshop will be in Philadelphia on October 28, 1997, from 9 a.m. to 5 p.m.; October 29, 1997, from 8:30 a.m. to 5 p.m.; and October 30, 1997, from 8:30 a.m. to noon. The second workshop will be in Chicago on November 12, 1997, from 9 a.m. to 5 p.m.; November 13, 1997, from 8:30 a.m. to 5 p.m.; and November 14, 1997, from 8:30 a.m. to noon.

ADDRESSES: The Philadelphia workshop will be held at the Korman Suites Hotel, 2001 Hamilton Street, Philadelphia, PA 19130, 215–569–7000. The Chicago workshop will be held at the Ramada Congress Hotel, 520 South Michigan Avenue, Chicago, IL 60605, 312–427–3800.

FOR FURTHER INFORMATION CONTACT: Francis X. Cameron, Special Counsel for Public Liaison, Office of the General Counsel, Nuclear Regulatory Commission, Washington D.C. 20555, Telephone: 301–415–1642.

SUPPLEMENTARY INFORMATION:

Background

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 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 staff of the Commission's approval, with comments, of the 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 staff's program to revise part 35 and associated guidance documents, the 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, the Organization of Agreement States, and the 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 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 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. In addition, alternative recommendations for revision of NRC's 1979 Medical Policy Statement have been developed. 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 contribute to 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.

Workshops

The Commission believes that it is important for interests affected by the medical use rulemaking to not only have an early opportunity to comment on the rulemaking issues, but also to have an opportunity to discuss the rulemaking issues with one another and the Agency. Accordingly, the Commission is convening two public workshops where the representatives of the interests that may be affected by the rulemaking will have an opportunity to discuss the rulemaking issues. Although the workshops are 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 workshop process to develop a consensus agreement of the participants on the rulemaking issues.

To have a manageable discussion, the number of participants in each workshop will be limited. The Commission, through the facilitator for the workshop, will attempt to ensure participation by the broad spectrum of interests that may be affected by the rulemaking. These interests include: Nuclear medicine physicians; physician specialists, such as cardiologists and radiologists; medical physicists; medical technologists; nurses; medical education and certification organizations; radiopharmaceutical interests; hospital administrators; patients rights advocates; Agreement States; Federal agencies; and experts in risk analysis. Other members of the public are welcome to attend, and the public will have the opportunity to comment on the rulemaking issues and the workshop discussions at periodic intervals during the workshops. Questions about participation may be directed to the facilitator, Francis X. Cameron.

To ensure that each workshop addresses the issues in a consistent manner, the workshops will have a common pre-defined scope and agenda focused primarily on the alternatives, with draft regulatory text, developed by the Part 35 Working and Steering Groups. However, the workshop format will be sufficiently flexible to allow for the introduction of additional related issues that the participants may want to raise. The workshop commentary will be transcribed and made available to the participants and the public.

Copies of the issue papers developed by the staff will be provided to the workshop participants. Also, copies will be available for members of the public in attendance at the workshops, as well as available through NRC's Public Document Room (U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555–0001) and on the Internet via NRC's Technical Conference Forum (http://techconf.llnl.gov/noframe.html).

Public input is solicited during the development of the proposed rule but, to be most helpful, should be received by March 1, 1998. Comments received after this date will be considered if it is practical to do so, but the Commission only is able to ensure consideration of comments received on or before this date. Written input and suggestions can be sent to Secretary, Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff. Hand-deliver comments to 11555 Rockville Pike, Rockville, MD, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

Dated at Rockville, Md., this 6th 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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NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150–AE38

Acceptability of Plant Performance for Severe Accidents; Scope of Consideration in Safety Regulations

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking: Withdrawal.

SUMMARY: The Nuclear Regulatory Commission (NRC or Commission) is withdrawing an advance notice of proposed rulemaking that outlined alternative approaches to generic regulation addressing the challenges from severe accidents for future light water reactors. The Commission has decided that a rule change to provide generic requirements for performance during postulated severe accidents is not warranted at this time. The basis for this decision is that a purpose for the rule was to provide guidance for future designs and to facilitate then ongoing design certification rulemaking. With all current design certification rulemaking either complete or nearing completion and future applicants not foreseen, expenditure of the resources to promulgate the rule is not warranted.

FOR FURTHER INFORMATION CONTACT: Charles E. Ader, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–5622.

SUPPLEMENTARY INFORMATION: On September 28, 1992, (57 FR 44513), the Commission published an advance notice of proposed rulemaking (ANPRM) to consider amending its regulations to provide generic requirements to address the challenges from severe accidents for future light water reactors. The advance notice of proposed rulemaking outlined three alternative approaches to the specification of requirements addressing severe accident performance. The first alternative, described as a hardware oriented rule, would specify reasonable design features or design characteristics directed towards prevention or mitigation of explicitly identified risk significant phenomena. The risk significant phenomena identified were: hydrogen generation, transport and combustion, high pressure melt ejection, core concrete interactions and basemat ablation, long term containment overpressurization, steam explosions from fuel-coolant interactions, and containment bypass. These phenomena represent the potential contributors to containment failure or bypass and thus the mechanisms for large offsite radioactive release. Alternative 2, described as a phenomena oriented rule, was a modification of the first alternative wherein an overall containment performance goal would be specified along with the phenomena to be considered, as identified above. The designer would then be required to perform analyses of the impact of those phenomena and develop and propose the design features to meet the goal. Regulatory guides would address analytical methods, acceptance criteria and design criteria for hardware. This approach, similar to Alternative 1, would be an overlay on the existing design basis specified in 10 CFR part 50 and justified on an enhanced safety basis. The third alternative, described as a general design criteria (GDC) oriented rule, involved development of a set of new design requirements to address specific challenges and issued as changes to Appendix A, ''General Design Criteria'' to 10 CFR part 50. Each new design criterion would describe the nature of the challenges as well as the success criterion and involve the development of Regulatory Guides to provide additional guidance on analysis methods and assumption. This approach was similar to the other alternatives, especially Alternative 2, but differs in that the existing 10 CFR part 50 design basis would be modified to include severe accidents.

A primary purpose for the generic severe accident rulemaking was to add consistency and standardization to the resolution of severe accident issues for future designs based on current technical information. While, in general, consistency among many design reviews is best achieved through generic rules, as a practical matter, since the number of new applicants is likely to remain quite limited, it is more efficient to proceed with design-specific reviews. In fact, the Commission is not aware of any new applicants in the foreseeable future.