June 4, 1998

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

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

PURPOSE:

To request Commission approval to publish in the *Federal Register* a proposed rule to amend 10 CFR Part 35, "Medical Use of Byproduct Material."

SUMMARY:

In its Staff Requirements Memorandum (SRM) - COMSECY-96-057, "Materials/Medical Oversight (DSI 7)," dated March 20, 1997 (Attachment 1), the Commission directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. The program for revising Part 35 and the associated guidance document has provided more opportunity for input from potentially affected parties than is provided by the typical notice and comment rulemaking process. The draft proposed rule, that is attached for Commission approval to publish in the *Federal Register* for comment, is consistent with a risk-informed, performance-based approach to regulation.

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

BACKGROUND:

In its SRM dated June 30, 1997, "SECY-97-115, Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material' and Associated *Federal Register* Notice" (Attachment 2), the Commission approved the staff's proposed plan for the revision of Part 35 and the Commission's 1979 Medical Use Policy Statement (MPS). The staff implemented that plan by establishing a Working Group and Steering Group that included headquarters and regional licensing and inspection staff and representatives of the Organization of Agreement States and the Conference of Radiation Control Program Directors.

The program for revising Part 35 and the associated guidance document 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. Early public input was solicited by requesting input through *Federal Register* notices; holding public meetings of the Working and Steering Groups; meeting with medical professional societies and boards; putting background documents, rulemaking alternatives, and a "strawman" draft proposed rule on the Internet and in the NRC's Public Document Room; and convening two facilitated public workshops. Significant regulatory issues were discussed at the Part 35 Workshop that was held in conjunction with the All Agreement States Meeting in October 1997, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) meetings in September 1997 and March 1998, and the ACMUI subcommittee meetings in February 1998. These interactions, and the comments received, are summarized in the proposed *Federal Register* notice (Attachment 3).

DISCUSSION:

In response to the SRM discussed above, staff has developed a draft proposed revision of Part 35, draft associated guidance, and a proposed revision of the MPS. The staff's proposed revision of the MPS has been transmitted separately for Commission approval for publication in the *Federal Register*. The draft proposed rule is consistent with the proposed revised MPS and is generally consistent with the current MPS (see Attachment 3, Section VII of the Supplementary Information).

Approach. The staff developed the proposed revision of Part 35 based upon the Commission's directions in the SRMs of March 20, 1997**,** and June 30, 1997. In addition, the staff moved to eliminate requirements from the draft proposed rule that were contained elsewhere in the Commission's regulations. Part 35 licensees will continue to be required to comply with these requirements, such as ALARA in Part 20, but the staff believes that there is no need to duplicate requirements, unless more specific requirements are needed for medical licensees, such as the frequency of area surveys.

The draft proposed rule provides for an overall change in regulatory philosophy. Consistent with a risk-informed, performance-based approach to medical use licensing, the amount of information needed from an applicant to possess and use byproduct material would be reduced. An applicant for an NRC medical use license would have to develop, maintain, and implement procedures, but would no longer be required to submit these procedures as part of the license application. Furthermore, licensees would be provided maximum flexibility in developing their procedures because most of the requirements are stated in terms of the objectives to be achieved.

The staff has ensured, to the extent possible, that the regulations include all of the requirements for medical licensees. This responds to numerous comments that performance-based rules result in placement of requirements in guidance documents and license conditions. As a result, some prescriptive sections appear in the draft proposed rule where the requirements are necessary for safe operations. This approach was also taken with the development of the associated guidance document for medical use licensees. The draft guidance document provides model procedures to assist the applicant in developing various procedures required by the regulations, but it does not contain additional requirements. Licensees may choose to follow

the specific models provided in the guidance document or develop alternatives to achieve the objectives (Attachment 4). Although the staff is providing this draft guidance for reference, it is not specifically seeking approval from the Commission on this draft guidance at this time.

The revised Part 35 includes several structural changes. The draft proposed rule has a modality-based structure; the current Teletherapy Subpart has been expanded to codify the requirements for remote afterloaders and gamma stereotactic radiosurgery devices, which are currently regulated through license conditions; a new subpart is proposed to allow for easier licensing of new medical procedures that use byproduct material or radiation from byproduct material for uses that are not specifically addressed in the current Part 35; and all of the requirements for records and reports have been moved to separate subparts.

In addition, the staff reviewed the applicable industry guidance and standards to determine if the needed standards are available; and, if they are available, to determine if they are consistent with NRC's regulatory needs and, if so, whether they should be incorporated or referenced in Part 35. The draft proposed rule takes into account industry standards, where appropriate. However, the staff has opted to codify the objectives to be accomplished, rather than referencing industry standards in the regulation, so that licensees would have increased flexibility in demonstrating compliance.

Specific Issues: Early in the rulemaking process, the staff identified five significant rulemaking issues, developed alternatives for them, and specifically sought public input on them. Two of the issues, patient notification and precursor events, were forwarded in SECY-98-054, "Commission Resolution of Significant Issues Associated with the Revision of 10 CFR Part 35, "Medical Uses of Byproduct Material" (March 22, 1998), for Commission direction (Attachment 5). Pending receipt of direction, the draft proposed rule includes the current requirements for patient notification and a requirement for capturing precursor events. (Attachment 6 contains the NRC Medical Visiting Fellow's view on patient notification following a medical event.) Revised requirements have been included in the proposed rulemaking for the other three issues: Radiation Safety Committee (RSC), Quality Management Program (QMP), and Training and Experience (T&E).

The requirement for a medical institution licensee to have an RSC has been deleted in the draft proposed rule. This change places the responsibility for the radiation safety program on the licensee management, but provides flexibility in using either an RSC, or other existing management committees and structures.

The requirements for a medical licensee to establish and maintain a written QMP, to annually review the QMP, and to submit the QMP for NRC review have been deleted. The draft proposed rule requires licensees to have written directives for high-risk procedures, and to develop, maintain, and implement procedures to provide high confidence that each administration is in accordance with the written directive. This approach is consistent with Commission direction to re-evaluate and revise the QMP provisions to focus on those requirements that are essential for patient safety.

T&E requirements in the draft proposed rule have been revised to focus on radiation safety. The didactic and practical training requirements are focused upon radiation safety and the safe handling of radioactive material, and have been scaled based upon the risk posed by the diagnostic or therapy modality. The T&E requirements were extensively discussed with medical societies and boards, and were the primary issue in public comments received on the rulemaking. Approximately 90 percent of these comments were from radiation oncologists who feel very strongly that the current requirements for authorized users of brachytherapy and therapeutic medical devices should be retained because of the high risk associated with use of these modalities and because radiation safety training and clinical competence are intertwined for uses of these devices. As the rulemaking progressed, comments were also received expressing a viewpoint that T&E should not be reduced for diagnostic uses.

The draft proposed rule also addresses other ongoing medical issues, including a petition for rulemaking filed by the University of Cincinnati requesting a 500 mrem dose limit for visitation of individuals confined in accordance with 35.75 (PRM-20-24); evaluation of the responsibilities of the authorized user and radiation safety officer, as a result of the Indiana, Pennsylvania brachytherapy incident; and the recommendations from internal staff audits. Revised requirements have also been developed in response to other ongoing rulemakings to address various technical and administrative issues identified in the Medical Management Plan, to revise brachytherapy procedures, and to eliminate or decrease the number of exemptions from the requirements for the medical uses of radiation by mobile services. In addition, a requirement for reporting unintended radiation exposure to an embryo, fetus, or nursing child has been proposed to respond to an ongoing rulemaking and to satisfy the NRC's requirement to report Abnormal Occurrences to Congress (Attachment 7, SRM-SECY-92-171, "Administration of Byproduct Material or Radiation from Byproduct Material to Patients Who May Be Pregnant or Nursing," June 25, 1992).

The schedule approved by the Commission in SRM-SECY-97-115 provides for the rulemaking to be completed by June 1999. Therefore, three facilitated public meetings are planned for August and September 1998 to discuss the proposed rule, as approved by the Commission for publication in the *Federal Register*, during the 75-day public comment period, projected to be from July 1 to mid-September 1998.

RESOURCES:

The resource levels expended on the proposed rulemaking have been somewhat greater than the resource levels identified in the FY 1998 and FY 1999 budget submissions. Resources have been reprogrammed from lower priority activities within NMSS. If the provisions in the proposed rule are approved in the final rule, increased resources to review and approve testing organizations and specialty boards will be required. The staff expects to refine the resource estimates based upon interactions with the public and professional societies during the public comment period, and to incorporate those resources within future program and budget reviews.

COORDINATION:

The Office of the General Counsel has no legal objection to this proposed rulemaking. 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.

RECOMMENDATION:

That the Commission:

1. Approve the notice of proposed rulemaking for publication in the *Federal Register*.
2. Note:
   a. The rulemaking will be published in the *Federal Register* for a 75-day public comment period;
   b. A Draft Regulatory Analysis has been prepared for this rulemaking (Attachment 8);
   c. A Draft Environmental Assessment has been prepared for this rulemaking (Attachment 9);
   d. The appropriate Congressional committees will be informed (Attachment 10);
   e. The Office of Public Affairs has determined that a press release should be issued for this proposed rulemaking (Attachment 11);
   f. A draft Office of Management and Budget (OMB) Clearance package is attached (Attachment 12);
   g. Copies of the *Federal Register* notice of proposed rulemaking will be distributed to all affected Commission licensees, Agreement States, and potential Agreement States. The notice will be sent to other interested parties upon request;
   h. The Enforcement Policy and inspection procedures will be reviewed and revised, if necessary, prior to publication of the final rule.

L. Joseph Callan
Executive Director for Operations

Attachments:
1. SRM-COMSECY-96-057, dtd 3/20/97
2. SRM-SECY-97-115, dtd 6/30/97
3. Proposed *Federal Register* Notice
4. Draft NUREG 1556, Vol. 9
5. SECY- 98-054, dtd 3/22/98
6. Memorandum dtd 5/27/98, M. Pollycove to H. Thompson
7. SRM-SECY-92-171, dtd 6/25/92
8. Draft Regulatory Analysis
9. Draft Environmental Assessment
10. Congressional Letters
11. Press Release
12. OMB Clearance Package

Attachments provided to Commission offices, OGC, SECY and NMSS only. Copies of enclosures are available on request from Cathy Haney at (301) 415-6825.

ATTACHMENT 10

The Honorable James M. Inhofe, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed for the Subcommittee's information is a copy of a notice of a proposed rulemaking, to be published in the *Federal Register* for a 75-day public comment period (Enclosure 1) . A copy of the press release for the rulemaking is provided in Enclosure 2.

The U.S. Nuclear Regulatory Commission (NRC) is proposing to revise its regulations in 10 CFR Part 35, "Medical Uses of Byproduct Material," as part of an overall program to revise the Commission's regulatory framework for medical use. The goal of this proposed rulemaking is to restructure Part 35 into a risk-informed, more performance-based regulation that focuses 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. Another component of the program, revision of NRC's 1979 "Medical Use Policy Statement," is being separately published and transmitted to the Subcommittee.

The process used to revise Part 35 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. Early public input was solicited through several different mechanisms:

requesting public input through *Federal Register* notices; holding open meetings of the government groups developing the revised rule language; meeting with medical professional societies and boards; putting background documents, options for the more significant regulatory issues associated with the rulemaking, and an early "strawman" revision of the draft proposed rule on the Internet and in NRC's Public Document Room; and convening public workshops. The staff benefitted from these interactions and received many useful comments.

Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:
1. *Federal Register* Notice
2. Press Release

cc: Senator Bob Graham

The Honorable Dan Schaefer, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington, DC 20515
Dear Mr. Chairman:

Enclosed for the Subcommittee's information is a copy of a notice of a proposed rulemaking, to be published in the *Federal Register* for a 75-day public comment period (Enclosure 1). A copy of the press release for the rulemaking provided in Enclosure 2.

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The process used to revise Part 35 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. Early public input was solicited through several different mechanisms: requesting public input through *Federal Register* notices; holding open meetings of the government groups developing the revised rule language; meeting with medical professional societies and boards; putting background documents, options for the more significant regulatory issues associated with the rulemaking, and an early "strawman" revision of the draft proposed rule on the Internet and in NRC's Public Document Room; and convening public workshops. The staff benefitted from these interactions and received many useful comments.

Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:
1. *Federal Register* Notice
2. Press Release

cc: Representative Ralph Hall

ATTACHMENT 11

Draft press release -- 5/20/98, 10:35 a.m.

NRC PROPOSES EXTENSIVE REVISIONS TO REGULATIONS
ON MEDICAL USES OF RADIOACTIVE MATERIAL

The Nuclear Regulatory Commission is proposing extensive revisions to its regulations on medical uses of radioactive material. The revisions, designed to be risk-informed and performance-based, focus regulation on the medical procedures that pose the highest risk from a radiation safety aspect.

The NRC regulates the use of radioactive material in medical diagnosis and treatment, as well as research. The material is administered to about eleven million patients a year.

In developing the proposed changes to the regulations, the NRC provided extensive opportunities for public input. Publicly announced meetings and workshops were held last year and this year where rulemaking alternatives for significant "cross-cutting issues" were discussed. The alternatives for the cross-cutting issues were discussed with the NRC's Advisory Committee on the Medical Uses of Isotopes, as well as with state regulators, medical professional societies, and the public at meetings in Philadelphia and Chicago. In addition, the rulemaking alternatives and an early "strawman" version

of the NRC staff's proposed revisions to the regulations were made available for comment on the Internet and in the NRC's Public Document Room in Washington, DC.

In general, the proposed changes to the regulations reflect an overall change in regulatory philosophy to make the regulations performance based and to delete some of the more detailed requirements. An applicant for an NRC medical-use license would have to develop and implement procedures, but would no longer be required to submit those procedures as part of the license application. Further, licensees would have maximum flexibility in developing their procedures, because most of the requirements in the proposed changes to the regulations are stated in terms of the objectives to be achieved, rather than stated with a list of prescriptive details.

The significant cross-cutting issues that were identified, and their resolutions in the proposed revisions to the regulations, are:

(1) **Patient notification/reportable events** -- The requirements in the current regulations for notifying individuals following a misadministration would remain unchanged, with the exception of substituting the term "medical event' for "misadministration." The term, defined in detail in the proposed revisions to the regulations, generally refers to the administration of radioactive materials or radiation in a manner that differs substantially from the physician's direction. Using "medical event" responds to objections that the term "misadministration" has possible connotations of carelessness and harm, which is not always the case. In addition, "medical event" is consistent with terms used to characterize events in non-medical activities regulated by the NRC. The proposed regulations would continue to require that, when a medical event occurs, licensees must notify the NRC, the referring physician and the affected patient -- unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. If the patient is a minor, or is unconscious and incapable of comprehending the information, it is expected that the licensee would report to the patient's responsible relative or guardian rather than to the patient.

(2) **Radiation safety committee** -- The proposed revisions to the regulations delete the requirement for a medical institution licensee to have a radiation safety committee, with specified membership and duties, to oversee the use of radioactive material. The key functions of the committee would be transferred to licensee management. The proposed regulations specify the responsibilities for and functions to be accomplished by the radiation safety program, including some of the functions previously listed as those of the radiation safety committee.

(3) **Quality management program** -- Provisions in this area have been revised to focus more on patient safety. Detailed requirements for a medical licensee to have a quality management program have been deleted. Instead, the proposed revisions to the regulations require licensees to have written directives for procedures involving greater risk. Licensees would also have to develop, implement and maintain procedures to provide high confidence that the right patient receives the correct dose at the correct treatment site, consistent with the physician's written directive. This proposed revision not only eliminates unnecessary details, but is more consistent with the recently proposed revision to the agency's NRC's medical policy statement, which states that "NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides in accordance with the physician's directions."

(4) **Training and experience** -- Requirements in both the current regulations and the proposed revisions differ for diagnostic versus therapeutic uses of nuclear material. The proposed regulations basically retain the current training requirements for therapeutic uses of sealed sources of radioactive material because of the high risk associated with the types of material in such uses. However, the proposed revisions would reduce some of the training requirements for diagnostic and therapeutic procedures using radioactive materials in unsealed form, because of the lower risk associated with these procedures. Training and experience were the primary concerns expressed by the public comments during development of the proposed changes to the regulations. Most of the commenters thought the current requirements should be retained. Under the proposed revisions, the current training requirements would stay in effect for two years to allow licensees time to implement the new requirements. During the intervening period, licensees would have the option of meeting either the current or the revised requirements.

(5) **Precursor events** -- The proposed revisions to the regulations require licensees to notify the NRC after identifying any defects, exclusive of ordinary equipment failures, in equipment (hardware and/or software), radioactive material, or procedures supplied by a manufacturer or vendor that, in the opinion of the radiation safety officer or an authorized user, could lead to a medical event.

The proposed changes to the regulations also address a petition for rulemaking filed by the University of Cincinnati. The petition requests a 500-millirem radiation dose limit for certain individuals visiting patients who are required to be confined to the hospital while receiving radiation treatment, where the visitors are determined by the physician to be necessary for the patient's emotional or physical support. The current limit of 100 millirems for visitors is the same as for members of the public under other circumstances. The proposed regulations would respond to this petition by allowing licensees the discretion to permit visitors to receive up to 500 millirems in a year from exposure to hospitalized radiation patients.

In addition, the proposed changes add a requirement for reporting unintended radiation exposure of an embryo, fetus, or nursing child, and add specific requirements for medical uses of radiation by a licensee at temporary job sites and for specific technologies that are not currently addressed in the regulations. They also add a section to allow easier licensing of new medical procedures that use radioactive material or radiation.

Details of these and other aspects of the proposed changes to the regulations are contained in a *Federal Register* notice to be published shortly. Interested persons are invited to submit comments within 75 days of publication of the *Federal Register* notice to the Secretary, U.S. Nuclear Regulatory Commission, Attention: Rulemakings and Adjudications Staff.

The NRC plans to hold three public meetings in August and September to discuss the proposed revisions to the regulations. Details of time and place will be announced later.

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