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.

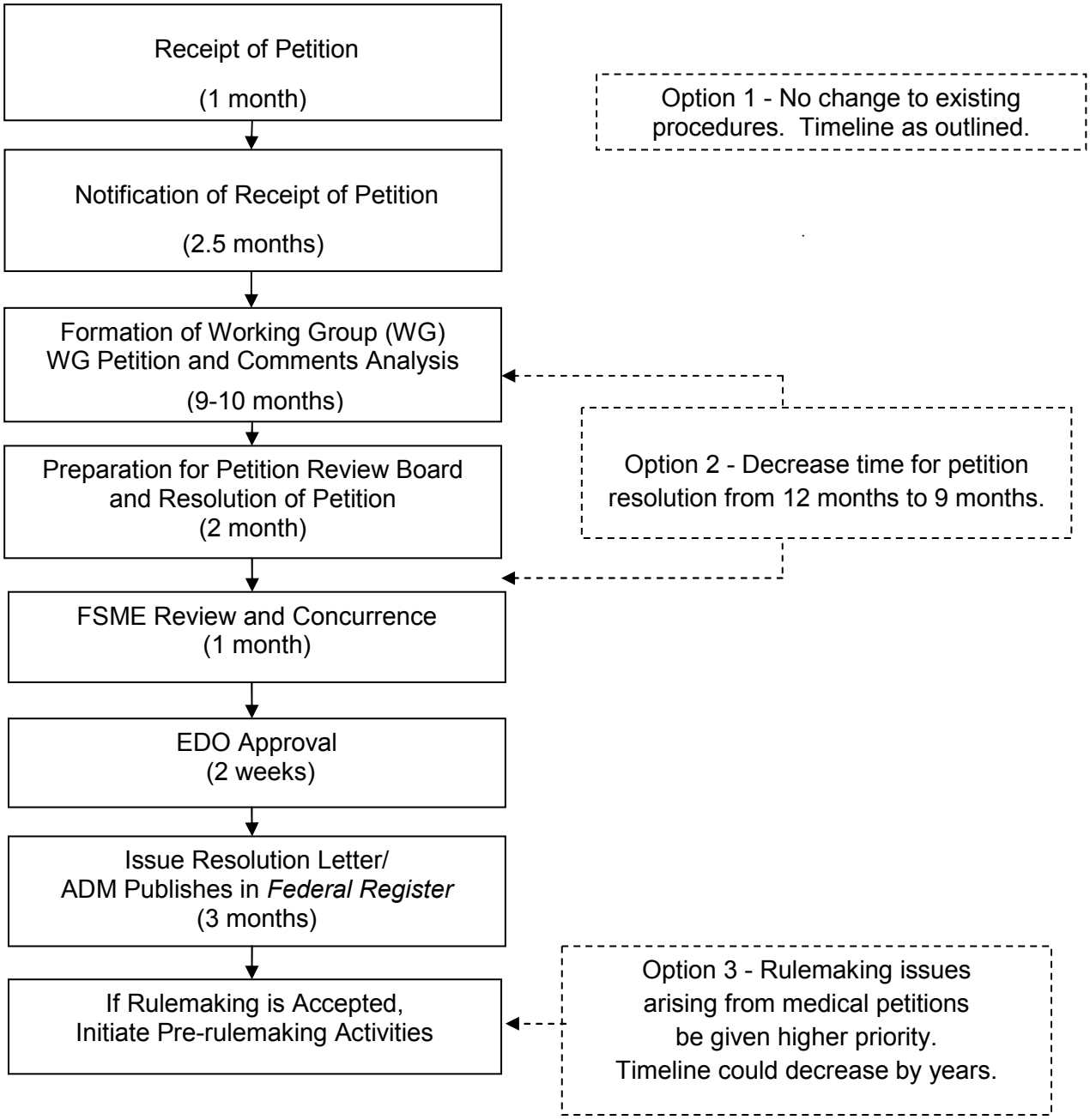
Other Alternatives:

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:

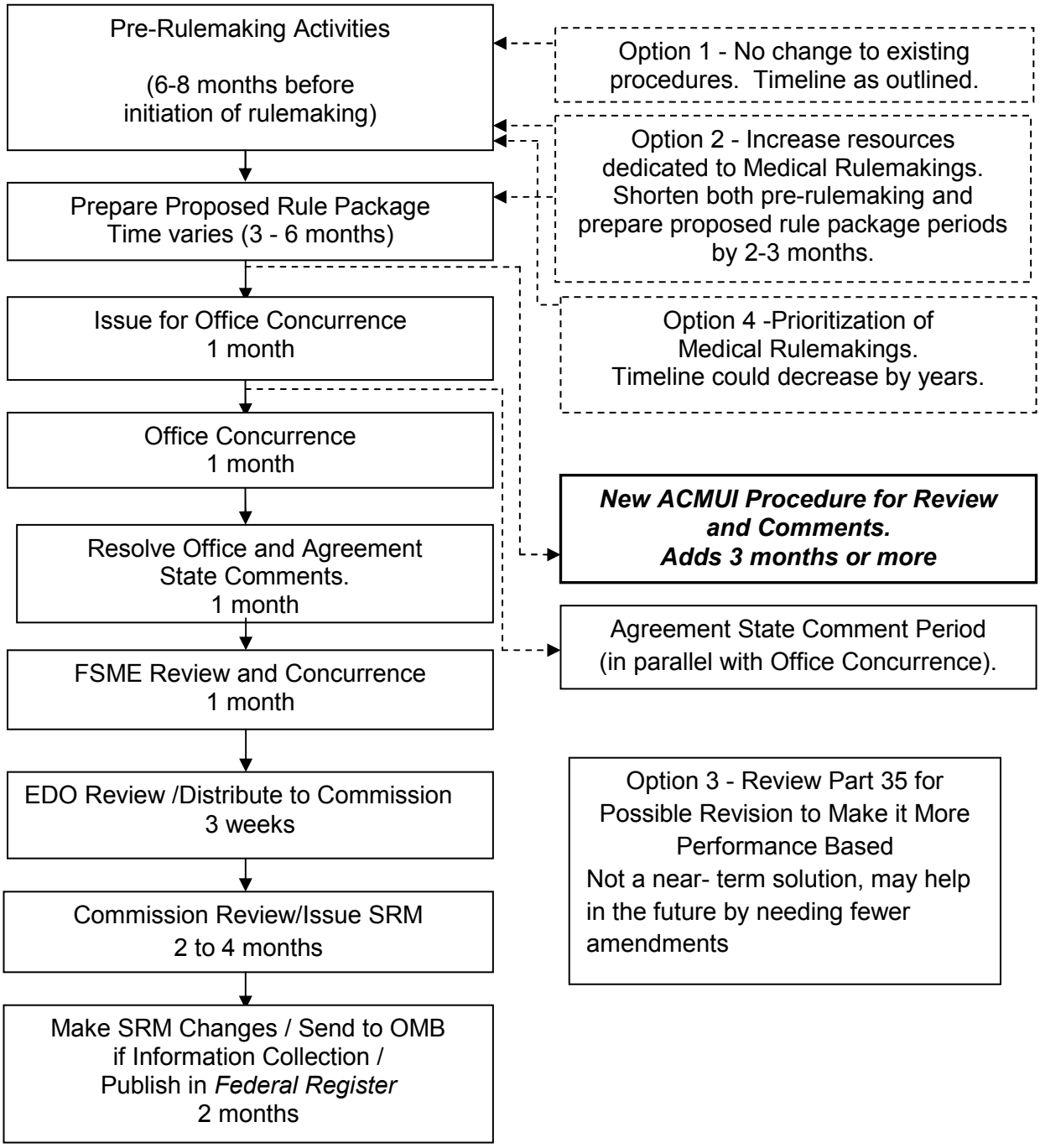
The staff recommends Option 1, that is, no change to existing rulemaking process. Options 2 and 3 may streamline the medical rulemakings but are resource intensive and would adversely impact other priority work. In addition, Option 3 has a longer lead time to develop. Option 4, elevating medical rulemakings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

ESTIMATED TIMELINE TO RESOLVE A PETITION



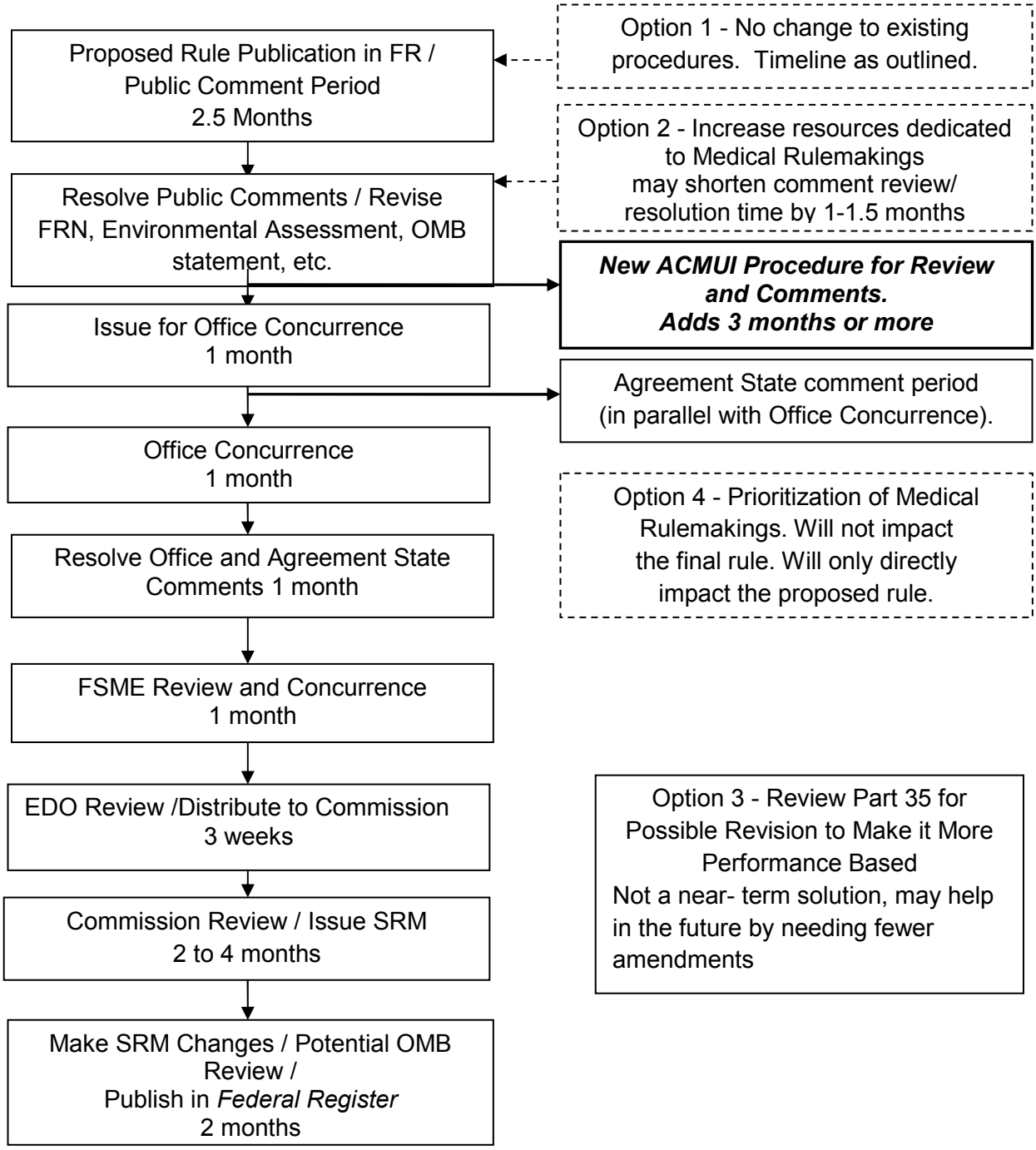
SUMMARY: The EDO's goal is to resolve petitions in one year from the date of publication in the *Federal Register*.

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.