SECY-98-263

November 9, 1998

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

SUBJECT: PROPOSED RULE: REVISION OF 10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL

PURPOSE:

To provide the Commission with early feedback on significant concerns raised at the public meetings on the proposed revision of 10 CFR Part 35, "Medical Uses of Byproduct Material;" to obtain Commission direction on performing a risk assessment on the medical uses of byproduct material and extending the public comment period; and to request a "point of contact" from each Commission office for this rulemaking.

BACKGROUND:

In its Staff Requirements Memorandum (SRM) - COMSECY-96-057, "Materials/Medical Oversight (DSI 7)," dated March 20, 1997 (Attachment 1), the Commission directed the revision and restructuring of Part 35 into a risk-informed, more performance-based regulation, (i.e., focus Part 35 on those procedures that pose the highest risk, from a radiation safety standpoint). Therefore, during the development of the regulation, the staff considered information on risk provided by members of the public and professional societies, professional medical standards of practice, and event databases maintained by NRC, to determine where oversight of low-risk activities could be decreased and where there needed to be continuation, or even broadening, of the regulations governing high-risk activities. As a result of these considerations, staff believes that the proposed rule is risk-informed and in accordance with both the Commission's direction and the strategy and goals for nuclear materials safety outlined in Strategic Plan: Fiscal Year 1997-Fiscal Year 2002 (pp.9-12, September 1997)..

CONTACTS: Catherine Haney, NMSS/IMNS
(301) 415-6825
Diane S. Flack, NMSS/IMNS
(301) 415-5681

Throughout the development of the proposed rule and associated guidance, public workshops were held and opportunities for comment from potentially affected parties were provided, which are not provided by the typical notice and comment rulemaking process. The Federal Register notice for the proposed rulemaking summarized comments received during the developmental stages and noted that there would be a 90-day public comment period that closes on November 12,1998 (63 FR 43515, August 13, 1998).

During the public comment period on the proposed rule, significant regulatory issues have been discussed at facilitated public workshops in San Francisco, Kansas City, and Rockville, between August and October 1998. In addition, these issues were discussed at a Part 35 workshop held in conjunction with the All Agreement States Meeting in October 1998. Summaries of the comments made at the facilitated public meetings have been prepared for the meetings held in San Francisco and Kansas City (Attachment 2). The summary of the Rockville meeting is being prepared and will be forwarded under separate cover. Transcripts of the facilitated public meetings and the workshop are available on the NRC rulemaking website. At the Rockville meeting, the participants specifically requested that two of their concerns -- the need for a risk assessment and extension of the public comment period -- be forwarded to the Commission before the end of the comment period.

On October 30, 1998, a formal request for an extension of the comment period, to allow for the development of the risk analysis and rule accordingly, was submitted to Chairman Jackson by eight professional organizations (Attachment 3). The letter indicates that the 90-day comment period provides ". . . insufficient time to offer meaningful comments on the proposal. . . ." It also states that "Concern was raised that the current activity surrounding risk analysis (the uncompleted report from the Nuclear Byproduct Material Risk Review Group) is not adequate." These organizations offer to ". . . present to the Commission a proposal that describes in detail the type of risk analysis that [they] believe must be performed along with an estimate of the time involved." Finally, the request states that ". . . operating under the existing rules on a temporary basis, in order to develop an appropriate replacement, is preferable to an incomplete and unsupported proposed regulation." The Agreement States endorsed this letter at the recent All Agreement States Meeting.

DISCUSSION:

SIGNIFICANT CONCERNS STATED DURING THE MEETINGS INCLUDED:

- **Risk assessment**: Some participants believed that NRC has not adequately assessed the risk of the various modalities for medical use because a formal risk assessment was not done. Three major comments were made on the need for a risk assessment: (1) NRC has not fully accounted for the low risk in diagnostic nuclear medicine; (2) relative risk must be considered because risk can occur from both action and inaction in medicine; and (3) NRC should perform a risk assessment, with stakeholders involved in the selection of the methodology, and publish the results for comment before it proceeds with any revision of its medical use program.

- **Comment period**: The majority of the participants at the public meeting believed that: (1) the 2-year period for revising the rule and associated guidance did not provide enough opportunity for them to provide input and work with the staff in developing the rulemaking; and (2) the 90-day

public comment period was too short to review, thoroughly understand, and comment on such a major rulemaking. Although the comment period is longer than the minimum 75-day comment period, the participants noted that the comment period for Part 35 is no longer than for less significant rulemakings. In addition, some participants stated that the schedule for the rulemaking should include re-publication of the proposed rule after it has been revised to incorporate the public comments.

- **Training and experience**: Issues ranged from the broad issue of whether NRC should specify the number of hours of training for various individuals, to modality-specific issues presented by medical specialists (e.g., endocrinologists and cardiologists).

- **Board certification**: Issues include the proposed criteria to review medical specialty boards that want to be examining organizations, and the current process used by boards to approve individuals.

- **Radiation Safety Committee**: Concerns were raised over the proposed deletion of the requirement for a Radiation Safety Committee (RSC), because some participants believe the RSC is imperative for effective implementation of a licensee's radiation safety program.

OPTIONS FOR COMMISSION DIRECTION ON THE NEED TO PERFORM A RISK ASSESSMENT AND TO ADJUST THE SCHEDULE FOR THE RULEMAKING:

Option 1: Status quo: Proceed with proposed rulemaking as approved in SRM-98-128.

Pros: Maintains current schedule to revise, restructure, and update Part 35 (e.g., allows for timely incorporation of regulations for therapy modalities and emerging technologies that are not specifically addressed in the current rule).

Current schedule allows time for staff to meet with both the full ACMUI and the ACMUI diagnostic and therapeutic subcommittees to discuss the technical content of the rule. Meetings with the subcommittees proved very valuable in the development of the proposed rule, because these meetings provided opportunities for discussions on specific modalities and requirements. Staff would continue to use risk information to determine appropriate changes to specific provisions of the proposed rule as part of the analysis of the comments.

Cons: Not responsive to stakeholders' request to extend the public comment period.

Allows less opportunity for stakeholders to review the proposed rule and identify any specific problems, such as a need for clarification of the rule language.

Option 2: Extend the comment period for 30 days, but don't perform a risk assessment.

Under this option, the comment period for the proposed rule would be extended for 30 days and no change would be made in the final due date for the rule (Option 2A) or the final due date would be extended for a corresponding 30 days (Option 2B).

Pro: Provides additional time for the public and stakeholders to review and submit comments on the proposed rule and the draft regulatory guidance.

Con: Not responsive to stakeholders' comments on performing a risk assessment.

NOTE: If Option 2A is approved and the due date for the rule is not extended by the same amount of time that the public comment period is extended, the staff's continued interaction with the ACMUI, public, and medical community during the resolution of the comments would be severely curtailed. For example, staff would not be able to meet separately with the ACMUI subcommittees and still maintain the current schedule, because this time would be needed to evaluate comments. Therefore, the schedule would only permit the staff to meet with the full ACMUI one more time before publication of the final rule. In addition, selection of Option 2A would result in less time for resolution of comments and, therefore, could adversely affect the quality of the final rule.

Option 3: Perform a risk assessment and extend the date for completion of the rule.

Under this option, the comment period for the proposed rule would need to be significantly extended to accommodate some type of risk assessment: a formal risk assessment for the entire rule (Option 3A); a formal risk assessment focused on the diagnostic modalities (Option 3B); or a relative risk assessment (Option 3C). The participants at the Rockville meeting requested that representatives of the medical community be part of an advisory committee that oversees a formal risk assessment (Option 3A) on the entire rule. This would include their involvement in all the phases of the risk assessment, from selection of the risk assessment methodology to review of the results. A relative risk assessment (Option 3C) would evaluate the risk associated with the use of byproduct material in medicine versus the risks in other areas of medicine. All the alternatives would entail collecting available information, either on absolute risk or on relative risk in other areas of medicine, with the assistance of stakeholders. The results of the risk assessment would be published for comment and form the basis for the revision of Part 35.

Pro: Responsive to participants' comments that the regulations should be risk-based. The revision would be risk-based, rather than risk-informed. If a relative risk assessment were performed, the rule would be based on the relative risk of all areas of medicine, rather than on the specific risk associated with use of byproduct material in medicine.

Cons: This option is not consistent with either the Commission's direction to develop a risk-informed rule that is focused on radiation safety (SRM-

COMSECY-96-057) or the strategy and goals for nuclear materials safety outlined in Strategic Plan: Fiscal Year 1997-Fiscal Year 2002.

The data necessary to perform a relative risk assessment may either not be available or be problematic. The National Academy of Sciences Report on Radiation in Medicine: A Need for Regulatory Reform (National Academy Press, 1996) included both a risk assessment and a discussion of the comparative risk of ionizing radiation in medicine to risks in other medical modalities (Chapter 4). The NAS report concluded that "no comprehensive raw data are available to make exact comparisons" between risks of medical modalities (pg. 124). Both ACMUI (at a May 8, 1997, Commission briefing) and the NAS Report (pg. 128) recognized that quantifying levels of risk in radiation medicine is problematic.

Significant additional time and resources would be needed to perform the risk assessment and complete the rulemaking.

OBTAIN "POINT OF CONTACT" FROM EACH COMMISSION OFFICE

The staff requests that each Commissioner designate a member of his/her office to serve as a point of contact with the staff for this rulemaking. This would be especially useful if the current schedule for the rulemaking, to be completed in June 1999, were retained. Having a point of contact would enable: (1) the Commission to be promptly informed of any significant issues raised by the stakeholders and to be provided with options for resolution of these issues; and (2) the staff to receive timely Commission direction on resolution of these issues and to continue with development of a final rule within the approved schedule.

RESOURCES:

Option 1 (status quo) would have no resource impact. Option 2 (extend the comment period) would result in at least a 0.5 FTE increase in the resources identified in the FY 2000 budget submission for the rulemaking. Option 3 (perform some type of risk assessment) would require different level of resources, depending on which sub-option is approved. Option 3A would require the most resources because it includes a formal risk assessment on the entire rule; estimated resources for this sub-option are up to 10 FTE over a 5-year period plus several million dollars for an outside contract to perform the risk assessment. None of these resources are included in the present budget submission or in the Operating Plan.

RECOMMENDATION:

The staff recommends Option 2B which is responsive to the unanimous request of the participants at the Rockville workshop for extension of the comment period and will not unduly delay the final rule.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. The Office of the Chief Information Officer has reviewed the proposed rule for information technology and information management implications and concurs in it.

William D. Travers
Executive Director for Operations

Attachments:
1. SRM-COMSECY-96-057, dtd 3/20/97
2. Summaries of Public Meetings
3. Letter to Chairman Jackson, dtd 10/30/98