RULEMAKING
AFFIRMATION

May 31, 2000 SECY-00-0118

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: FINAL RULES - 10 CFR PART 35, "MEDICAL USE OF BYPRODUCT MATERIAL" and 10 CFR PART 20, "STANDARDS FOR PROTECTION AGAINST RADIATION"

PURPOSE:

To request Commission approval of: (1) a final rule that revises 10 CFR Part 35 to make it risk-informed and more performance-based, and to codify requirements for certain therapeutic devices; and (2) a final rule that revises 10 CFR Part 20 in response to a Petition for Rulemaking (PRM) from the University of Cincinnati.

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 final rule, that is attached for Commission approval to publish in the Federal Register, is consistent with a risk-informed, performance-based approach to regulation. Also provided, for Commission approval is a draft notice that will revise the Enforcement Policy to make it consistent with the rule.

CONTACT: Cathy Haney, NMSS
(301) 415-6825

BACKGROUND:

In its SRM COMSECY-96-057, the Commission directed the revision and restructuring of Part 35. During the rulemaking process, the staff forwarded several Commission Papers that either provided information on the major issues addressed during the rulemaking or requested direction on specific issues. A chronological list of these papers and associated SRMs is provided in Attachment 2.

Members of the public, stakeholders, Agreement States, non-Agreement States, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) provided input and discussed the proposed requirements for medical use licensees on numerous occasions. Since August 1997, the staff held seven facilitated public workshops with stakeholders and made formal presentations at approximately 20 professional society meetings. We also discussed key rulemaking issues three times with the full ACMUI and four times with ACMUI subcommittees. In addition, staff discussed the rulemaking at the 1997, 1998, and 1999 annual "All Agreement States" meetings.

In SECY-99-201, "Draft Final Rule - 10 CFR Part 35, 'Medical Use of Byproduct Material," staff provided the Commission with: (1) draft final regulatory text for the revision of Parts 20 and 35; (2) a summary of the public comments received on the proposed rule, the staff's draft responses to the comments, and resulting changes made in the proposed rule; and (3) a comparison of the requirements in the current Part 35, as codified in 10 CFR Chapter I, and the draft final rule. In its SRM on SECY 99-201, dated February 16, 2000 (Attachment 3), the Commission approved the staff's draft final rule language and responses to public comments subject to the comments and changes provided in the SRM and its attachment. The Commission directed that the staff incorporate the changes and submit the final Part 35 rulemaking package, including the guidance document, to the Commission. The SRM also directed the staff to consider several issues when finalizing the rulemaking package. These issues and their resolution are discussed in Attachment 4.

The final rule grants, in part, a PRM filed by the University of Cincinnati, dated April 7, 1996 (PRM 20-24), because the request pertains to the medical use of byproduct material (Attachment 5). The petition requests that the U.S. Nuclear Regulatory Commission (NRC) amend 10 CFR 20.1301, "Dose limits for individual members of the public," to allow visitors to individuals confined pursuant to 10 CFR 35.75, to receive up to 5 milliSievert (mSv) (0.5 rem) while visiting. Detailed information on the petition is provided in Section II of the attached final rule (Attachment 6).

DISCUSSION:

Attachment 6 is the draft Federal Register notice (FRN) for the final rule. As stated above, the final rule resolves the PRM filed by the University of Cincinnati. Attachment 7 is the guidance document associated with the revision to Part 35, NUREG 1556, Volume 9. The guidance document reflects a risk-informed, more performance-based approach to medical use licensing. This document provides guidance on preparing a byproduct material medical use license application as well as NRC criteria for evaluating such an application. There is also a reduction in the amount of detailed information that must be submitted by applicants to support an application for medical use of byproduct material. In addition, the document provides model procedures that are acceptable to NRC to meet the regulatory requirements. Applicants may choose to either adopt the model procedures or develop their own procedures.

In preparing the final rulemaking package, staff carefully reviewed the draft final FRN that was provided to the Commission in SECY-99-201. During this review we identified areas that needed to be revised to make the Statements of Consideration and rule text more consistent. In April 2000, the Office of Nuclear Material Safety and Safeguards (NMSS) forwarded the revised draft final FRN and supporting rulemaking documents to other NRC offices for their final review and concurrence. During that review, various minor changes were recommended. These changes were identified as a result of the complete review of the supporting documents that was conducted by various NRC staff members. This review has made the rule, Statements of Consideration, and all supporting documents more consistent. In addition, as a result of this review, two major issues were raised that had not been previously identified for consideration. These issues are discussed below.

The first issue relates to the paperwork reduction review that the Office of Management and Budget (OMB) will undertake of the recordkeeping and reporting requirements in 10 CFR 35.2045, 35.2047, 35.3045 and 35.3047. In particular, 10 CFR 35.2045 and 35.2047 require licensees to maintain information, in a record that is virtually identical to the information licensees are to report to the NRC under 10 CFR 35.3045 and 35.3047. This is of concern since OMB, as a general rule, does not approve information collections that require both the submittal and retention of the same information by a respondent. OMB's position is that if the information is reported, the agency has the information that it needs for its purposes, and therefore, there is no reason for the agency to require that respondents also maintain the records absent substantial justification for doing so.

We have developed alternative rule text (Attachment 8) for addressing OMB's possible concern. The alternative rule text would require that information on medical events and exposures to an embryo/fetus or a nursing child be reported in writing to the NRC and the referring physician. Under the alternative rule language, the recordkeeping requirements, 10 CFR 35.2045 and 35.2047, would be deleted in their entirety. The reporting sections, 10 CFR 35.3045 and 35.3047, would be revised to add a requirement for the licensee to annotate a copy of the report that is required to be submitted to the NRC with: (1) the names of the individuals involved; and (2) the social security number, or other identification number, of the individual who is the subject of the medical event, or the pregnant individual and nursing child, as applicable. This annotated report would then be provided to the referring physician. Licensees would presumably retain a copy of the report to respond to potential requests for a written description of the event. Upon Commission approval of the alternative rule text, staff will incorporate this text into the FRN and will revise the supporting documents.

The second issue relates to reporting requirements associated with the release of individuals, pursuant to 10 CFR 35.75. In the draft final rule forwarded to the Commission on August 3, 1999 (SECY-99-201), 10 CFR 20.1301 was modified to further clarify the Commission's long-standing view that patient release is governed by 10 CFR 35.75, not 10 CFR 20.1301. The Commission reiterated this position in the rulemaking entitled, "Criteria for the Release of Individuals Administered Radioactive Material" (62 FR 4120, January 29, 1997). The exclusion for patient release in 10 CFR 20.1301 has been revised to read ". . . exclusive of the dose contributions from . . . exposure to individuals administered radioactive material and released, which is governed by 10 CFR 35.75." This clarification has brought to our attention the fact that the reporting requirements in Part 20 do not apply if an individual receives an exposure in excess of 5 mSv (0.5 rem) from an individual released pursuant to 10 CFR 35.75. This reporting requirement is an issue regardless of whether Part 20 is clarified as noted above.

In most scenarios, licensees are required to report to NRC exposures in excess of the dose limits. The Statements of Consideration for the 1997 revision to 10 CFR 35.75 did not discuss whether reporting was required if the licensee (1) failed to comply with 10 CFR 35.75 and an individual received a dose in excess of 5 mSv (0.5 rem) or (2) if the licensee complied with 10 CFR 35.75 but, learned, after the fact, that another individual (including a nursing child) received a dose in excess of 5 mSv (0.5 rem). Since this issue was identified during final preparation of the rulemaking package, the staff has not had sufficient time to fully evaluate whether a reporting requirement is needed, and if so, at what level. In addition, this issue has not been discussed with the Agreement States, ACMUI, members of the public and other external stakeholders. We recommend that the issue be further explored with all stakeholders. Staff will then prepare a rulemaking plan that discusses options and alternatives, including a "no-action" option if the staff believes rulemaking is not necessary.

The Commission will also note that the "Supplementary Information" section of the FRN (Attachment 6) includes a statement on, "Assessment of Federal Regulations and Policies on Families." The revision of Parts 20 and 35 is the first rulemaking for which the Agency has assessed the impact of the rule on family well-being, pursuant to Section 654 of the Treasury and General Government Appropriations Act of 1999 (Act), Pub. L. No. 105-277, 112 Stat. 2681, 528-529 (1998), to be codified at 5 U.S.C. 601 note. For each rule that may affect family well-being, the agency is to conduct a seven-factor assessment that is contained in the statute. The head of each agency also is to certify to the OMB and to Congress that an assessment has been conducted for those policies and regulations having a potential effect on family well-being. Such certification must also provide an adequate rationale for implementing those policies and regulations that may negatively affect family well-being. If the Agency determines that its rule or policy has no impact on family well-being, no further action or notification is required. In this case, there was a potential for an impact, so an assessment was performed. The assessment (Attachment 9) finds that the Part 20 and 35 rulemaking will not negatively affect family well-being. Letters will be forwarded to the OMB and Congress certifying that the required assessment has been performed and reflecting the assessment's finding.

SECY-99-201 indicated that the staff would submit an inspection plan with the final rulemaking package. We are in the process of implementing the Medical Pilot Inspection Program that was approved by the Commission in SRM-SECY-00-0001, "Pilot Program for NMSS Initiative on Streamlining Inspection and Enforcement." The year-long pilot program focuses inspection on risk-informed outcomes and licensee performance. It is limited to inspection of medical use licensees using unsealed byproduct material (10 CFR 35.100, 35.200, and 35.300). We plan to use the experience gained from this program to revise all medical inspection procedures. This will help to ensure that the medical inspection procedures incorporate the risk-informed, more performance-based approach in the rulemaking.

As part of our continuing efforts in Strategic Planning, the staff plans to disseminate information on this rulemaking to our internal and external stakeholders. These efforts will include

continued interaction with professional societies and training for NRC staff involved in the implementation of the rule (e.g., inspectors, license reviewers, enforcement specialists, NMSS staff, etc.).

As a result of this rulemaking, we will also need to revise the examples in Supplement VI, NUREG-1600, "General Statement of Policy and Procedure for NRC Enforcement Actions." This revision to Supplement VI is provided in Attachment 11. This revision modifies the examples in the existing Enforcement Policy to remove the terms "quality management program" and "misadministration," and to use the new terms, "written procedures for administrations requiring a written directive," and "medical event."

As part of our review of NUREG-1600, we evaluated whether the term "programmatic" should be retained in Supplement VI. This evaluation was conducted to complete action on a commitment made by staff in SECY 99-219, "Proposed Revision of the Enforcement Policy to Address the Process for Assessing the Significance of Violations." We believe it is appropriate to maintain the term "programmatic." In 1993, this term was added to the medical examples in the Enforcement Policy to reflect a reduced severity level for isolated mistakes, recognizing that there is some baseline probability of medical error that is very difficult to further reduce. The term "programmatic" is used to contrast with "isolated." Programmatic deficiencies have, as their root cause, a correctable weakness in some part of the licensee's program for preventing medical events, such as a failure to train personnel. The staff will assure that the distinction between isolated and programmatic is not used as an alternate means of aggregating lesser violations to a higher severity level.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this paper for resource implications and potential impact on license fee and annual fee schedules and has no objections. Resources needed to prepare the final rulemaking package in Fiscal Year (FY) 2000 were reprogrammed from lower-priority rulemaking activities within NMSS. Resources needed to implement this rule are contained in the FY 2001 budget. The Office of the Chief Information Officer has reviewed the rule for information technology and information management and recommends that the alternative rule text in Attachment 8 be incorporated into the rulemaking.

RECOMMENDATIONS:

That the Commission:

1. Approve incorporation of the alternative rule text (Attachment 8) into the draft final Federal Register notice for Part 35 (Attachment 6);

2. Approve the "Final Rule" (Attachment 6), with alternative rule text incorporated, for publication in the Federal Register;

3. Approve the "Notice of Change to Enforcement Policy" for publication in the Federal Register (Attachment 11);

4. Certify that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities, to satisfy requirements of the Regulatory Flexibility

Act, 5 U.S.C. 605(b);

5. Certify that this rulemaking will not negatively affect family well-being (Attachment 10); and

6. Approve development of a rulemaking plan that provides the Commission with options, including the "no-action" option, for revising Parts 20 or 35 to add a requirement for a licensee to report events where an individual received an exposure in excess of 5 mSv (0.5 rem) from an individual released in accordance with 10 CFR 35.75.

7. Note:

   a. Staff will request that the Office of the Federal Register publish the Notice of Final Rulemaking and Notice of Change to the Enforcement Policy the same day in the Federal Register;

   b. The petitioner will be informed of the Commission's decision to grant, in part, its petition (Attachment 12);

   c. The rulemaking and changes to the Enforcement Policy will become effective six months after publication in the Federal Register;

   d. A regulatory analysis and environmental assessment will be placed in the NRC's Public Electronic Reading Room (Attachments 13 and 14);

   e. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the reasons for it, as required by the Regulatory Flexibility Act (Attachment 15);

   f. After the Commission approves the rule, it needs to be submitted to the OMB for approval under the Paperwork Reduction Act (44 U.S.C. 3501, et seq.) Any OMB comments must be considered before publication of the final rule in the Federal Register. The supporting statement for the rule is provided in Attachment 16;

   g. The appropriate Congressional committees will be informed of this rulemaking;

   h. The NRC has determined that this action is not a major rule under the Small Business Regulatory Enforcement Fairness Act of 1966, and has confirmed this determination with the Office of Management and Budget. The appropriate Congressional and General Accounting Office contacts will be informed (Attachment 17);

   i. A press release will be issued; and

j. Copies of the Federal Register notice of the final rulemaking and the revision to the enforcement policy will be distributed to all affected Commission licensees, Agreement States, and potential Agreement States, and to other interested parties, upon request.

/RA by Carl J. Paperiello Acting For/

William D. Travers
Executive Director
for Operations

Attachments:
1. SRM-COMSECY-96-057, dtd 3/20/97
2. Chronological List of Part 35 Commission Papers and SRMs
3. SRM-SECY-99-201, dtd 2/16/00
4. Closeout of Items in SRM-SECY-99-201
5. Letter from V. Morris, RSO, University of Cincinnati, dtd, 4/7/96
6. Draft Final Federal Register Notice for Part 35
7. NUREG 1556, Volume 9
8. Alternative Rule Text for 10 CFR 35.3045 and 35.3047
9. Assessment of Federal Regulations and Policies on Family
10. Draft Final Federal Register Notice for Enforcement Policy
11. Letter to University of Cincinnati
12. Draft Final Regulatory Analysis
13. Draft Final Environmental Assessment
14. Regulatory Flexibility Analysis
15. Supporting Statement for Submittal to OMB
16. Small Business Regulatory Enforcement Fairness Act Forms

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