

POLICY ISSUE NOTATION VOTE

March 10, 2011

SECY-11-0035

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: INTEGRATED PLAN, TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS* PART 35, MEDICAL USE OF BYPRODUCT MATERIAL, ACTIVITIES AND OPTIONS FOR STREAMLINING THE MEDICAL RULEMAKING PETITION AND RULEMAKING PROCESSES

PURPOSE:

This paper provides the staff's Integrated Plan (IP) for activities associated with continued implementation of and possible amendments to the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material."

Additionally, this paper provides the staff's response to the Commission direction to provide options and recommendations for streamlining the medical rulemaking petition (hereafter referred to as "medical petition") and rulemaking processes without compromising the opportunities for full stakeholder involvement or the appropriate time for in-depth staff review and consideration. This paper does not address any new commitments.

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SUMMARY:

The enclosed IP (Enclosure 1) provides for the Commission's information a description of the paths forward and scheduling for activities presently planned for continued implementation of and possible amendments to the requirements in 10 CFR Part 35. The Commission requested this IP in Staff Requirements Memorandum (SRM)-SECY-10-0062 "Re-proposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions," dated August 10, 2010. Included in the plan are those activities required by two additional SRMs.¹

The second enclosed document titled "Streamlining Medical Petition and Rulemaking Processes" (Enclosure 2) provides options and staff's recommendations for streamlining the medical petition and rulemaking processes. The Commission requested these options and recommendations in staff requirements memorandum SRM-M101020, "Briefing on Medical Issues, 9:00 a.m., Wednesday, October 20, 2010," dated October 28, 2010. Based on the staff's analysis, the staff recommends maintaining the status quo for medical rulemakings and several enhancements to the petition program to expedite consideration of petitions.

BACKGROUND:

In SRM-SECY-05-0234, dated February 15, 2006, the Commission directed staff to proceed directly with the development of a proposed rule to modify both the written directive (WD) requirements in 10 CFR 35.40(b)(6) and the medical event (ME) reporting requirements in 10 CFR 35.3045 for permanent implant brachytherapy medical use, to convert from dose-based to activity-based criteria. In SRM-SECY-08-0080, dated July 25, 2008, the Commission approved publication of a proposed rule to amend 10 CFR Part 35 sections involving reporting and notification of MEs for permanent implant brachytherapy and also to clarify requirements for this usage.

The proposed rule was published in the *Federal Register* on August 6, 2008 (73 FR 45635), for public comment. Most of the 57 comment letters received primarily opposed parts of the rulemaking. During late summer and early fall of 2008, a substantial number of MEs involving permanent implant brachytherapy were reported to the NRC. Based on its evaluation of this information, including an independent analysis by an NRC medical consultant, the staff believed that a number of these MEs would not be categorized as MEs under the proposed rule. This would be inconsistent with the original regulatory intent because staff was directed to simply clarify the requirements for reporting to the NRC, and notify referring physicians and patients of MEs involving permanent implant brachytherapy.

Additionally, the evaluation of the circumstances and data from the MEs reported in 2008 prompted the staff to reevaluate the regulations related to training requirements and time frames for licensees to assess the dose to the treatment site for permanent implant brachytherapy. Subsequently, the staff modified the proposed rule language and rationale to reflect this new information, and in SECY-10-0062, "Re-proposed Rule: Medical Use of

¹ SRM-M090625B entitled "Meeting with Advisory Committee on the Medical Uses of Isotopes (ACMUI), 1:30 p.m., Thursday, June 25, 2009," dated July 1, 2009, and SRM-M100708B entitled "Briefing on Proposed Rule on Part 35 Medical Events Definitions – Permanent Implant Brachytherapy, 1:30 p.m., July 8, 2010," dated July 21, 2010.

Byproduct Material – Amendments/Medical Event Definitions,” dated May 18, 2010, recommended that a revised proposed rule be published for public comment.

In SRM-SECY-10-0062, dated August 10, 2010, the Commission disapproved the staff’s recommendation to publish the re-proposed amendments to Part 35 in the *Federal Register*. Instead, the Commission directed the staff to work closely with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and the broader medical and stakeholder community to develop event definitions that will protect the interests of patients, allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the agency to detect failures in process, procedure, and training, as well as any misapplication of byproduct materials by authorized users. Additionally, the staff was directed to hold a series of stakeholder workshops to discuss issues associated with the ME definition. Finally, the SRM directed staff to provide the Commission with an IP, denoting schedule and Agreement States participation, for completing this rulemaking along with other activities in the medical area, such as developing guidance for incorporating ACMUI input into major medical policy issues and for licensing and inspection programs. This paper conveys the IP to the Commission, for information, as Enclosure 1.

In addition, in SRM-M101020, the Commission further directed the staff to include, as part of the IP, options and recommendations for streamlining the medical petition and rulemaking processes without compromising the opportunities for full stakeholder involvement or sufficient time for in-depth staff review and consideration. This paper also provides, as a separate enclosed document for Commission vote (Enclosure 2), the requested options and recommendations for streamlining the medical petition and rulemaking processes.

DISCUSSION:

1. Integrated Plan for Part 35 Guidance and Rulemaking

The enclosed IP, titled “Integrated Plan for Part 35 Guidance and Rulemaking,” lists the outstanding SRMs by number and title. For each SRM, the SRM requirement is listed as a bulleted item. The Path Forward section presents the staff’s intended actions to fulfill the requirement. A schedule for completion of the listed requirements, is also included in each section. The IP concludes with an integrated schedule for all of the requirements from all of the listed SRMs.

In reviewing the IP, it is beneficial to be aware of the current status of various activities referenced in it, including:

- An “expanded” Part 35 rulemaking began in July 2010. The 28 items being addressed include the Commission-directed modifications to the training and experience attestation requirements (SRM-SECY-08-0179, “Recommendations on Amending Preceptor Attestation Requirements in 10 CFR Part 35, Medical Use of Byproduct Material”, dated November 20, 2008, and SRM-COMSECY-09-0028, “Update on 10 CFR Part 35 Rulemaking Activities including Request to Rebaseline One Issue”, dated January 12, 2010), and extending grandfathering to certain certified individuals (73 FR 27773, May 14, 2008, resolution of petition for rulemaking PRM-35-20), as well as multiple

issues that developed and became apparent through implementation of the 2002 revised Part 35 and its 2005 modifications to training and experience requirements.

The staff is developing a regulatory basis for modifying the Part 35 requirements for WDs and reporting MEs involving permanent implant brachytherapy by June 2012, and these modifications will then be ready for inclusion in the ongoing “expanded” Part 35 rulemaking. This integrated approach to Part 35 rulemaking, rather than a sequential approach in which modifying the Part 35 requirements for WDs and reporting MEs would be deferred until the current “expanded” Part 35 rulemaking was completed, will have support from some stakeholders but will be opposed by others. The Agreement States generally view a combined rulemaking effort as more effective and efficient. The opponents will primarily support the changes to the training and experience provisions of the rule sooner because the resolution of their issues will be delayed, and will also be concerned that their issues would be tied to other more controversial issues, such as ME reporting requirements, increasing the risk of further delays.

- The ACMUI unanimously voted to approve the report of its Permanent Implant Brachytherapy Subcommittee (PIBS) at the October 20, 2010, ACMUI meeting. Reference Agencywide Documents Access and Management System (ADAMS) Accession Number ML103540385. The PIBS report included the caveat that it was to be considered as an interim report that may be revised in the future in response to additional input, such as that expected to be received from stakeholders at the upcoming public workshops. These workshops are currently being planned for June 2011. The ACMUI final report on prostate brachytherapy is scheduled to be provided to the NRC staff in the fall of 2011, after the stakeholder workshops. The staff would then use the ACMUI report to develop recommendations that would be conveyed to the Commission in a Notation Vote Commission paper.
- As required by SRM-M100708B, staff developed internal procedures that require inclusion of ACMUI recommendations and dissenting views along with staff’s assessment of the ACMUI recommendation and dissenting views for all major medical policy issues that are submitted to the Commission, including proposed and final rules. Policy and Procedure (P&P) 2-5 entitled, “FSME Procedure for Interacting with the Advisory Committee on the Medical Uses of Isotopes during Development of Major Medical Policy Issues” was issued on January 12, 2011, effective immediately. The SRM also asked the staff to develop a Commission paper outlining possible improvement mechanisms for providing the Commission with the ACMUI’s feedback regarding medical issues, including an implementation plan for the ACMUI reporting to the Commission. This project is in progress and on track to be completed by the current due date of April 1, 2011.

2. Streamlining Medical Petition and Rulemaking Processes

To provide the Commission with options to streamline the medical petition and rulemaking processes, the staff formed a working group (WG). The WG reviewed the recommendations made in SECY-07-0134, “Evaluation of the Overall Effectiveness of the Rulemaking Process Improvement Implementation Plan,” and the Commission direction in SRM-SECY-07-0134

dated October 25, 2007. These included delegating to the Director of FSME the authority to release, for public comment, draft rule text, statements of consideration, and the technical basis for a proposed rule, and to hold workshops prior to submission of a proposed rule to the Commission. In addition, the staff is currently reassessing the process used to prioritize rulemaking across the agency's business lines to ensure that agency priorities are reflected in rulemaking priorities. As discussed at the October 20, 2010 Commission meeting on medical use of radiation, the Commission's objective to enhance stakeholder participation and engagement may counteract staff's efforts to streamline and expedite its rulemaking process. The WG also examined the Office of Federal and State Materials and Environmental Management Programs (FSME) P&P 6-10, Revision 1, which provides procedures for preparation and review of petition and rulemaking packages, to identify possible options. All medical petitions and rulemakings follow the general petition and rulemaking procedures outlined in P&P 6-10. Based on existing procedures and review of prior recommendations, staff formulated the regulatory options and recommendations described below and in Enclosure 2.

To streamline the petition process, staff developed and considered 3 options: Option 1) No Change to Existing Petition Process; Option 2) Assign a Higher Priority for Petition Resolution and Closure; and Option 3) Increase the Prioritization of Rulemakings that Arise from Petition Actions. The staff recommends Option 2, which would shorten the petition resolution time to 9 months by giving medical petitions a higher priority. This option would provide sufficient time for in-depth staff review and not result in any additional needed resources. The improvements under the other options related to evaluating the acceptance criteria for denial of a petition and other process improvements would need changes through rulemaking, whereas Option 2 can be more readily implemented.

For rulemakings, the staff developed and considered the following 4 options: Option 1) No Change to Existing Rulemaking Process; Option 2) Increase Resources Dedicated to Medical Rulemakings; Option 3) Make Part 35 More Performance Based; and Option 4) Increase Priority for Medical Rulemakings. The staff recommends Option 1, that is, no change and to more fully utilize the existing processes and budgeted resources to engage stakeholders in the rulemaking development process. Options 2 and 3 may streamline the medical rulemakings, but are resource intensive, adversely affect other assignments and Option 3 is not a near term solution. Option 4, elevating medical rulemakings to a higher priority, could result in other high priority work being deferred and may lead to the perception that non-medical safety issues are not treated commensurate with their safety significance.

RECOMMENDATIONS:

The staff's recommendations for streamlining the medical petition and rulemaking processes, as fully discussed in Enclosure 2, are summarized as follows:

- **REGULATORY OPTIONS FOR MEDICAL PETITIONS** - The staff recommends that the Commission approve Option 2 to decrease the petition resolution time to 9 months for medical petitions.

- **REGULATORY OPTIONS FOR MEDICAL RULEMAKINGS** - The staff recommends that the Commission approve Option 1, that is, no change to existing process and to fully implement existing flexibilities in stakeholder interactions that are available in the current process.

RESOURCES:

Some portions of the attached IP, such as the workshops, are not included in the budget. An additional 0.5 full-time equivalent (FTE) would be needed in the remainder of Fiscal Year (FY) 2011; however, the staff can accommodate this by deferring lower priority work in the medical area.

No additional resources are needed for any of the three options for medical petitions. The staff recommends Option 2 to streamline the medical petition process. For implementation of streamlining the medical rulemaking process, the additional resources (0.1 to 0.2 FTE and 35 to 50K per stakeholder meeting) can be met in the current budget for FY 2011 and FY 2012. Beyond FY 2012, resources will be requested through the budget process. For the other options considered, Options 2 and 3 would require significantly more resources, each around 4.2 FTE per FY. Option 4 could result in high priority rules being deferred.

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 paper for resource implications and has no objections.

In parallel with providing this paper to the Commission, and in accordance with P&P 2-5, "FSME Procedure for Interacting with the Advisory Committee on the Medical Uses of Isotopes during Development of Major Medical Policy Issues," we are seeking the ACMUI views on the approach in the IP of combining with the ongoing "expanded" Part 35 rulemaking, the still-to-be-determined modifications to the Part 35 requirements for WDs and reporting MEs involving permanent implant brachytherapy. We will advise the Commission if the ACUMI provides a committee view regarding this combined rulemaking approach.

/RA by Mike Weber for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:

1. IP for Part 35 Guidance and Rulemaking
2. Streamlining Medical Petition and Rulemaking Processes

- **REGULATORY OPTIONS FOR MEDICAL RULEMAKINGS** - The staff recommends that the Commission approve Option 1, that is, no change to existing process and to fully implement existing flexibilities in stakeholder interactions that are available in the current process.

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Enclosures:

1. IP for Part 35 Guidance and Rulemaking
2. Streamlining Medical Petition and Rulemaking Processes

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OFC	D: DILR	OGC	D: CFO	TechEd	D: FSME	EDO	
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