RULEMAKING ISSUE
(Notation Vote)

June 5, 1997 SECY-97-115

FOR: The Commissioners

FROM: L. Joseph Callan
Executive Director for Operations

SUBJECT: PROGRAM FOR REVISION OF 10 CFR PART 35, "MEDICAL USES OF BYPRODUCT MATERIAL" AND ASSOCIATED FEDERAL REGISTER NOTICE

PURPOSE:

To obtain Commission approval of: (1) the staff's proposed program for revising 10 CFR Part 35, associated guidance documents, and the Commission's 1979 Medical Policy Statement, if necessary; and (2) a Federal Register notice (FRN) of proposed rulemaking for publication to solicit public comments regarding 10 CFR Part 35 restructuring into a risk-informed, more performance-based regulation.

CATEGORY:

This paper addresses significant rulemaking issues requiring Commission consideration and approval.

BACKGROUND:

The Commission, in its "Staff Requirements Memorandum (SRM) - COMSECY-96-057, Materials/Medical Oversight (DSI 7)," directed the staff to submit a program, for Commission approval, for revising Part 35, associated guidance documents, and, as necessary, the Commission's 1979 Medical Policy Statement (Attachment 1).

L-4-1 PT35 Medical Use...
X CyR-14
X O&M-6 (0111)

CONTACTS: Catherine Haney, NMSS/IMNS
(301) 415-6825

Susanne Woods, NMSS/IMNS
(301) 415-7267

SECY NOTE: TO BE MADE PUBLICLY AVAILABLE AT COMMISSION BRIEFING ON JUNE 13, 1997

D/1 DS14

The staff was also directed to describe how Part 35 could be restructured into a risk-informed, more performance-based regulation. In addition, a listing of issues was provided for staff consideration during development of the program. The staff reviewed the Commission's direction and is prepared to move forward with the revision to Part 35 and associated guidance documents.

DISCUSSION:

The staff plans to establish a steering group and a working group. This approach is described in Management Directive 6.3, "The Rulemaking Process." The steering group will be comprised of representatives, at the Division Director level or higher, from the following offices: Office of Nuclear Material Safety and Safeguards (NMSS); Office of Nuclear Regulatory Research (RES); Office of the General Counsel (OGC); Office of Enforcement (OE); and Office of State Programs (OSP). The Director, Division of Industrial and Medical Nuclear Safety, NMSS, will chair the steering group. In addition, the steering group will include an Agreement State Program representative. The working group will be comprised of Nuclear Regulatory Commission staff and representatives from both an Agreement State and a non-Agreement State.[1] Representation will include NMSS, RES, OGC, and OSP. The nominated Agreement State representative is also a member of the Conference of Radiation Control Program Directors (CRCPD), Inc., Suggested State Regulation Committee (SSR) on Medical Regulation. The staff plans to work toward parallel development of the NRC rule and the CRCPD suggested state regulations to facilitate state development of their corresponding rules.

Attachment 2 describes the staff's proposed program for the revision to Part 35 and associated documents. The staff plans to use a fresh start approach, soliciting initial ideas and suggestions from the medical community and the public. Previously identified issues will also be factored into the revision, including: recommendations of the Indiana, Pennsylvania, Incident Investigation Team; recommendations from internal staff audits; open rulemakings and results of analyses in medical issues papers.

The staff plans to use a process for revising Part 35 and associated guidance documents that provides more opportunity for input from potentially affected parties than is provided for by the typical notice and comment rulemaking process. This process includes solicitation of public comment on several occasions. The first opportunity begins with the publication of an FRN (Attachment 3) that solicits initial input into the development of Medical Policy Statement options and regulatory alternatives. To the extent possible, commentors will be asked to provide specific examples of draft rule language. During this period, two public meetings are planned to further solicit the initial public input. The second opportunity for public input will include a public comment period and a set of facilitated public meetings based upon draft rulemaking alternatives. The staff plans to provide the draft rule alternatives to the Commission prior to soliciting comment. During these meetings the staff will work with participants to review and refine the details of the proposed rule. Based upon the results of these public interactions, a proposed rule, regulatory analysis, and environmental assessment

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[1]The Organization of Agreement States recommended that the non-Agreement States be represented on this working group.

will be prepared, along with draft guidance documents. Following Commission approval, the proposed rule will be published for comment, and a second set of facilitated public meetings would be completed. The meetings are expected to be focussed upon areas of controversy, and upon the draft guidance, as a mechanism to refine the rule and guidance into final form.

The revision of the medical regulations will be a complex and controversial process, because of the diversity of activities, modalities and risk that fall within the umbrella of medical use, the corresponding diversity in medical community positions, and the varied availability of professional codes and standards. Given these facts, the proposed program represents an aggressive schedule. The staff emphasizes that the proposed plan does not account for any possible requests for extensions on public comment periods associated with the initial FRN, the notice requesting comment on the rulemaking alternatives, or on the proposed rule. Requests for comment extensions cannot be granted without causing a change to the end dates for the final rulemaking. The staff projects that the final rule will be published in April 2000 (Attachment 2).

The staff plans to provide NRC's medical licensees, professional medical societies, and the Agreement States (for distribution to their licensees) with copies of the initial FRN of proposed rulemaking. The staff plans to meet with and solicit comments from several professional societies, including, among others: (1) Society of Nuclear Medicine; (2) American College of Nuclear Physicians; (3) Health Physics Society; (4) American Association of Physicists in Medicine; (5) the American College of Cardiology; and (6) the American College of Radiology. The staff will also attempt to identify patient's rights groups and forward them copies of both the FRN and applicable documents for their comment. To this end, the staff arranged for a two-hour discussion with the American College of Nuclear Physicians and Society of Nuclear Medicine at their combined meeting in San Antonio, Texas, on June 4, 1997. The staff intends to make documents pertaining to this rulemaking and electronic comment submittal available on the Internet, using a separate page within the current RES rulemaking bulletin board.

Contractors and consultants are expected to assist the staff during the rulemaking process. Contractors, in particular, will be used to consolidate public comments and prepare the regulatory analyses for the revised rule. In addition, the staff will pursue the use of technical medical experts as consultants to the working group. Specifically, the project is expected to enlist experts for diagnostic and therapeutic uses of radioactive material. Further, the use of contracted facilitators for public meetings is being considered, in addition to the support of the OGC Special Counsel for Public Liason and Agreement State Programs.

The staff believes that, at this time, providing the Commission with a description of how Part 35 can be restructured, without the benefit of public comment, is premature and that it may lead stakeholder groups to believe that the staff has already decided on a particular approach. Ideas generated at the first stages of comment will be validated and tested during the subsequent facilitated public meetings planned for spring 1998 and early 1999. The result will be the staff's proposed rule and associated guidance for Commission consideration in December 1998.

The staff used the guidance in the Strategic Assessment Direction Setting Issues Papers Number 7, "Materials/Medical Regulations," and Number 12, "Risk Informed, Performance-

Based Regulations," as well as the SRM (COMSECY-96-057) to prepare a proposed FRN and associated press release (Attachments 3 and 4). The FRN of proposed rulemaking contains a list of issues, presented in the form of questions, for consideration by the public. The staff recognizes that the questions are to assist with the formulation of comments and that the commentary received need not be limited as response to the questions presented. Rather, the overriding issues are both the identification of necessary changes (additions and deletions) to Part 35 requirements and the assessment of risk for a risk-informed, more performance based regulation with sufficient oversight of public health and safety. The staff also poses the question of whether quantitative or qualitative criteria should be considered in determining the "risk" for each modality. Public comments, the Commission SRM issues, and the staff reports on medical issues (as previously noted) will be used for developing the framework and associated text of the proposed rule.

The staff discussed revision of Part 35 with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) at the April 1997 Committee meeting. As a mechanism for generating discussion during the last two public meetings of the ACMUI, the staff identified a possible approach for restructuring Part 35 by modality (e.g., teletherapy, radiopharmaceutical therapy), based upon risk. ACMUI comments addressing the Part 35 revision are summarized in the proposed FRN (Attachment 3). The ACMUI's discussion will be available as additional background information for public commentors, and will be considered by the working group in preparing rulemaking proposals. The staff intends to continue active involvement of the ACMUI in the ongoing development process, including Committee meetings, additional reviews of guidance documents developed during the Part 35 revision process, and possible supplemental technical input from ACMUI subcommittees.

RESOURCES:

The Offices of Nuclear Material Safety and Safeguards, Research, General Counsel, and State Programs have identified the following resource requirements for this effort in their recent budget submissions. These resource levels will be considered in the FY 1999 budget review process.

	FY 1998		FY 1999		FY 2000	
Office	$K	FTE	$K	FTE	$K	FTE
NMSS	39	3.0	60	3.0	0	0.3
RES	150	1.9	50	1.0		
OGC*	0	0.3-0.6	0	0.3-0.6		
OSP	0	0.5	0	0.5		

*OGC effort includes any process design and the possible option of facilitation support for the public meetings from the Special Counsel for Public Liaison and Agreement State Programs.

NMSS management will monitor resource use closely for this rulemaking.

RECOMMENDATION:

That the Commission approve the following: (1) the proposed Part 35 revision program; (2) issuance of the attached FRN; and (3) the attached press release.

COORDINATION:

OGC reviewed this paper and has no legal objection. The Chief Financial Officer has no objection to this paper. The Office of Chief Information Officer has reviewed the plan for information management implications and concurs in it; however, since the revision to 10 CFR Part 35 contains information collection requirements, it must be submitted to the Office of Management and Budget for review no later than the date the proposed rule is published in the Federal Register.

L. Joseph Callan
Executive Director
for Operations

Attachments: 1. SRM dated March 20, 1997
2. Program for Revising
10 CFR Part 35 and Associated Documents
3. Proposed Federal Register notice
4. Press Release

DISTRIBUTION:
Commissioners
OGC
OCAA
OIG
OPA
OCA
CIO
CFO
EDO
SECY

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Friday, June 20, 1997.

Commission staff office comments, if any, should be submitted to the Commissioners NLT June 13, 1997, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

Action: Paperiello/NMSS
Morrison, RES
Cys: Callan
Thompson
Jordan
Norry
Blaha
Bangart, SP
Ross, AEOD

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

SECRETARY

March 20, 1997

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary

SUBJECT: STAFF REQUIREMENTS - COMSECY-96-057
MATERIALS/MEDICAL OVERSIGHT (DSI 7)

With respect to the overall materials program, the Commission continues to support its preliminary views on this issue which were a combination of two options -- Continue the Ongoing Program with Improvements (Option 2) and Decrease Oversight of Low-Risk Activities with Continued Emphasis in High-Risk Activities (Option 3). For the longer term, the Commission also believes that consideration should be given to broadening NRC's regulatory oversight to include one or more of the higher-risk activities identified in Option 1.

With respect to the medical program, the Commission was not persuaded by the National Academy of Sciences, Institute of Medicine (IOM) report that recommends that NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine. The Commission continues to believe that the conclusions in the report were not substantiated and that the recommendations should not be pursued.

The Commission continues to support the use of ACMUI and professional medical organizations and societies in developing regulatory guides and standards as was proposed in the Commission's preliminary views. In the longer term, the Commission would be willing to consider taking on broader regulatory responsibilities for higher risk activities involving other sources of ionizing radiation but such efforts should not divert resources from the 10 CFR Part 35 rulemaking discussed below.

In lieu of a rulemaking plan in the context of Management Directive 6.3 the staff should submit a program for Commission approval for revising 10 CFR Part 35, and associated guidance documents, and the Commission's 1979 Medical Policy Statement, if necessary. The program should describe how 10 CFR Part 35 can be restructured into a risk-informed, more performance-based regulation by a suspense date of 6/30/99. In developing the program the staff should consider the following:

(1) Focusing Part 35 on those procedures that pose the highest risk.

(2) For diagnostic procedures, staff should consider regulatory oversight alternatives consistent with the lower overall risk of these procedures.

(3) The staff should address how best to capture not only relevant safety-significant events, but also precursor events.

(4) Changing the nomenclature from "misadministration" to "medical event" or comparable terminology.

(5) Part 35 should be redesigned so that it can incorporate necessary regulatory requirements for new treatment modalities in a timely manner.

(6) The Quality Management Program provisions (10 CFR Part 35.32) should be re-evaluated and revised to focus on those requirements that are essential for patient safety, e.g., confirming patient identity, requiring written prescriptions and verifying dose. To the maximum extent possible, the requirements should be revised to be risk-informed. Given this objective, a mixed approach of performance-based rules and otherwise prescriptive regulations should be pursued.

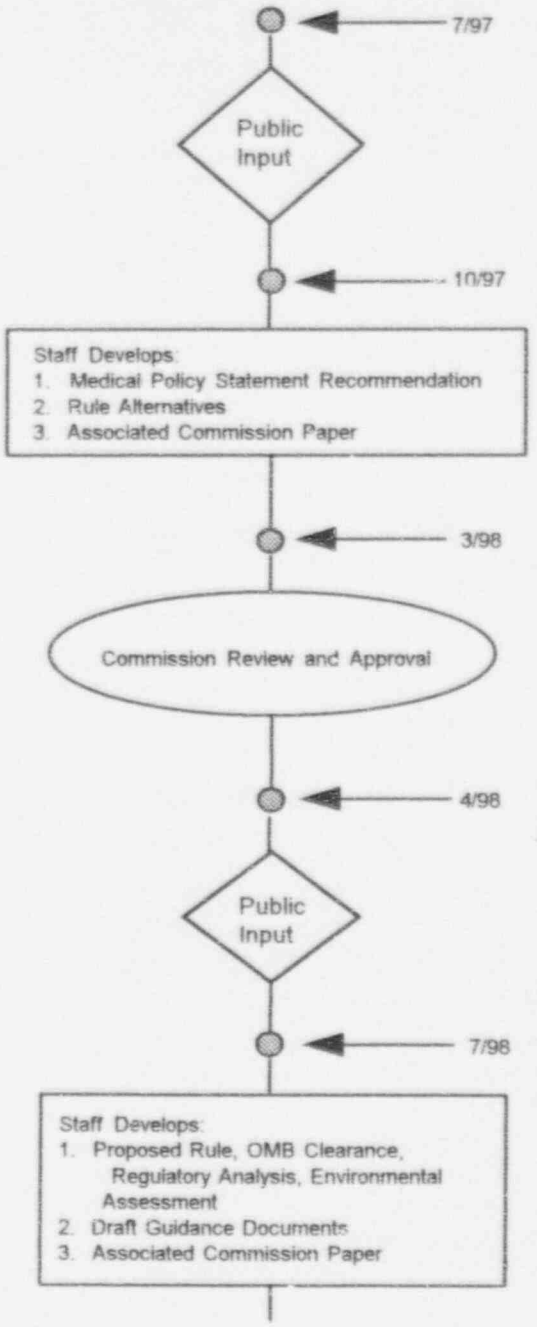
(7) The staff should consider the viability of using or referencing available industry guidance and standards within Part 35 and related guidance to the extent that they meet NRC needs.

(8) The staff should consider a rulemaking process that provides more opportunity for input from potentially affected parties than is provided by the normal notice and comment rulemaking process but would be less consumptive of resources and time than the process recently used in the development of NRC's rule on radiological criteria for license termination.

The staff's program to implement the above should be submitted to the Commission for its consideration no later than June 6, 1997. The program should target June 30, 1999 as the date for completing the rulemaking process. This rulemaking and associated guidance development is a very high priority for the Commission. The Commission is prepared to provide additional resources to the extent necessary to complete the rulemaking process on this schedule.

(NMSS/RES) (~~EDO~~ - Program) (SECY Suspense: 6/6/97) 9700065
(NMSS/RES) (~~EDO~~ - Complete Rulemaking) (SECY Suspense: 6/30/99) 9700065

PROGRAM FOR REVISING 10 CFR PART 35, ASSOCIATED GUIDANCE DOCUMENTS, AND 1979 MEDICAL POLICY STATEMENT*



Publish Federal Register notice for early input with 90 day comment period
ACMUI input, professional society meetings, and two public meetings

Working group, Steering Committee, and consultant develop documents with review and approval from Steering Committee

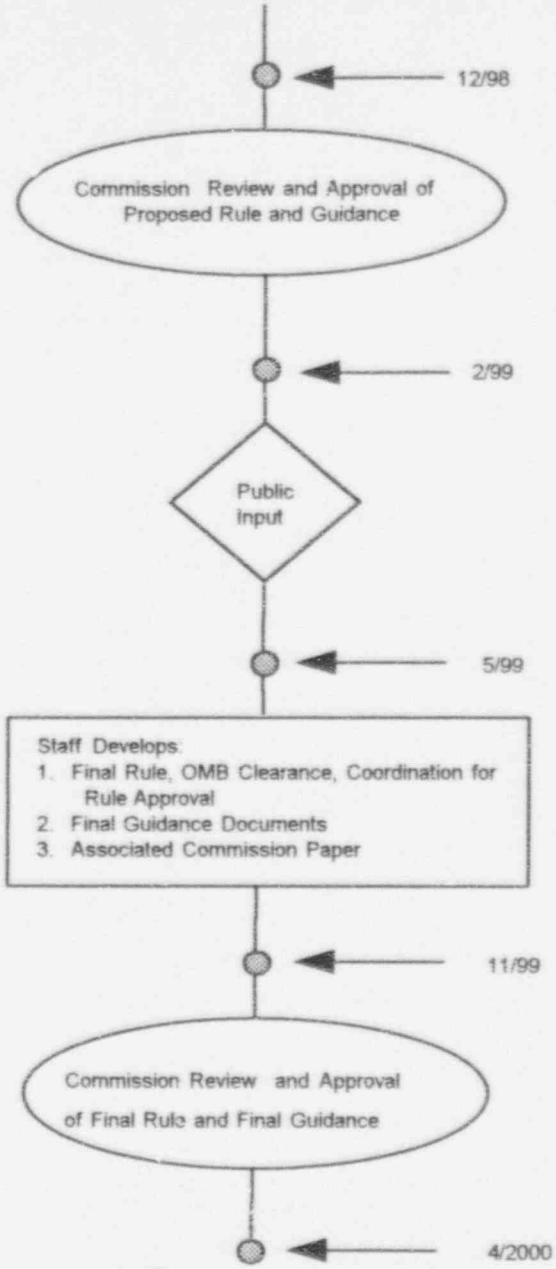
Commission review and approval of Medical Policy Statement recommendations and rule alternatives for public release and publication in Federal Register

Proposed rule alternatives published in Federal Register for 90-day comment period
Two facilitated public meetings to examine alternatives in detail

Working Group, Steering Committee, and consultants develop documents, with review and approval of Steering Committee
Preparation of OMB clearance and supporting documents
Review with ACMUI and Agreement States
Additional coordination as necessary

Attachment 2

PROGRAM FOR REVISING 10 CFR PART 35, ASSOCIATED GUIDANCE DOCUMENTS, AND 1979 MEDICAL POLICY STATEMENT* (Continued)



12/98 Commission review and approval for Federal Register publication and public comment

2/99
- Publish proposed rule and announce availability of draft guidance in Federal Register, including 90 day comment period
- Two facilitated public meetings focusing on high risk activities, controversial issues and guidance

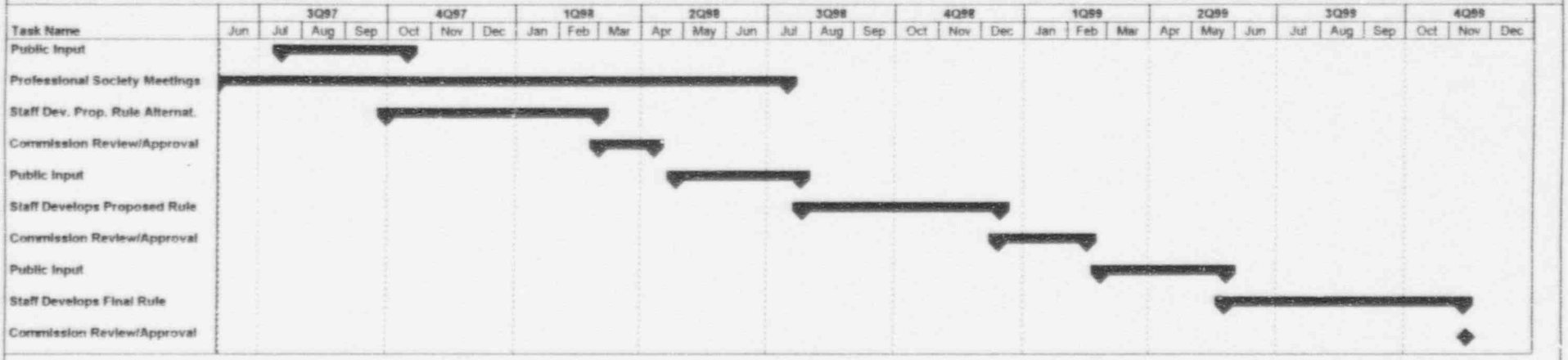
5/99
- Working Group, Steering Committee, and consultants develop documents, with review and approval of Steering Committee
- Preparation of OMB clearance and supporting documents
- Review with ACMUI and Agreement States
- Additional coordination as necessary

11/99 Commission review and approval of final rule and final guidance for release to the public

4/2000 Publish Final Rule

*The program presented represents ongoing efforts of the Working Group, Steering Committee, and project consultants, including extensive NRC Office coordination, ACMUI consultation, Agreement and non-Agreement State interaction, and numerous meetings with professional organizations, stakeholders, and the public.

PROGRAM FOR REVISING 10 CFR PART 35,
ASSOCIATED GUIDANCE DOCUMENTS , AND THE 1979 MEDICAL POLICY STATEMENT



ATTACHMENT 3
[7590-01-P]

NUCLEAR REGULATORY COMMISSION

RIN-3150-AF74
Medical Use of Byproduct Material:
Issues and Request for Public Comment

AGENCY: Nuclear Regulatory Commission

ACTION: Notice of Proposed Rulemaking

SUMMARY: The U. S. Nuclear Regulatory Commission (NRC) is developing a program for revision of 10 CFR Part 35, "Medical Use of Byproduct Material." The decision to revise Part 35 resulted from the NRC Strategic Assessment and Rebaselining Initiative (SA), a process involving identification of the direction-setting issues and associated options for the future of NRC activities. Specifically, the SA effort included medical use regulation. With this notice, the Commission is initiating a proposed rulemaking action which will culminate in the developement of a final rule for approval in late 1999. This notice describes issues proposed to be included in this rulemaking. The Commission plans to further propose specific rulemaking text for public comment during 1999 (approximately February 1999).

In order to provide the public the most effective opportunity to participate in developing the rule text, the Commission is requesting public comment on the issues identified by the questions in this notice within 90 days of the issuance of this notice. Comments received after this initial 90 day period will be considered along with the comments received on the proposed text anticipated for publication in 1999. However, because of schedule requirements, it may not be practicable for the Commission to consider those comments received after the 90 day period in preparing the detailed proposed rulemaking text.

DATES: The comment period expires _____ (90 days after the FRN is issued).

ADDRESSES: Send written comments and suggestions to Secretary, Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Docketing and Service Branch. Hand-Deliver comments to 11555 Rockville Pike, Rockville, MD, between 8:00 a.m. and 4:00 p.m. on Federal workdays.

Written comments may also be submitted electronically on the Internet via NRC's interactive rulemaking web site, through the NRC home page (http://www.nrc.gov). This site provides the ability to upload comments as files (any format), if your web browser supports this function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, (301) 415-5905; e-mail CAG@nrc.gov.

FOR FURTHER INFORMATION REGARDING THIS NOTICE CONTACT:

Catherine Haney, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6825 or Susanne Woods, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-7267.

SUPPLEMENTAL INFORMATION:

Background

NRC examined the issue of 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 SA process. In particular, medical oversight was addressed in the Strategic Assessment Direction-Setting Issue Paper Number 7 (DSI 7) (released September 16, 1996).

In their "Staff Requirements Memorandum (SRM) - COMSECY-96-057, Materials/Medical Oversight (DSI 7)," dated March 20, 1997, the Commission directed staff to revise Part 35, associated guidance documents, and, if necessary, the Commission's 1979 Medical Policy Statement. Further, the SRM stated, "With respect to the medical program, the Commission was not persuaded by the National Academy of Sciences, Institute of Medicine (IOM) report that recommends that NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine. The Commission continues to believe that the conclusions in the report were not substantiated and that the recommendations should not be pursued."

The Commission SRM specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. Further, during development of the rule and associated guidance, as well as during review of the Medical Policy Statement, the NRC staff was directed to consider the following issues:

1. Focusing Part 35 on those procedures that pose the highest risk.
2. Regulatory oversight alternatives, for diagnostic procedures, that are consistent with the lower overall risk of these procedures.
3. The best way to capture not only relevant safety-significant events, but also precursor events.
4. The need to change from the term "misadministration" to "medical event" or other comparable terminology.
5. Redesigning Part 35 so that regulatory requirements for new treatment modalities can be incorporated in a timely manner.
6. Revising the requirement for a quality management program (10 CFR 35.32) to focus on those requirements that are essential for patient safety.
7. The viability of using or referencing available industry guidance and standards, within Part 35 and related guidance, to the extent that they meet NRC needs.

The NRC staff discussed items 1-7 and solicited preliminary views from the Advisory Committee on the Medical Uses of Isotopes (ACMUI) at the April 1997 Committee meeting. [Transcripts of this meeting are available by contacting the NRC Public Document Room and

on the Internet (as specified in the reference information provided).]

The ACMUI discussed their views and recommendations during a briefing of the Commission on May 8, 1997. The ACMUI concurred with NRC's position to continue the ongoing medical program with improvements, and to decrease oversight of low-risk activities with continued emphasis of high risk activities. The committee supported the use of professional medical organizations and societies in developing a performance based regulation. The ACMUI recommended consideration of a quality improvement approach as an alternative to the present Quality Management Program. Further, the committee recommended, to the Commission, that the 1979 Medical Policy Statement be revised to reflect that NRC will regulate radiation safety of patients only where justified by the risk to the patients and only where voluntary standards or compliance with the standards are inadequate. The ACMUI believed that the assessment of the risks justifying regulations should reference comparable risks and comparable modes of regulation for other types of medical practice. In addition, they believed that the NRC should not intrude into medical judgments affecting patients and into other areas that the ACMUI considered to be traditionally a part of the practice of medicine.

This notice initiates a proposed rulemaking action which will culminate in the development of a final rule for approval in 1999. In order to provide the public the most effective opportunity to participate in developing the rule text, the Commission is requesting public comment on the issues identified by the questions in this notice and on the ACMUI recommendations within 90 days of the issuance of this notice. Comments received after this initial 90 day period will be considered along with the comments received on the proposed text that is anticipated for publication in 1999. However, because of schedule requirements, it may not be practicable for the Commission to consider those comments received after the 90 day period in preparing the detailed proposed rulemaking text. Further, the staff recognizes that the questions are to assist with the formulation of comments and that the commentary received need not be limited as response to the questions presented. Rather, the overriding issues are both the identification of necessary changes (additions and deletions) to Part 35 requirements and the assessment of risk for a risk-informed, more performance-based regulation with sufficient oversight of public health and safety. The NRC staff is interested in ideas, proposals, and comments on the structure and content of a revised Part 35, given the Commission guidance and direction as described above. To the extent possible, commentors are asked to provide specific examples of draft rule language.

Requests for Comments on General Considerations

NRC has identified the following areas of Part 35 for consideration and is seeking comments on these issues, as well as any others, offered for consideration during the revision to Part 35:

1. How should the Part 35 requirements be revised to be risk-informed and more performance-based? How should performance be measured to provide both NRC licensees and NRC with an objective basis for determining regulatory compliance?

2 How should risk be assessed for medical uses and the regulation be modified to focus on procedures posing the highest risk? What quantitative or

qualitative criteria should be considered in determining the "risk" for each modality?

3. What oversight should exist for diagnostic procedures that is commensurate with the associated risks?

4. What specific events or incidents should be reported to NRC? [e.g., machine failure, leaking source, software failure, hardware failure] What criteria should be used for determining if the event is reportable (e.g., threshold)? Are there modality-specific events that should be reported? Should the term "misadministration" be changed to "medical event" or comparable terminology?

5. How should the regulation be redesigned to incorporate necessary regulatory requirements for new modalities? Should Part 35 be structured such that requirements for a particular modality are grouped together?

6. Which Quality Management Program provisions should be re-evaluated and revised to focus on requirements that are essential for patient safety? Are different provisions appropriate for each of the different modalities?

7. Which standards and guidance developed by professional societies and other organizations are applicable to NRC-regulated medical uses of radioactive material and how could they be incorporated within the regulatory framework of Part 35 and/or associated guidance?

8. How should the issues of training and experience be addressed? What individuals or groups should be subject to such requirements?

9. Which new issues/modalities should be incorporated into Part 35?

10. Should the 1979 Medical Policy Act Statement (44 FR 8242) be modified to increase flexibility for a risk-informed, more performance-based approach to medical regulation?

Reference Information

1. Strategic Assessment Direction-Setting Issues Paper Number 7 is available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555-001. [Telephone: (202) 634-3273; fax: (202) 634-3343].

2. The memorandum "Management Review of Existing Medical Use Regulatory Program (COMIS-92-026)" (dated June 16, 1993) is available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555-001. [Telephone: (202) 634-3273; fax: (202) 634-3343].

3. Radiation in Medicine: A Need for Regulatory Reform (1996) is available from

the National Academy Press at 2101 Constitution Avenue, N.W., Box 285, Washington, DC 20055.

4. Summary minutes and transcripts of the ACMUI April 1997 meeting or transcripts of the May 8, 1997, Commission briefing are available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555-001. [Telephone: (202) 634-3273; fax: (202) 634-3343].

   Transcripts of the May 8, 1997 briefing are also available by Internet at http://www.nrc.gov.

5. The NRC Medical Policy Act Statement of 1979 was published in the Federal Register, Volume 44, page 8242, on February 9, 1979.

Dated at Rockville, Maryland, this day of May, 1997.

For the U. S. Nuclear Regulatory Commission

John C. Hoyle, Secretary of the Commission

ATTACHMENT 4

Draft press release, 5/22/97, 3:00 p.m.

NRC SEEKS COMMENTS ON PLANS TO REVISE

REGULATIONS ON MEDICAL USES OF LICENSED RADIOACTIVE MATERIAL

The Nuclear Regulatory Commission is seeking public comments on planned revisions of its regulations on medical uses of licensed radioactive material.

The Commission has examined its medical use program in great detail during the last four years. It conducted an internal management review, commissioned an external review by the National Academy of Sciences' Institute of Medicine, and included medical use as one of the issues examined during its recent strategic assessment and rebaselining initiative.

The Commission has now directed the NRC staff to revise its regulations, associated guidance documents and, if necessary, its 1979 medical policy statement. Notwithstanding the Institute of Medicine's recommendation that the NRC should not be the federal agency involved in the regulation of ionizing radiation in medicine, the Commission believes the report's conclusions were not substantiated and therefore should not be followed.

In developing revisions to the medical use regulations, the NRC intends to focus primary attention on procedures that pose the highest risk. Issues on which the NRC would like public comments include:

- How should risk be assessed for medical uses and the regulation be modified to focus on procedures posing the highest risk? What quantitative or qualitative criteria should be considered in determining the risk?
- What oversight should exist for diagnostic procedures that is commensurate with the associated risks?
- What specific events or incidents should be reported to the NRC (for example, machine failure, leaking radiation source, software failure, hardware failure)?
- How should the issues of training and experience be addressed? What individuals or groups should be subject to such requirements?

Other issues on which the NRC is particularly seeking comments are described in a Federal Register notice published on _____.

Interested persons are invited to submit comments and suggestions by_____ _____(90 days after publication of the Federal Register notice). Written comments should be addressed to the Secretary, Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemakings and Adjudications Staff. Comments may also be submitted electronically, as described in the Federal Register notice.