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.

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.

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

- 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/

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

Integrated Plan for Part 35 Guidance and Rulemaking
(WITS 201000193/ EDATS: SECY-2010-0425)

This "Integrated Plan for Part 35 Guidance and Rulemaking," (IP) identifies the outstanding Staff Requirements Memoranda (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 each requirement. A schedule for completion of the listed requirements is also included in each section. The IP concludes with an integrated schedule for fulfilling the requirements from the listed SRMs.

A. SRM-SECY-10-0062, "Re-proposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions," dated August 10, 2010, and SRM-M101020, "Briefing on Medical Issues, 9:00 A.M., Wednesday, October 20, 2010…"

- Work closely with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and broader medical and stakeholder community to develop event definitions. Plan to be provided via Commissioner's Assistants (CA) Note. **Due: March 25, 2011 (201000192).**

- Hold a series of stakeholder workshops to discuss issues associated with the medical event definition. Plan to be provided via CA Note. **Due: March 25, 2011 (201000192).**

- Develop Integrated Plan denoting schedule and Agreement State 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**. Due: March 8, 2011 (201000193).**

- As part of the integrated plan for completing the activities in the medical arena which was directed by the Commission in SRM-SECY-10-0062, the staff should include options and recommendations for streamlining the medical rulemaking petition and rulemaking processes without compromising the opportunities for full stakeholder involvement or the appropriate time for in-depth staff review and consideration. **Due: March 8, 2011 (201000264).**

- Include in the integrated plan a proposed schedule for completion of the final rule written directive requirements in 10 CFR 35.40(b)(6) and the medical event reporting requirements in 10 CFR 35.3045 for permanent implant brachytherapy medical use to convert from dose-based to activity-based. **Due date to be reset following receipt of 201000193 (200600079).**

- Provide revised guidance documents for final rule to amend 10 CFR Part 35, medical events and requirements for permanent implant brachtherapy (to be distributed to affected external stakeholders and made publically available) per current SRM. **Current Due Date: March 31, 2011 (200800307).** Due date to be reset following receipt of 201000193.

Path Forward:

1. **Develop Medical Event Reporting Guidance for Part 35 Current Rule and Expanded Rulemaking**:

   Obtain regional alignment on implementation issues associated with the current medical event reporting requirements for prostate brachytherapy and prepare draft inspection and licensing guidance. In addition, the staff will prepare guidance documents for the final expanded rule.

   - Share the draft licensing and inspection concept with both the ACMUI and Organization of Agreement States (OAS) for high-level feasibility review.

   - Use the draft guidance as a starting point for conducting a series of stakeholder workshops.

   - Schedule:

     A. Current rule

     - 3 months to develop and vet with regions. (Completion March 2011)
     - Provide to OAS and ACMUI for feasibility review (March–April 2011)

     B. Final Expanded Rule Guidance (200800307), pending Commission decision (proposed new due date - October 2014)

2. **Conduct Stakeholder Workshops**:

   Hold two stakeholder workshops. The locations will be determined based on consideration of factors to maximize stakeholder participation. Locations being considered include Rochester, Minnesota (Mayo Clinic), New York, New York (Memorial Sloan Kettering), and Denver, Colorado (Denver Federal Center). Additionally, the spring 2011 ACMUI meeting will be devoted to Part 35 rulemaking issues.

   The following Part 35 rulemaking topics will be discussed at the workshops to gather input from a spectrum of stakeholders:

   - Medical event reporting requirements for prostate brachytherapy – newly developed draft guidance for the current rule and the ACMUI prostate subcommittee interim report will serve as the starting point for discussions at the workshops.

   - Controversial Part 35 “expanded” rulemaking topics (e.g. modification of preceptor attestation requirements, grandfathering some certified individuals as authorized, naming assistant RSOs on medical licenses, etc.)

   - Patient release issues.

   Anticipated dates of workshops: June 2011

3. **Initiate Expanded Rulemaking:**

The currently in-progress "expanded" Part 35 rulemaking will be further expanded to include permanent implant medical event (ME) reporting requirements, because with the plan described in item 1, there may only need to be clarifications to the rule, rather than a new approach taken. Input from the workshops will be used for the expanded Part 35 rulemaking.

The staff believes that the Integrated Plan (IP) and the new procedure for addressing ACMUI views on major medical policy issues would have impacts on the current "expanded" Part 35 rulemaking schedule.

Current OEDO schedule for the Expanded Part 35 rulemaking (200900016) (per January 12, 2010 SRM re: COMSECY-09-0028) is:

Proposed Rule	March 8, 2012
Final Rule	September 23, 2013

In following the IP, the new Commission due dates for the current rulemakings (200600079 and 200900016) would be:

Proposed Rule	December 2012
Final Rule	October 2014

New Schedule for Expanded Rulemaking

1.	Conduct stakeholder workshops	June 2011
2.	Consolidate comments from the workshops	July - September 2011
3.	Complete ME rule Regulatory Basis	June 2012
4.	Complete proposed rule and provide to Commission	December 2012*
5.	Publish proposed rule	March 2013
6.	Allow 120 days for comments (typically, the Agency gives 75 days, but the large number of issues justify at least 120 days)	July 2013
7.	Conduct 3 public meetings during the comment period	April - July 2013
8.	Final Rule to Commission	October 2014**

* One year from consolidating comments, plus 3 months to accommodate the new ACMUI procedure

** One year from the close of comment period, plus 3 months to accommodate the new ACMUI procedure

B. SRM-M090625B, "Meeting with Advisory Committee on the Medical Uses of Isotopes (ACMUI), 1:30 P.M., Thursday, June 25, 2009…," dated 7/1/09.

- The Commission looks forward to the advice of the ACMUI on recommendations for improvements to the NRC's processes and regulations as an outgrowth of the investigation of the Department of Veterans Affairs medical events and any regulatory changes for permanent implant brachytherapy programs. **(200900138, due December 22, 2010 (extension sent to OEDO for March 31, 2012))**

Path Forward:

The ACMUI final report on prostate brachytherapy will be provided to the NRC staff in the fall of 2011, after the stakeholder workshops. (As noted above, ACMUI has requested to have the benefit of the stakeholder workshops before finalizing its report.) The staff would then use the ACMUI recommendations to develop recommendations that would be conveyed to the Commission in a Notation Vote SECY paper.

C. SRM-M100708B, "Briefing on Proposed Rule on Part 35 Medical Events Definitions – Permanent Implant Brachytherapy, 1:30 P.M., Thursday, July 8, 2010…," dated July 21, 2010.

- Develop internal guidance that requires that for all major medical policy issues that are submitted to the Commission, including proposed and final rules, the staff should include ACMUI recommendations and dissenting views **(201000183, complete)**.

- Staff should work with OGC to provide the Commission with a paper outlining possible improvement mechanisms for providing the Commission with the ACMUI's feedback regarding medical issues, including the pros and cons of restructuring ACMUI such that it reports to the Commission. The paper should provide an implementation plan for ACMUI reporting to Commission **(201000184, due April 1, 2011)**.

Path Forward:

1. The staff has developed a procedure for providing ACMUI input to the Commission on major medical issues. (Completed January 12, 2011)

2. The staff is preparing a SECY paper on potential improvement mechanisms, including the pros and cons of ACMUI reporting to the Commission. This paper is currently scheduled to be provided to the Commission by April 1, 2011

INTEGRATED SCHEDULE

DATE	ACTIVITY
01/21/11	Develop internal guidance on how ACMUI input will be provided to the Commission on major medical policy issues (project complete: FSME Policy and Procedure 2-5, effective January 12, 2011).
03/11	Prepare draft inspection and licensing guidance for current ME reporting requirements.
03/11-04/11	OAS and ACMUI perform high level feasibility review of inspection and licensing implementation approach for ME reporting requirements.
03/08/11	Provide to Commission - Integrated Plan plus recommendations for streamlining medical use rulemaking and petition processes.
03/25/11	Provide CA note on plans for holding stakeholder workshops associated with the development of the ME definition.
04/01/11	Provide to Commission - improvements to ACMUI reporting and implementation plan for reporting to Commission.
04/11	April ACMUI Meeting (focus on Part 35 rulemaking issues).
06/11	Conduct two stakeholder workshops.
07/11-09/11	Consolidate comments from workshops.
11/11	Revise draft licensing and inspection guidance for current ME rule and provide to regions and licensees.
04/12	Transmit Commission paper with recommendations on medical event reporting for permanent implant brachytherapy use.
06/12	Complete ME rule Regulatory Basis.
12/12	Provide to Commission-Proposed Expanded Rule (includes ME rule).
03/13	Publish proposed rule.
04/13-07/13	Allow 120 days for public comments (typically the Agency gives 75 days, but the large number of issues justify 120 days).
04/13-07/13	Conduct 3 public meetings during the comment period.
10/14	Provide to Commission- Final Rule.

STREAMLINING MEDICAL RULEMAKING PETITION AND RULEMAKING PROCESSES

BACKGROUND

In a Staff Requirements Memorandum (SRM) dated October 28, 2010, staff was directed to provide options and recommendations to the Commission for streamlining the medical petition and rulemaking processes without compromising the opportunities for full stakeholder involvement or the appropriate time for in-depth staff review and consideration. Staff was directed to include this information in the Integrated Plan (IP) for completing the activities in the medical area (SRM-SECY-10-0062).

Staff formed a working group (WG) to address the Commission directive. The WG examined the Office of Federal and State Materials and Environmental Management Programs (FSME) Policy and Procedure 6-10 (P&P 6-10), Revision 1, which provides procedures for preparation and review of petition and rulemaking packages by FSME staff, to identify possible options to streamline the medical rulemaking processes. All medical rulemakings follow the general rulemaking procedures outlined in P&P 6-10. The WG also reviewed 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. Based on these reviews, staff formulated the regulatory options and recommendations outlined below.

In SECY-07-0134, Section 4.1, staff made a recommendation to the Commission to examine the U.S. Nuclear Regulatory Commission's (NRC's) petition process. In the SRM on SECY-07-0134, the Commission supported the recommendation regarding the need for the Agency to look for efficiencies in the NRC petition process with a goal of reducing the time needed to complete an action. The Commission noted that the staff's overall effort to improve the petition process "should focus on provisions that would make the NRC process more efficient while improving the process' transparency and consistency." In a memorandum to the Executive Director of Operations (EDO), dated December 5, 2007, the staff outlined proposed revisions to the petition process that would immediately enhance efficiency and effectiveness. These revisions dealt with modifying the process for documenting the resolution of petitions and a new definition for closure of petition. The modifications were subsequently approved by the EDO.

A petition is resolved when the Petition Review Board makes a decision to either consider the petition in a rulemaking or to deny the petition. The decision is documented in an EDO Daily Note and in a meeting summary. Once the petition is resolved, the WG develops a closure package (letter to the Petitioner and a *Federal Register* notice) that documents the NRC's basis for consideration of the issues in rulemaking or denying the petition. The Agency goal is to have the closure package to the EDO within 3 months of the resolution. Resource constraints and/or the complexity of the petitioner's request can impact the staff's ability to meet the time goals for resolution and closure. Petitions are not typically assigned as high priority because they typically do not involve matters that warrant prompt safety or security attention.

If the petition is to be considered in rulemaking, it is added to the NRC's list of rulemakings and prioritized under the NRC's Rulemaking Common Prioritization process. Petition issues can be

added to an ongoing rulemaking, a future planned rulemaking or can be added as a new unplanned rule. If the Petitioner has not provided an adequate regulatory basis to begin a rulemaking, the staff must develop an acceptable regulatory basis before beginning the proposed rule. It is possible that some low priority petition issues may never result in a rulemaking due to the rulemaking priority process and resource constraints (i.e., low priority rulemakings are generally not budgeted). In addition, the staff, under the purview of the Rulemaking Coordinating Committee (RCC), is evaluating the current prioritization process, the acceptance criteria for docketing a petition, the criteria for denial of a petition, an appeal process, as well as other possible process changes.

An example of a low priority issue raised in a petition is the Ritenour Petition, PRM 35-20, filed by E. Russell Ritenour, Ph.D., on behalf of the American Association of Physicists in Medicine on September 13, 2006. The petition requested that the training requirements for experienced Radiation Safety Officers and medical physicists be amended to recognize board certified physicists and radiation safety officers as grandfathered for the modalities that they practiced as of October 24, 2005. In resolution of the Ritenour petition, the NRC determined that there was merit to the petition and informed the petitioner (73 FR 27773, May 14, 2008) that the issues raised in the petition would be considered in a future rulemaking, if a robust regulatory basis could be developed to support the issue. The petitioner did not provide an adequate regulatory basis to support a rulemaking resulting in the NRC staff having to develop a regulatory basis. In developing the basis, the NRC surveyed the Certifying Boards and developed information necessary to assess the petitioner's issue. Since the issues raised by the petitioner did not involve any significant health and safety issues as the affected individuals can apply for continued user status through the alternate pathway, the rulemaking was not considered a high priority item in the common prioritization process. However, the issue (training requirements for experienced individuals) has been included in the expanded Part 35 rulemaking.

The staff notes that all rulemakings are subject to the common prioritization of rulemaking process. The common prioritization of rulemaking process is an agency-wide effort and medical rulemakings are weighted against other rulemakings based on safety and security implications. Classification of the rulemakings through this system directly impacts the schedule and amount of resources committed to each rulemaking. Generally, low priority rulemakings and some medium priority rulemakings are not funded and are worked during downtime from higher priority work. Therefore, if a medical rulemaking is determined to be low or medium priority through this process, resource allocations to the rule will impact the schedule and will be reflected in the time it takes to publish proposed and final rules. The staff is currently reassessing the rulemaking prioritization process across the agency with the objective of ensuring rulemaking priorities and assigned resources reflect agency priorities.

Additionally, staff's schedule to complete medical rulemakings has been further lengthened by the new requirement that the staff should include the Advisory Committee on the Medical Use of Isotopes (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. This new procedure, which has been developed in coordination with the ACMUI, will require an additional 90-120 days to prepare the Commission paper on the proposed rule, depending on the complexity of the issues.

In the SRM on SECY-07-0134, the Commission delegated to the FSME Director the authority to release draft rule text, statements of consideration, and the regulatory basis for public review and to hold workshops prior to submission of a proposed rule to the Commission. Early stakeholder engagement can support the production of a more fully developed regulatory basis that addresses known stakeholder concerns. A robust regulatory basis supports sound decision making on the rulemaking. Obtaining input on preliminary rule text or draft statements of consideration can also lead to better rulemaking and earlier and more meaningful stakeholder involvement. Early engagement of stakeholders can result in a proposed rule that has fewer issues raised during the public comment period, and therefore the final rule can be completed more effectively and efficiently. In recent years, outside stakeholder engagement has been more limited for medical related rulemakings. Staff intends to more fully incorporate the full range of Commission approved stakeholder interaction options in future rulemakings. Additional resources would be required to conduct stakeholder interactions. Engaging stakeholders on preliminary draft rule text and statements of consideration would cost an estimated 0.1 to 0.3 full time equivalents (FTE) per engagement because of the time needed to prepare documents for publication and to analyze comments received. In addition, it would cost between $35K and $50K for each workshop of a 2-3 day duration. The additional resources can be accommodated in the current budget.

In addition, stakeholder engagement will be conducted during the regulatory basis development stage for most medical rulemakings; the exception would be rules that are purely administrative. These interactions would include the use of issue papers to obtain early input on topics, publication of draft regulatory basis documents for public comment, holding public workshops and meetings, and meetings with the ACMUI. While the WG estimates that stakeholder engagement at this stage will result in the expenditure of additional resources and may increase the time necessary to develop the regulatory basis, stakeholders often can identify flaws and oversights in the regulatory basis based on their knowledge and experience. Stakeholders may also be able to offer data that can be used to support the development of the regulatory basis. A more robust regulatory basis that has already addressed most of the stakeholder's concerns should result in a better proposed rule and more stakeholder support could reduce the amount of time needed to develop the proposed rule package. A better proposed rule should result in fewer issues being raised during the public comment period and therefore could result in the final rule being completed earlier. Also, requests to extend the comment period at the proposed rule stage may decrease.

The staff will also provide review and comment by the Agreement States for proposed rule language and compatibility designations for sections of rule text. Agreement States are represented on medical rule Working Groups and Steering Committees.

The direct final rule (DFR) process is a technique for expediting the issuance of noncontroversial rules. The process is used when the NRC believes that the rule is noncontroversial and that a significant adverse comment will not be received. Staff has used this process for medical rules in the past where the staff believed that no significant adverse comment would be received (e.g. Authorized User Clarification, 74 FR 33901, July 14, 2009; and Minor Corrections and Clarifications, 72 FR 45147, August 13, 2007). Staff will continue to use the DFR process for medical rules that meet the criteria. The DFR process significantly reduces the rulemaking time because the direct final rule and its companion proposed rule are published in the *Federal Register* at the same time, while offering the public the opportunity to

challenge the agency's view that the rule is noncontroversial. If any of the comments received are a significant adverse comment, the agency publishes a withdrawal of the direct final rule. If no significant comment is received, the NRC publishes a subsequent document that confirms the effective date. However, most medical rules do not meet the criteria for a DFR because of significant stakeholder interest in the rulemakings and diverse and opposing stakeholder views on the topics addressed by the rulemakings.

REGULATORY OPTIONS FOR MEDICAL RULEMAKING PETITIONS

Option 1: No Change to Existing Petition Process

This option would result in no change to the petition process that is currently in place.

Under the current process, a WG is formed to evaluate the petition and make a recommendation to a Petition Review Board on the merits of the petition. The Agency goal is to resolve the petition within 1 year of the petition being noticed in the *Federal Register* by determining whether the petition should be considered in the rulemaking process or whether the petition should be denied.

Under this option, the staff would continue to process medical petitions under the current process. The goal is to have the petition resolved within 1 year of publication and closed 3 months after the petition is resolved, for a total of 15 months. Any rule coming from the petition would be added to the rule queue and prioritized as appropriate using the existing criteria. Since this option makes no changes to our current process, no additional resources would be needed to implement this option.

Option 2: Assign a Higher Priority for Petition Resolution and Closure

Under Option 2, the staff would give a higher priority to medical petition resolution and closure. The petition resolution and closure would become a primary assignment. In addition, the WG formed to resolve the petition would be informed that the action is a priority. The WG could begin the evaluation process before the end of the comment period. The goal of resolving a petition within 1 year of the publication of the petition in the *Federal Register* could be shortened to 9 months. The petition closure goal would remain 3 months after resolution. This action would result in the Petitioner being notified of the results of the petition review earlier. If any petition issues were to be considered in rulemaking, the issue would be added to the NRC's Common Prioritization of Rulemaking (CPR) process, and the petition issue would be prioritized based on its merit. Staff believes that this option can be more readily implemented because petitions, being fewer in number, are not as formally prioritized as the rulemakings are prioritized in the CPR process. However, the staff notes that if a medical petition is given a high priority, the action could result in another rulemaking activity being delayed. No additional resources would be needed to implement this option.

Option 3: Increase the Prioritization of Rulemakings that Arise from Petition Actions

Under Option 3, the staff would elevate the priority of any medical rulemaking that originates from a petition. This would result in any regulatory basis development work necessary to support the rulemaking being given a high priority so that work would begin promptly after

petition resolution and closure. Action on the proposed rule would also be given a high priority and work would begin as soon as an acceptable regulatory basis was completed. Petition items would not be included with other items, unless the rule was already under development. This could result in actions originating from a petition being added to the regulations much more quickly (in some cases shorter in time by years, depending on the issue and priority). However, this is outside of the existing rulemaking prioritization process and could result in some otherwise higher priority items being deferred and may lead to the perception that medical safety issues are not necessarily being considered commensurate with their safety significance. Depending on the timing of petitions, this could also result in a queue of medical rulemakings as only one Part 35 rulemaking can be submitted to the Office of Management and Budget (OMB) at a time for Paperwork Reduction Act review. No additional resources would be needed to implement this option.

(Please see the attached timeline for resolution and completion of petitions for rulemaking.)

Staff Recommendation:

In summary, the staff recommends Option 2 to assign a higher priority for petition resolution to further streamline the medical petition process. This option would shorten the petition resolution process (i.e., to proceed or not with rulemaking) from 1 year to 9 months. This option would not result in any additional resources, although it may delay other assignments (e.g., rulemakings). Other improvements under consideration related to evaluating the acceptance criteria and criteria for denial of a petition and other process improvements under the purview of the RCC would need changes through rulemaking, whereas Option 2 can be more readily implemented in the near term.

REGULATORY OPTIONS FOR MEDICAL RULEMAKINGS

Option 1: No Change to Existing Rulemaking Process

This option would result in no changes being proposed to the existing rulemaking processes. The processes described above in the background section are already well established.

Option 2: Increase Resources Dedicated to Medical Rulemakings

Under Option 2, resources dedicated to the completion of medical rulemakings would be tripled. The increase in resources would have to include an increase in the resources for offices supporting rulemaking activities such as the Office of the General Counsel (OGC). This would result in a greater number of staff available to engage in completing medical rulemakings.

Improvements to the medical rulemaking timeline would be realized for both the proposed and final rules. Specifically, increased resources would result in staff being available to hold multiple public meetings and to form multiple working groups on separate technical aspects of medical rulemakings. For example, the technical aspects of the Part 35 Expanded Rulemaking could be broken up into three parts and examined by three separate working groups. This could expedite of the process at three distinct steps (see pages 10-11 for a pictorial representation of the process, each step is represented by a rectangle). For the proposed rule, the timeline would be shortened during the “pre-rulemaking activities” and “preparation of the proposed rule package”

steps. This projected timeline acceleration is based on increased staff resources available to conduct concurrent public meetings during the pre-rulemaking period and to participate on working groups drafting the rule language and completing other parts of the proposed rule package.

For the final rule, the timeline could be shortened during the "resolution of comments" period. Additionally, an increase in the amount of staff dedicated to addressing the comments during the final rule stage is predicted to shorten the time to complete the final rulemaking. No efficiency to the timeline would be realized during the concurrence (which includes the ACMUI and Organization of Agreement States (OAS) review and comment periods), approval, or publishing periods. Staff estimates that a total of 2-3 months may be saved during the proposed rule phase and about 1-1.5 months for comment resolution for the final rule. One limitation of this approach is that OMB's Paperwork Reduction Act review process does not allow for more than one change to a specific Part of the CFR at any given time. This means that amendments to Part 35 cannot be split into two (or more) concurrent rulemakings because each Part 35 rulemaking will be held in the queue for clearance by OMB, potentially negating any acceleration gained in conducting parallel rulemakings. Another challenge is the potential of added burden to outside groups such as the OAS and the Conference of Radiation Control Program Directors (CRCPD) because of the increase in staff needed to support multiple working groups (working groups traditionally include at least one member from OAS and/or CRCPD).

The resources required to implement this option are estimated to be an additional 4.2 FTE. This is based on the current staffing of 2.1 FTE for the "expanded" medical rulemaking in Fiscal year 2012 and would bring the total staffing to 6.3 FTE for medical rulemakings, with travel and contract funds provided within current out-year budgets. If additional medical rulemakings were added to the NRC rulemaking queue, the number of staff dedicated to medical rulemakings would have to be increased appropriately. The staff notes that the increase in FTE should be focused on increasing technical staff knowledgeable about the medical uses of radioactive materials. This would allow FSME to hire subject matter experts who have detailed understanding of the intricacies of developing proposed changes to Part 35. Staff would like to emphasize that if this option were to be adopted without a substantial increase to the existing resources as outlined, staff, including technical support staff, would have to stop work on other high priority rulemakings in order to achieve the productivity and acceleration to the timeline estimated under this option. If sustained rulemaking support in the medical use program were not required, these staff resources would be reallocated to support other NRC program needs.

Option 3: Make Part 35 More Performance Based

Staff notes that Part 35 was revised in 2002 (76 FR 20250, April 24, 2002), with the goals of focusing NRC's regulations on those medical procedures that pose the highest risk to workers, patients, and the public, and structuring its regulations to be more risk informed and more performance based.

Under this option Part 35 will be reevaluated in its entirety, on a section-by-section basis, to identify those sections that could be structured to be more performance based and less prescriptive. This would give licensees greater flexibilities consistent with the revised Medical Policy Statement (MPS) published on August 3, 2000 (65 FR 47654).

In implementing the current regulations in Part 35, staff has identified 28 issues that need to be amended. In addition, Part 35 was amended in July 2009 (74 FR 33901) using the Direct Final Rule process to make clarifications with regard to the training and experience (T&E) requirements that were published in 2005 (70 FR 16336, March 30, 2005). Although the T&E requirements are risk informed (for example, fewer training hours required for those authorized users who want to be approved for diagnostic procedures than for therapeutic authorizations), they are more prescriptive than the T&E regulations prior to the 2005 revision.

Staff understands that prescriptive requirements are easier for the inspection staff because check lists can be created, and relatively new staff can evaluate a program more easily. In the case of performance based regulations, a more knowledgeable staff is needed to develop licensing and inspection guidance and to evaluate licensed programs. Staff notes that it is a challenge to hire personnel with a medical background, especially for the Agreement States with budget constraints.

This option would be time and resource intensive and is not a near term solution. Staff estimates, based on the effort on the 2000 rulemaking, that an additional 4.0 FTE would be required each year over a 4-year period. However, this comprehensive analysis has the potential over the long-term to increase the effectiveness and efficiency of the overall medical regulatory framework by making Part 35 more performance based, which would lead to fewer amendments being needed in the future.

Option 4: Increase Priority for Medical Rulemakings

Under Option 4, the staff would elevate the priority of all medical rulemaking to high. This would result in any regulatory basis development work necessary to support the rulemaking being given a high priority. Action on the proposed rule would also be given a high priority, and work would begin as soon as an acceptable regulatory basis was completed. This could result in medical rulemakings being completed much more quickly (in some cases shorter in time by years, depending on the issue and priority). However, this could result in other high priority work being deferred and may lead to the perception that non-medical safety issues are not being considered in the rulemaking process commensurate with their safety significance.

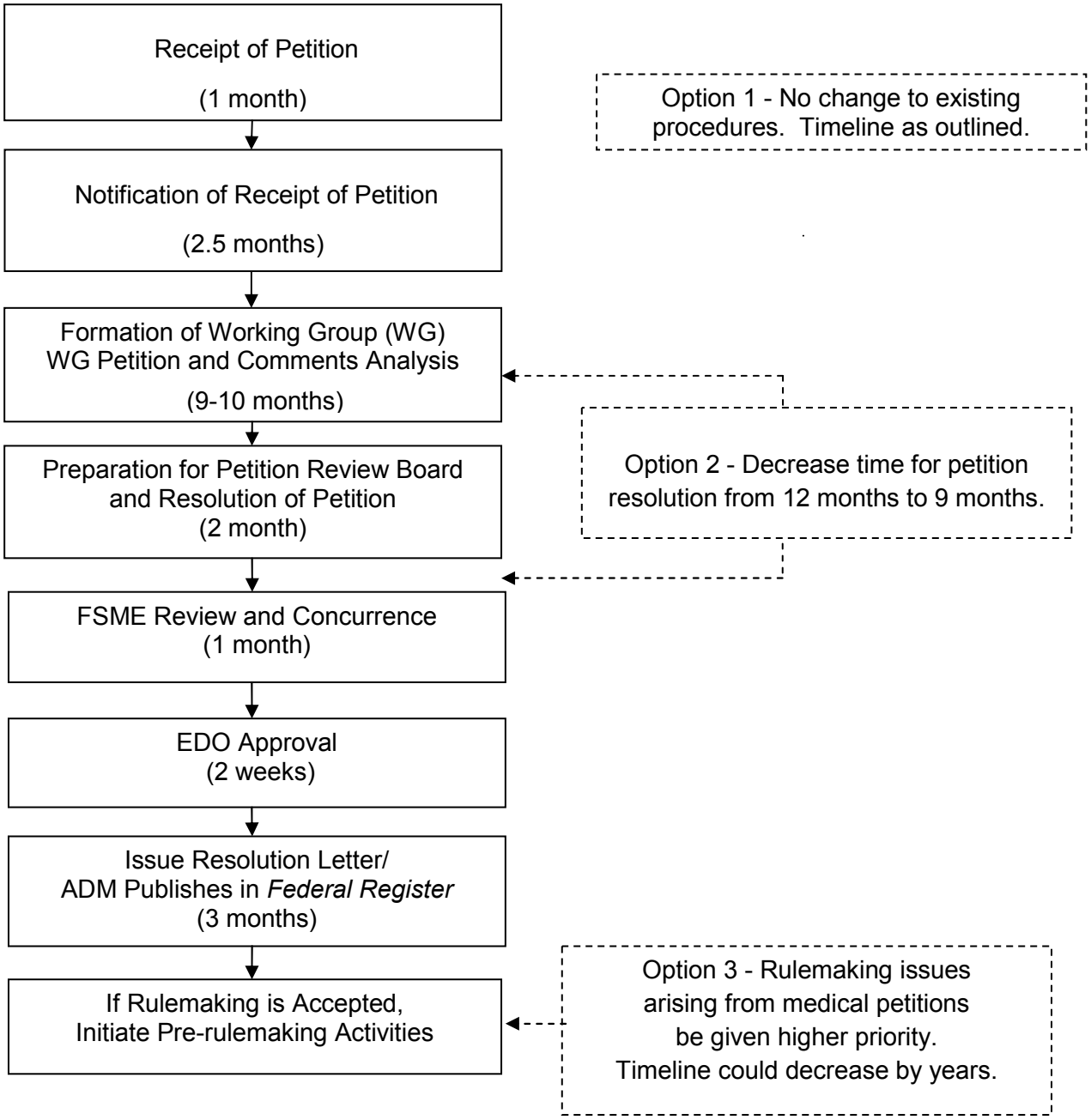
Other Alternatives:

The staff notes there are other approaches that could be taken to attempt to expedite the rulemaking process. For example, the Commission could permit the EDO to issue proposed medical rules without Commission review. The Commission will have the opportunity to review the draft final rule at the final rulemaking stage. Other approaches could also be explored such as adjusting roles and responsibilities among offices, such as in previous rulemakings where OGC was assigned the lead for the rulemaking. The staff is aware that the Commission is currently considering these approaches in the context of the rulemaking to revise the requirements in Part 26. It might be beneficial to conduct high priority rulemakings like the Part 26 revisions using one or more of these approaches and use the insights gained from these rulemakings to enhance the more general rulemaking process.

Staff Recommendation:

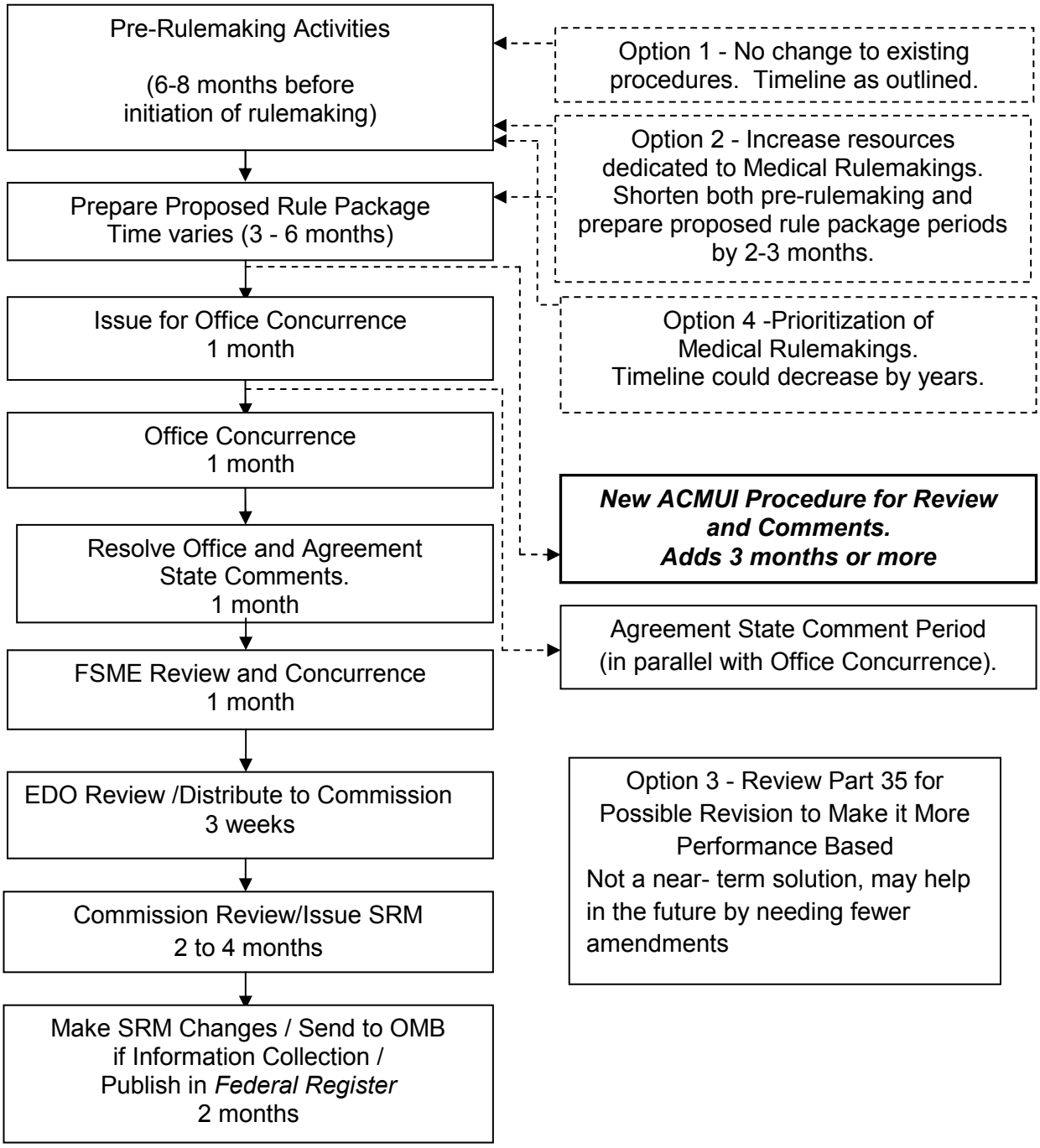
The staff recommends Option 1, that is, no change to existing rulemaking process. Options 2 and 3 may streamline the medical rulemakings but are resource intensive and would adversely impact other priority work. In addition, Option 3 has a longer lead time to develop. Option 4, elevating medical rulemakings to a higher priority, could result in other high priority work being deferred.

ESTIMATED TIMELINE TO RESOLVE A PETITION



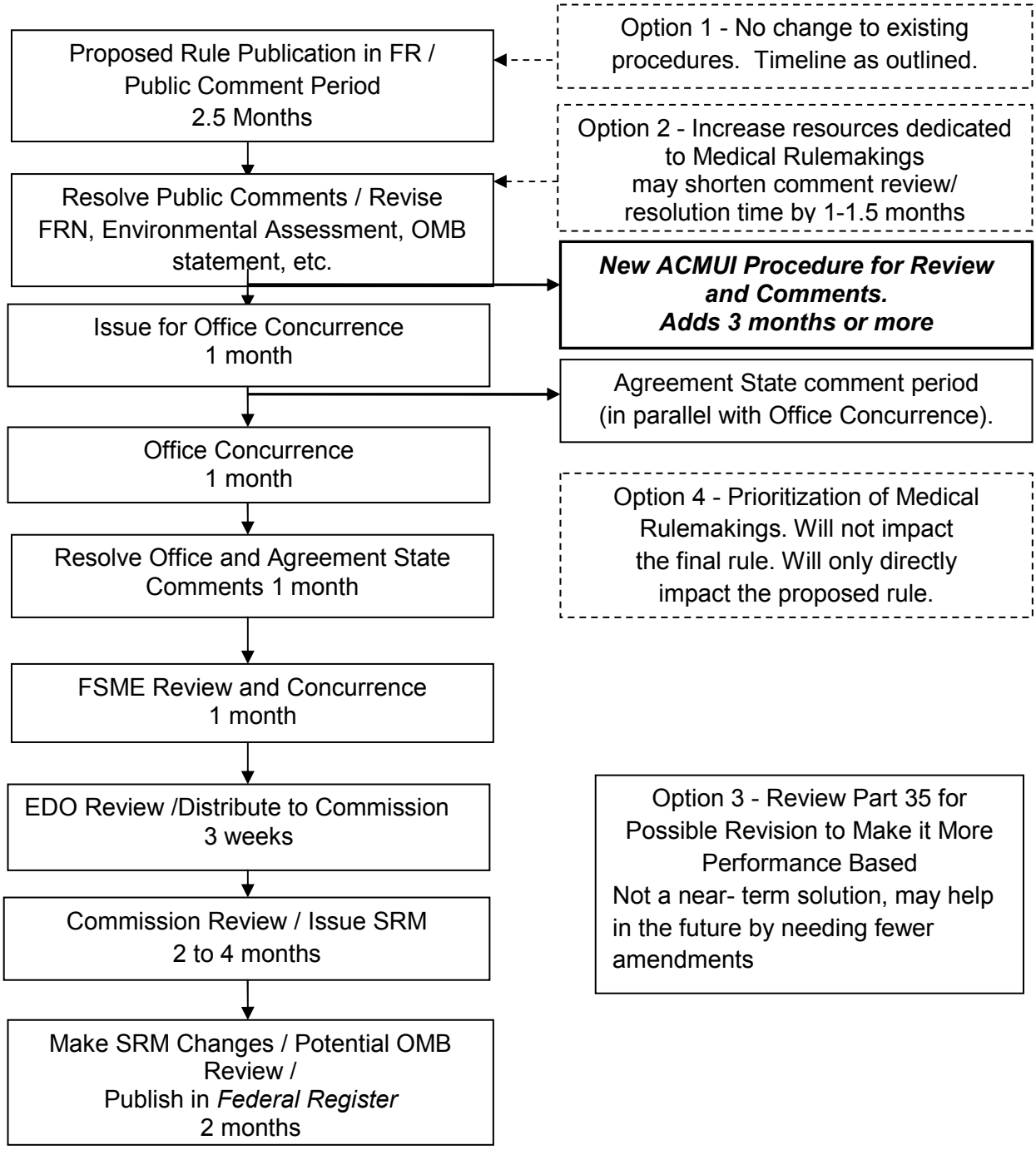
SUMMARY: The EDO's goal is to resolve petitions in one year from the date of publication in the *Federal Register*.

ESTIMATED TIMELINE FOR A PROPOSED RULE



SUMMARY: A proposed rule may typically take one year to provide to the Commission, and an additional 4 to 6 months to publish the rule in the *Federal Register* after submission of the paper to the Commission.

ESTIMATED TIMELINE FOR A FINAL RULE



SUMMARY: A final rule may typically take one year to provide to the Commission, and an additional 4 to 6 months to publish the rule in the *Federal Register* after submission of the paper to the Commission.