

Assessment of Rulemaking Process Improvements

1.0 BACKGROUND

In a Commission Staff Requirements Memorandum (SRM) (COMNJD-06-0004/COMEXM-06-0006), dated May 31, 2006, the Rulemaking Coordination Committee (RCC) was directed to:

- Conduct an evaluation of the overall effectiveness of the inter-office Rulemaking Process Improvement Implementation Plan (RPIP);
- Assess the effectiveness of the Commission's directives numbered 1 through 5 in the May 31, 2006, SRM aimed at improving the efficiency and timeliness of the rulemaking process;
- Identify any other potential options that could streamline the rulemaking process;
- Address the feasibility, as well as advantages and disadvantages, of reducing contractor dependence in the rulemaking area, including addressing the necessary steps to ensure that when contracting is needed, it is accomplished in the most efficient and effective manner possible; and,
- Examine ways to improve the early collaboration with affected offices particularly the Office of the General Counsel (OGC) and the Office of Information Services (OIS) regarding allocation of resources prior to the proposed rule stage to make the most efficient use of resources.

In order to address these issues the Office of Nuclear Reactor Regulation (NRR) formed and led a working group composed of staff from NRR, the Office of Federal and State Materials and Environmental Management Programs (FSME), OGC, and the Office of Administration (ADM). The working group developed a charter (ADAMS Accession ML070190616) and coordinated this report with the Office of Nuclear Security and Incident Response (NSIR), the Office of New Reactors (NRO), the Office of Nuclear Materials Safety and Safeguards (NMSS), and OIS.

The report is arranged into the following primary areas of examination. Section 2.0 reviews each of the rulemaking process improvements (RPIs) identified by the previous task force in 2002. Section 3.0 discusses the Commission's May 31, 2006 SRM directives. Section 4.0 explains two areas that the working group believes hold potential additional process improvements. Section 5.0 provides an assessment of the agency's use of contractor support in developing its rulemakings and the feasibility, as well as the advantages and disadvantages, of reducing dependency on contractors in the rulemaking arena. Section 6.0 discusses the issue of early office collaboration. Section 7.0 contains the overall conclusions from this rulemaking streamlining effort. Section 8.0 contains a summary of the working group's recommendations.

2.0 ASSESSMENT OF PROCESS IMPROVEMENTS FROM THE RPIP

The RPIP developed 36 RPIs that were integrated into the agency's rulemaking process over several years ending in March 2006. The working group reviewed each of these recommendations to determine whether the recommendation was implemented and whether the goal of improving the rulemaking process was achieved. While not all recommendations

were implemented, the working group believes that from a broad perspective, the RPIP resulted in an improved rulemaking process, as described below.

For the current effort, the Commission has directed the staff to focus on improvements that would increase the efficiency and timeliness of the agency's rulemaking process. The working group evaluated the RPIP recommendations and determined that 15 of the 36 recommendations, if more effectively implemented, could potentially further improve the rulemaking process. The remaining 21 recommendations were screened out of this effort for one or more of the following reasons:

1. The implementation of the recommendation is complete and some efficiencies have been realized. These improvements tend to be one-time improvements. (Screen out 1)
2. The implementation of the recommendation is complete and some efficiencies have been realized. Further improvements are possible, but such improvements, if achievable, are judged to have a minimal impact on the actual process and were not pursued further. (Screen out 2)
3. The recommendation was not implemented as part of the original process improvement effort. The reasons for not implementing the recommendations remain valid, and this effort proposes not implementing the recommendation. (Screen out 3)
4. The implementation of the recommendation is complete. The recommendation may not have resulted in gains in efficiency. It may have improved management of the rulemaking process. Further improvements, if achievable, are judged to have a negligible impact on streamlining the rulemaking process and were not pursued further. (Screen out 4)

Table 1 (below) summarizes the working group's effort to screen the RPIP recommendations and identifies those that the working group pursued further. In some cases, recommendations have been grouped and addressed together when they touch on similar programmatic areas, and where the underlying issue is common to multiple recommendations. The assessment of the RPIP recommendations is presented in qualitative terms.

Table 1. SCREENING OF PROCESS IMPROVEMENTS FROM THE RPIP

RPI #	RECOMMENDATION	ACTION	COMMENTS
RPI-1	Simplify Rulemaking Plans	Addressed in Section 2.1 Technical Basis	This recommendation has been implemented but should be broadened in scope. It has been grouped with four other RPIs that relate to the need for an acceptable technical basis.
RPI-2	Revise the Concurrence Process	Addressed in Section 2.2 Concurrence Process	Both FSME and NRR adopted improved concurrence procedures; however, further improvements are possible. This RPI is grouped with RPI-36.

RPI #	RECOMMENDATION	ACTION	COMMENTS
RPI-3	Create a Rulemaking Screening Process	Addressed in Section 2.1 Technical Basis	This recommendation is grouped with the RPIs associated with the technical basis. To make further improvements in this RPI and more effectively screen rulemakings requires an increased knowledge of the technical basis to determine whether the effort is warranted and whether sufficient information has been developed to begin rulemaking.
RPI-4	Complete the Technical Basis Before Initiating Rulemaking Plan	Addressed in Section 2.1 Technical Basis	Further improvements are possible. This RPI is grouped with 4 other RPIs that relate to a need for an acceptable technical basis before rulemaking commences.
RPI-5	Centralize NRR Rulemaking Management	Screen out 1	This RPI is completed and is a one-time improvement. Centralizing rulemaking expertise has improved the overall process and resulted in a greater consistency in rulemakings.
RPI-6	Conduct a Pilot Rulemaking with OGC in the Lead	Screen out 3	A pilot was conducted. In general, OGC does not have the resources to develop substantive technical bases for highly technical rules but can conduct other rulemakings.
RPI-7	Conduct a Pilot Rulemaking with Agreement States in the Lead	Screen out 3	Because there are very few opportunities to implement this recommendation, the working group upholds the decision that this recommendation be put on hold until a good candidate rule is identified by the staff.
RPI-8	Consider Use of a Shorter Comment Period for Some Proposed Rules	Screen out 3	Not implemented. Although not a requirement, the NRC voluntarily implements an executive order that requires a 75-day comment period for technical rules. The agency's openness goal and, more importantly, the value-added from external stakeholder comments, also provide a sufficient basis for not implementing this recommendation.
RPI-9	Engage External Stakeholders at an Earlier Stage of the Process	Addressed in Section 2.1 Technical Basis	This recommendation has been implemented but should be broadened in scope. This RPI is grouped with 4 other RPIs that relate to the need for an acceptable technical basis before rulemaking commences.
RPI-10	Hold a Pilot Public Meeting on Rulemaking	Screen out 3	This recommendation was not implemented. It is not related to streamlining, and the reasons for not implementing this recommendation remain valid.
RPI-11	Develop More Detailed Criteria for Enhanced Public Participation	Addressed in Section 2.1 Technical Basis	Further improvements are possible. This RPI is grouped with 4 other RPIs that relate to the need for an acceptable technical basis before rulemaking commences.
RPI-12	Develop Mechanisms to Receive Public Comments via E-mail and FAX	Screen out 1	This RPI has been completed and is a one-time improvement. This recommendation is not judged to significantly streamline the rulemaking process. It does enhance public participation and improves the rulemaking process from an openness standpoint.

RPI #	RECOMMENDATION	ACTION	COMMENTS
RPI-13	Develop an Internal Rulemaking Status Web Page	Addressed in Section 2.4 Timeliness, Resource Expenditures, and Internal Rulemaking Status Web Page	This RPI was not previously implemented. A decision for proceeding with a central database was deferred because of uncertainty posed by pending internal and external developments, which would strongly influence the approach taken. This RPI is grouped with RPI-19 and RPI-20. Refer to Section 2.4 for a discussion.
RPI-14	Remove Most Rulemakings from the Chairman's Tasking Memorandum	Screen out 1	This RPI is complete and is a one-time improvement.
RPI-15	Reassess and Streamline the Rulemaking Activity Plan (RAP)	Screen out 2	This RPI has been completed; while further improvements could be made to the RAP, those changes would not improve the timeliness or effectiveness of rulemaking.
RPI-16	Develop Training Material Explaining the Rulemaking Process	Addressed in Section 2.3 Training	All the training-related recommendations have been implemented to some degree, but further improvements in training tools and communication are warranted to meet staff needs and expectations. This RPI is grouped with RPI-17, RPI-18, and RPI-29.
RPI-17	Develop Regulatory Analysis Training for Rulemaking Staff	Addressed in Section 2.3 Training	All the training-related recommendations have been implemented to some degree, but further improvements in training tools and communication are warranted to meet staff needs and expectations. This RPI is grouped with RPI-16, RPI-18, and RPI-29.
RPI-18	Develop Training on the Information Collection Clearance Process	Addressed in Section 2.3 Training	All the training-related recommendations have been implemented to some degree, but further improvements in training tools and communication are warranted to meet staff needs and expectations. This RPI is grouped with RPI-16, RPI-17, and RPI-29.
RPI-19	Create a Database on Rulemaking Resource Expenditures and Timeliness	Addressed in Section 2.4 Timeliness, Resource Expenditures, and Internal Rulemaking Status Web Page	This RPI is grouped with RPI-13 and RPI-20. Refer to Section 2.4 for a discussion.
RPI-20	Develop More Accurate Performance Measures for Rulemaking	Addressed in Section 2.4 Timeliness, Resource Expenditures, and Internal Rulemaking Status Web Page	This RPI is grouped with RPI-13 and RPI-19. Refer to Section 2.4 for a discussion.
RPI-21	Develop a TAC Management Process That Includes TAC Discipline	Screen out 4	This RPI has been completed and is a one-time improvement. Enhancements to TAC management/discipline improve the agency's understanding of how it uses its resources and can lead to improved budgeting, but has an insignificant impact on process streamlining.
RPI-22	Use PA Codes Dedicated to Rulemaking	Screen out 4	This RPI has been completed and is a one-time improvement. Use of rulemaking PA codes improves the agency's accounting for resource expenditures, but has an insignificant impact on process streamlining.

RPI #	RECOMMENDATION	ACTION	COMMENTS
RPI-23	Include Only Rulemaking Activities in the Expended Rulemaking Budget	Screen out 4	This RPI has been completed and is a one-time improvement. This improvement enhances the agency's accounting for its rulemaking budget, but has an insignificant impact on process streamlining.
RPI-24	Develop Standardized Criteria for Prioritizing Rules	Screen out 4	This RPI has been completed and is a one-time improvement. The use of standardized prioritization criteria has improved the rule prioritization process. Further refinements to the criteria would not result in streamlining the rulemaking process.
RPI-25	Develop ADM and OGC Rule Checklists	Screen out 1	This RPI is almost completed and is a one-time improvement. NRR will also incorporate checklists into its next update of LIC-300.
RPI-26	Develop a Rulemaking Package Checklist	Screen out 1	This RPI has been completed and is a one-time improvement.
RPI-27	Create a Rulemakers' Web Page	Screen out 2	This RPI has been completed and is a one-time improvement. The Rulemaker's website is a valuable tool for agency staff. While improvements could be made to the website, the working group determined that they would not serve to streamline the rulemaking process.
RPI-28	Issue Guidance Documents with Proposed Rules	Addressed in Section 2.5 Guidance Documents	Further improvements are possible.
RPI-29	Complete Management Directive 3.54 "Collection of Information and Reports Management"	Addressed in Section 2.3 Training	All the training-related recommendations have been implemented to some degree, but further improvements in training tools and communication are warranted to meet staff needs and expectations. This RPI is grouped with RPI-16, RPI-17, and RPI-18.
RPI-30	Resolve the Inconsistency between Agency Practice and Agency Guidance on Inclusion of the OMB Supporting Statement with the Regulatory Analysis	Screen out 2	This RPI has been completed. The information collection analysis is no longer an integral part of the regulatory analysis. This enables work on the information collection package to be completed in parallel with the rest of the rulemaking package. The working group believes that significant additional gains in efficiency and timeliness for this portion of the rulemaking process are not likely.
RPI-31	Revise Office Procedures to Include Additional Detail of a "How-to" Nature	Screen out 2	Office procedures are periodically revised to address changes in the rulemaking process and to provide clarification where needed. The working group believes that while this periodic update is necessary and useful, further enhancements to it (<i>i.e.</i> , either more frequent updates or with greater detailed guidance) would not translate into any significant streamlining of the rulemaking process.

RPI #	RECOMMENDATION	ACTION	COMMENTS
RPI-32	Revise Regulations Handbook to Include More Examples and Explanations	Screen out 2	Most of the examples have been moved to the Rulemaker website. This makes it easier to facilitate changes and to provide new information to rulemakers without the need to republish the handbook. The working group believes that making this information available via the website improves the process and further enhancements (e.g. more examples and explanations provided on the website) would not translate into any significant streamlining of the rulemaking process.
RPI-33	Eliminate Publication of Separate Notices for Rulemaking Information Collections	Screen out 1	This RPI has been completed and is a one-time improvement.
RPI-34	Assign an OIS and ADM Member to Each Working Group	Screen out 1	This RPI has been completed and is a one-time improvement. Implementation of this recommendation has been beneficial because potential issues have been raised and addressed at an earlier stage in the rulemaking process due to the presence of the OIS or ADM individual on the rulemaking working group.
RPI-35	Develop working group member and task leader expectations and responsibilities	Screen out 2	This recommendation has helped raise awareness of working group and task leader expectations. Actual implementation is dependent on the skills and diligence of the individual and the workload of the rulemaking working group member.
RPI-36	Improve working group communications among members and management.	Addressed in Section 2.2 Concurrence Process	This RPI is grouped with RPI-2. The working group believes that there are additional opportunities for improvement as discussed in Section 2.2 "Concurrence Process."

2.1 Technical Basis

2.1.a Background

Five of the recommendations from the RPIP effort relate to the topic of technical basis development. These RPIs are:

- RPI-1 Simplify Rulemaking Plans
- RPI-3 Create a Rulemaking Screening Process
- RPI-4 Complete the Technical Basis Before Initiating Rulemaking Plan
- RPI-9 Engage External Stakeholders at an Earlier Stage of the Process
- RPI-11 Develop More Detailed Criteria on Enhanced Public Participation

Aspects of all of these recommendations have been implemented to some degree. This section addresses remaining avenues for improvement related to the development of the technical basis.

2.1.b Assessment

The foundation of all effective regulations is a well-defined technical basis. The program offices have taken steps to implement the technical basis-related RPI actions. Both NRR and FSME have attempted to return to the basic principles of rulemaking plans, including identifying the technical basis. In several agency rulemakings currently in development, the staff has been permitted to bypass the rulemaking plan stage entirely resulting in a significantly shortened schedule with no detrimental impact to the quality of the rule. However, both NRR and FSME continue to have instances where staff has entered into rulemaking with unresolved technical or policy issues associated with the contemplated rulemaking.

Both NRR and FSME have developed processes to screen requests for rulemaking to ensure that the requests contain an adequate technical basis; however, experience with the screening process indicates that there is the potential to significantly improve this part of the rulemaking process. The screening process is intended to reject requests containing either no technical basis or an inadequate basis so that the rulemaking is not initiated. However, in practice, this has not been implemented successfully. Examples of this includes receiving incomplete technical bases (TB) and then proceeded with rulemaking in an effort to meet the overall rulemaking schedule and developing rulemaking schedules before the TB is complete. In most cases departure from the screening process negatively impacts the rulemaking schedule.

When technical development and rulemaking are pursued concurrently, rulemaking staff must often revisit key issues and re-write rulemaking documents during the review to accommodate the emerging technical basis and reflect the consequent changes in policy direction. This results in schedule delays and increased resource expenditures that are not consistent with the agency's commitment to regulatory efficiency.

Engaging external stakeholders early in the development of the technical basis was identified as a process improvement (RPI-9). Stakeholders often can identify flaws and oversights in the technical basis based on their knowledge and experience and may be able to offer data that can be used to support the development of the technical basis. Licensees can provide valuable insights regarding whether a particular issue is a safety problem at their site, and whether the actions contemplated by the staff are practical and address the issue. Early stakeholder participation can support the production of a more fully-developed technical basis that in turn supports a sound Commission decision on whether to pursue rulemaking.

Moreover, once the rulemaking begins, stakeholders will already have a familiarity with the technical issues and thus can provide better-informed comments on the proposed rule. Generally rules that have received early public participation during the technical basis development stage receive fewer adverse public comments in the proposed rule stage because there are fewer contentions with regard to the underlying basis for the proposed rule. Although in most cases there may be fewer comments on the underlying technical basis, there will be controversial rules with numerous comments on the interpretation of the technical basis and the policy decisions represented by the proposed requirements. On the whole, however, with fewer (and less technically substantive) comments on the proposed rule providing information that was not considered during the rule's development, staff is able to avoid course changes and minimize re-work associated with changes in the technical basis. Thus staff is better positioned to deliver a final rule that is well-reasoned, readily accepted by stakeholders, and on schedule.

Ideally, this up-front investment in the development of a complete and robust technical basis should result in a reduction in the overall resources and calendar time spent to complete a rulemaking.

A well developed technical basis includes input from internal stakeholders in order to comprehensively address the scope of the problem. Improving early interaction with regional personnel, especially regional inspectors in the field, can benefit rulemaking efforts involving specific technical and safety issues and the efficacy of enforcing and inspecting proposed requirements. Early regional interaction can also help identify other regulatory instruments for addressing these issues; these instruments can be proposed to decision-makers as options to rulemaking. FSME frequently invites regional staff to participate on rulemaking working groups, however, resource constraints do not always allow their participation. Other internal stakeholders could include the Advisory Committee on Reactor Safeguards (ACRS).

There is a need for guidance describing the content of a sound technical basis to facilitate the technical staff's timely development of an adequate technical basis. Rulemaking staff should develop basic guidance that includes acceptance criteria to provide a minimum threshold for when a technical basis will be judged as adequate and to enable rulemaking to commence. Efforts to improve the guidance on developing a technical basis are underway in FSME and will be initiated in NRR.

2.1.c Recommendations

There should be continued emphasis placed on the development of a complete and adequate technical basis prior to the initiation of rulemaking. To facilitate this recommendation, the working group recommends that the technical basis supporting each rulemaking be approved prior to proceeding with the rulemaking. For NRR, the working group recommends that the rulemaking approval board be the group that approves the technical basis.

Staff guidance should be developed that identifies the elements of a complete and adequate technical basis. This guidance should be used by the technical support organizations to develop the rulemaking technical basis and by the group or authority that approves the technical basis to ensure that the technical basis is sufficient for proceeding with rulemaking.

In addition, this guidance should include emphasis on engaging internal and external stakeholders during the development of the technical basis.

The following change should be made to the current rulemaking schedule: in the event that deficiencies in the technical basis are identified after the rulemaking has commenced, the rulemaking should be suspended until an adequate technical basis has been completed. Only at that point would a new rulemaking schedule be developed (subject to the agreement of the EDO and/or Commission as applicable) and the rulemaking effort recommence. The working group believes the recommended schedule change should encourage the staff to refrain from proposing rulemaking until there is a high degree of certainty that an adequate technical basis exists. Likewise, the risk of schedule failure should cause the staff to exercise discipline by critically reviewing the technical basis and refusing to initiate rulemaking until they are satisfied the technical basis is sound.

2.2 Concurrence Process

2.2.a Background

The recommendations from the RPIP that relate to the concurrence process are:

- RPI-2 Revise the Concurrence Process
- RPI-36 Improve Working Group Communications

The RPIP focused on methods to compress the concurrence process. The RPIP indicated that:

Compression of the concurrence chain can succeed only if working group members keep management fully informed throughout the rulemaking process. Working groups should brief management earlier in the process and ensure that management is consulted regularly as the rule is developed. Working and steering group members must reliably represent the interests of their respective offices and strive to have office concerns addressed and resolved early in the rule development process, well before concurrence begins.

2.2.b Assessment

Progress has been made in implementing RPIP recommendations relating to the concurrence process. Organizational changes have eliminated review at the section leader level of the management chain; NRR has also discontinued the requirement for concurrence from both the deputy director and the director. Other improvements that have resulted in shorter rulemaking schedules include reduced interaction with the ACRS and the Committee for Review of Generic Requirements (CRGR) at the proposed rule stage and an effort by management to focus its review efforts more on significant technical and policy issues and less on editorial changes. Rulemaking working groups have facilitated concurrence by providing a means for members to keep their management informed of major developments or changes in policy direction.

The Office of the Chief Financial Officer (OCFO) has streamlined its concurrence on rulemaking packages (Ref. May 1, 2007 memorandum, ML071210374) by removing the need for OCFO review and concurrence on rulemaking packages where OCFO has reviewed and approved the resource and fee implications in the rulemaking plan.

A recent reorganization brought the functional responsibility for centralized technical editing services to the Office of Administration; technical editing now is managed by the Chief of the Rulemaking, Directives and Editing Branch (RDEB). In order to make the most efficient use of its resources, the branch has revised the scope of technical editing for rulemaking packages. RDEB now will perform all technical editing services for rulemaking packages. This will consolidate the technical edit and review, formerly performed by two organizations, into one review by one branch. The working group believes that these changes will result in some streamlining of the review/concurrence process.

Despite these gains, the working group believes that there are a number of areas for further improvement in the concurrence process. For large packages, even simple editorial comments can become very time consuming to implement. Even worse, changes in a policy approach or the introduction of new technical issues during the concurrence process, while infrequent, do occur; the subsequent adjustment to the rulemaking package can mean a significant amount of rework. This problem is usually caused by an inadequate technical basis, which can be addressed by the working group's recommendations in Section 2.1.

In any process, there is significant potential for delay throughout the concurrence chain. The rulemaking process has many layers of managers who need to concur, so there is a high potential for delays, especially where key personnel have a heavy workload or there are limited resources. This issue is magnified at those places within the concurrence process where there are "choke" points through which a large number of agency documents must pass (*i.e.*, high level management or key support groups like OIS and OGC). OGC usually will not provide a finding of no legal objection until all of its comments have been addressed and they are provided with a "clean" copy.

Managers reviewing rulemaking documents should continue to focus their review on technical and programmatic matters within their areas of responsibility. Technical staff should focus their review on matters that are germane to their technical areas of responsibility. This emphasis can be implemented through routine management interactions.

Project managers (PMs) need to ensure that managers know exactly where the rulemaking package is in the concurrence chain. PMs may need to be more proactive in preventing delays in the concurrence process. If they encounter a choke point while shepherding a package through concurrence, they should attempt alternative paths, such as obtaining concurrence from authorized deputies. Another mechanism that can expedite concurrence is a briefing for the manager that highlights the key points of the rule and provides an opportunity to ask questions. By proactively managing the concurrence chain, PMs can assist management in being more aware of actions on their desk and the need to delegate them to someone with the time to review the package.

The OMB information collection process remains challenging. This is due in part to the subjective nature of information collection analysis, and the fact that much of this process originates with OMB and is, therefore, outside the NRC's control. Further, process complications have recently developed due to the mandated use of OMB's Regulatory Information Services Center/OIRA Consolidated Information System (ROCIS) for information collection submissions. The ROCIS system only allows the processing of one request in a subject area at a time. For example, if OMB is referencing 10 CFR Part 50's information collection renewal package, and a proposed or final rule package that primarily references Part 50 for information collections is submitted to OMB, OMB must first complete the review on the Part 50 renewal package before the proposed or final rule package will be accepted by ROCIS.

The concurrence issues noted above are not unique to rulemaking. Instead, these issues are more visible in the rulemaking process because it involves a large number of offices and all levels of management and advisory committees, and as a result, resolving conflicting views and comments can be a significant challenge. Although better information sharing may help to identify differing views earlier in the process, there will be occasions where these views will arise during the concurrence process. Consequently, completing these rulemakings will take

longer than initially planned. Of special concern is resolving differing professional views or opinions. While an important part of a balanced process, they can greatly protract the concurrence period. Recent NRR experience with the new nonconcurrence process suggests that this process has the potential to cause significant delays in the schedule for a rulemaking, by requiring those who previously concurred to determine if re-concurrence is needed.

In general, the working group believes that the concurrence process from a procedural standpoint is sound, but there are opportunities for improvement per the recommendations described below.

2.2.c Recommendations

Managers reviewing rulemaking documents should continue to focus their review on technical and programmatic matters within their areas of responsibility.

Technical staff should focus its review on matters that are germane to its technical areas of responsibility. This emphasis can be implemented through routine management interactions.

OGC's finding of no legal objection should be provided contingent upon its comments being incorporated into the rulemaking documents if OGC specifies that its comments are of the nature that do not require further OGC review.

Efforts should be made to identify differing views earlier in the process through better information sharing. If the deliberations during the development of the rule indicate strong disagreements among the staff, additional time will need to be planned for the concurrence process.

The new nonconcurrence process as applied to rulemaking should be re-examined to determine whether it can be simplified to remove the need to have people re-concur as a result of a nonconcurrence.

Additional guidance should be placed into LIC-300 and other rulemaking guidance documents that emphasizes the need for rulemaking PMs to follow up with managers reviewing rulemaking packages.

2.3 Training

2.3.a Background

Several of the RPI recommendations concern training:

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| RPI-16 | Develop Training Material Explaining the Rulemaking Process |
| RPI-17 | Develop Regulatory Analysis Training for the Rulemaking Staff |
| RPI-18 | Develop Training on the Information Collection Clearance Process |
| RPI-29 | Complete Management Directive 3.54 |

The RPIP task force report included several recommendations related to training for internal stakeholders. All the training-related recommendations have been implemented to some degree, but further improvements in training tools and communication are warranted to meet staff needs and expectations.

2.3.b Assessment

The training related RPIs have been implemented and have been effective at improving the knowledge of the people involved with implementing the rulemaking process.

The RPIP task force envisioned a short training session developed by NRC staff that would provide an overview of how rulemaking is conducted. In practice, this need has been met by building on an annual half-day introductory course on rulemaking developed by NMSS, now FSME, for its own staff. The course placed an emphasis on FSME office processes and was designed for new FSME employees, interns, and continuing FSME staff new to rulemaking. In response to requests by other offices, FSME staff instructors modified the course to make it suitable for a more generic NRC audience and added additional material on rulemaking resources. In 2006 FSME, with ADM support, presented four sessions of the course; special sessions were given just for staff from OGC, NSIR and the Regions (by video conference).

In 2004, NRC staff from RES, NRR, NMSS and OGC presented two training sessions, open to all NRC staff, on regulatory and backfit analyses. The three staff presentations and the question and answer session that constituted the training were videotaped and have been made available to staff, with the accompanying slides, on the NRC Rulemaker website, an internal resource for agency rule writing staff. In addition, in 2006 staff from various offices developed modular training material on other rulemaking topics, including information collection requirements and NRC coordination with agreement states. These materials have also been posted on the NRC Rulemaker website and are available for use by offices to customize training sessions to the needs of different organizations and by individual staff seeking to educate themselves about the rulemaking process.

Staff has also revised a number of rulemaking reference materials, including the Regulatory Analysis Guidelines (NUREG/BR-0058, Revision 4, September 2004), the U.S. NRC Regulations Handbook (NUREG/BR-0053, Revision 6, September 2005) and two key Management Directives: MD 6.3, "The Rulemaking Process" (June 2, 2005) and MD 3.54, "NRC Collections of Information and Reports Management" (May 22, 2006).

In the past two years a number of seasoned agency rulemaking staff have retired or become eligible for retirement. This has resulted in a reduction in the NRC's knowledge base. Additionally, the level of awareness among rulemaking PMs regarding the RPIs is not consistent. The staff has increased efforts to provide in-house training to new rulemaking staff, but knowledge gaps remain. A formal program with required training is beyond current staffing capabilities; however, more awareness of the existing training resources available to staff and better communication of changes to the rulemaking process could better prepare staff for rulemaking tasks and prevent delays. If resources become available, NRR should enhance its existing qualification program for rulemaking PMs.

2.3.c Recommendations

The rulemaking LISTSERV, currently used by ADM to improve communication among the rulemaking staff, should be used more widely to promote the available online training, solicit interest in specific training opportunities, and gauge interest in other rulemaking areas for which no NRC-specific materials exist.

Training should be provided to rulemaking PMs to apprise them of the RPIs that have been implemented into the process (including any additional process improvements implemented as a result of this effort). In addition, NRR should enhance its existing qualification program for rulemaking PMs, if resources become available.

2.4 Timeliness, Resource Expenditures, and Internal Rulemaking Status Web Page

2.4.a Background

The RPIP recommendations related to this topic are:

- RPI-13 Develop an Internal Rulemaking Status Web Page
- RPI-19 Create a Database on Rulemaking Resource Expenditures and Timeliness
- RPI-20 Develop More Accurate Performance Measures for Rulemaking

Regarding RPI-13, in May 2004, the RCC formed a Rulemaking Database Working Group (RDWG) to investigate the feasibility and advisability of developing a web-based rule tracking system able to generate a variety of reports that differ in purpose, emphasis, format and level of detail. The RDWG reported to the RCC in January 2005 on the preliminary estimated cost of developing and maintaining such a system (*i.e.* developmental costs between \$450K and \$649K; annual maintenance, system enhancement, and user support costs of \$200K), its likely effects upon existing office work procedures, and e-Gov considerations to be taken into account when undertaking such a project. The RDWG recommended that the RCC defer making a decision about whether to develop a centralized rulemaking tracking system until internal and external developments, which would strongly influence the approach taken (*i.e.* the pending implementation of the planned agency-wide work tracking system and the coming government-wide move to the Federal Docket Management System (FDMS) developed as part of the interagency e-Rulemaking initiative) have advanced further.

The previous rulemaking process improvement efforts examined the issues of whether there existed accurate data on resource expenditures and whether there existed accurate timeliness data readily available for analysis. It concluded that the Time, Resource, and Inventory Management (TRIM) system could be used for resource information provided that Technical Assignment Code (TAC) discipline had been instituted.

From RPI-19 it was noted: "NRR will continue to use TRIM in conjunction with improved TAC control, and will strive for continuous improvement in accounting for and reporting rulemaking expenditures, and in forecasting the rulemaking budget. NMSS will continue to collect information using existing systems. An internal NMSS rulemaking database has been modified to collection (sic) additional information relevant to NMSS rulemaking expenditures and on-time performance."

From RPI-20 it was noted: “NRR tested performance measures recommended by the task force in a recent budget cycle. These preliminary performance measures will be continually reassessed as better data and more sophisticated analytical tools become available. NMSS formed a working group to assess, and, as appropriate, revise the performance measures recommended by the RPIP task force. On the basis of this analysis, the group proposed a new set of performance measures for NMSS rulemaking.” It was further noted that NMSS management was evaluating the measures to decide whether and when to pilot the measures. Additionally RPI-20 made the following recommendation:

Office-specific performance measures and planning tools should take into account the relative complexity of different types of rules typically dealt with in each office.

2.4.b Assessment

The development of a better rulemaking status and tracking systems would provide NRC management with better information with regard to ongoing and completed rulemakings. This data would help management focus attention where it is most needed to manage ongoing rulemakings to meet schedules, and would provide valuable information with regard to the rulemaking process itself. In addition, when sufficient data becomes available on key steps of the rulemaking process, more sophisticated process analysis techniques such as Lean Six Sigma can be considered.

The centralized, agency-wide rulemaking database has not been pursued to date. ADM believes that experience with a previous RES rulemaking database indicates that decentralized feeding of an agency-wide tracking system is unlikely to succeed without stringent oversight by participating office management. Maintaining a timely flow of information into the database would require close coordination between ADM and program office staff, may involve changes in office procedures, and may require continuing active support by office management. Some of the data in the system may be considered sensitive. ADM would need to coordinate with NRR, FSME, OGC and OIS to put appropriate controls in place.

To support the effort to streamline rulemaking tasks, effective task monitoring tools are essential. This was recognized by the previous process improvement efforts as discussed above in reference to RPI-19 and RPI-20. The previous recommendations focused principally on resource expenditures and schedules at the overall rulemaking task level (*i.e.*, resources to complete the rulemaking, time to complete the overall rulemaking). More detailed scheduler and resource reports would support enhanced monitoring. The working group concludes that through the use of these two tools, NRR (FSME has the necessary tools available) can more effectively monitor the progress and resource expenditures of ongoing rulemaking tasks on a task-specific basis, and this in turn will support determinations of whether the other recommendations detailed in this report and in previous efforts are streamlining the rulemaking process, and additionally reveal opportunities for new process enhancements. These same tools would also enable NRR to monitor its efforts to resolve petitions for rulemaking and achieve greater efficiencies for those tasks (note that if a petition is granted, the NRC is obligated to initiate a standard rulemaking). The increased detail can also provide valuable information to rulemaking PMs and NRR management on how to best allocate resources when process issues develop.

The new detailed rulemaking task report is already under development by NRR. The report is based on previous efforts (the Director's Quarterly Status Report and the Director's Quarterly Status Update) and expands the detail to a level that would enable identification of process issues. The working group supports the NRR rulemaking staff's desire to use the NRR's Work Planning Center to assist NRR rulemaking staff with developing rulemaking "budget vs. actual" resource reports that provide monthly and cumulative branch, division, and NRR expenditures for each rulemaking task, including both NRC staff hours and contract dollars. This information could then be used to identify and monitor on a monthly basis, out-of-standard resource expenditures and identify areas for appropriate management action. This new resource report is also under development.

The information from these two reports could then be used to feed a centralized, agency-wide rulemaking database (contemplated for RPI-13). If there is not a comparable application being used by and available through another agency, the NRC could create a centralized database that could be configured to generate a variety of rulemaking tracking reports in various formats, which in turn would help address a current issue regarding the proliferation of reports that rulemaking PMs must update. Once the centralized database is established, rulemaking PMs would keep it up to date on a frequent basis and would not be required to produce any of the various tracking reports.

However, the effort and resources needed to accomplish this task are not necessarily small. The effort is complicated by security issues associated with a web-based system and design considerations relating to sharing information with internal databases and external systems. The working group believes that although there would be a net reduction in resources (principally in ADM and NRR) spent updating the various tracking reports once this centralized database is up and running, there would also be annual maintenance, system enhancement, and user support costs associated with the centralized database plus the time spent providing input into the database. The development of the centralized database would require OIS and/or contractor assistance. ADM would be the owner of the database, but they would require the participating offices to maintain oversight to ensure the database is periodically updated. Given the significant resources required to establish a centralized database versus the potential reduction in resources to be gained through the use of such a database (which do not appear to be significant), the working group cannot recommend the development of such a database at this time.

2.4.c Recommendations

NRR should use two new tools to more effectively monitor the timeliness and resource expenditures associated with rulemaking tasks:

- 1) Rulemaking task detailed schedule reports
- 2) Rulemaking task resource expenditure reports

2.5 Guidance Documents

2.5.a Background

The RPIP recommendation that relates to this topic area is RPI-28 “Issue Guidance Documents with Proposed Rules.” The RPIP noted in regard to RPI-28 that the advantage of issuing associated guidance with the proposed rule would be that members of the public, licensees, and other stakeholders would have the necessary information to comment intelligently on the proposed rule. The RPIP also stated that current agency policy as expressed in the *Regulations Handbook* supports concurrent publication. However, the RPIP then noted that circumstances can make it difficult or impractical to publish a rule and associated guidance together, and a hard-and-fast rule enforcing concurrent publication may not be workable.

The RPIP indicated that the working group would examine the issue of concurrent publication further and (a) propose criteria for determining when concurrent publication should be mandatory, and (b) draft procedures for inclusion in the *Regulations Handbook*, Appendix A, that would facilitate concurrent publication of integrated rules and guidance. The RPIP discussed the need to consider resources and scheduling implications in the rulemaking plan for developing guidance. FSME divisions were reminded that concurrent publication is agency policy, and the issue has been addressed in the revised office template for rulemaking plans. New NRR guidance was included in LIC-300, Revision 1, “Rulemaking Procedures,” issued December 2003.

2.5.b Assessment

Developing implementation guidance concurrent with the rulemaking can reveal problems with proposed rule language, such as where it would be impractical or not feasible to implement and enforce proposed requirements. Implementation guidance can identify where proposed provisions would not achieve the desired objective, and provide no added value, or cause conflict with other requirements. As a result, the staff can eliminate unnecessary rule provisions and replace impractical rule provisions with requirements that can be sensibly implemented.

Feedback from stakeholders at the proposed rule stage based on insights from draft implementation guidance can also enable the staff to correct problems, improve the final rule and supporting statements of consideration (SOC), and avoid situations that call into question whether a final rule change is within the logical outgrowth of the proposed rule.

This process issue is closely related to technical basis issues. Development of implementation guidance requires a thorough understanding of the new requirements, which in turn is directly related to a sound understanding of the technical basis for the new requirements. Both efforts tend to feed each other.

The development of implementation guidance concurrently with the proposed rule does require increased resources initially, and can result in an extended schedule to publish a proposed rule. However, for technically complex rules where regulatory guidance is crucial to proper implementation of the rule requirements, the effort to develop the regulatory guidance is better spent during the proposed rule development stage where the benefits noted above can inform the proposed rule language, the technical basis, and the supporting SOC. To the extent that

the development of implementation guidance during the proposed rule portion of the rulemaking process reveals issues that can be corrected in both the guidance and proposed rule language, the net result should be a reduced expenditure of effort to revise the technical basis, implementation guidance, and rule language in response to public comments. As a result, the net total resources spent for the rulemaking should be reduced.

Resource limitations are a major stumbling block for achieving progress in this area. Typically, guidance is developed by the technical branches, not the rulemaking branches, and the technical branches have resource constraints due to other priority projects. Often resources for guidance development are not available, either because they were not budgeted or redirected to higher priority activities.

2.5.c Recommendations

Increased emphasis should be placed on issuing draft implementation guidance in conjunction with the issuance of the proposed rule for public comment.

3.0 SRM DIRECTED PROCESS IMPROVEMENTS

In addition to directing the staff to conduct an evaluation of the overall effectiveness of the RPIP, the Commission suggested five measures that should be implemented. These Commission recommendations are identified herein as SRM-1 through SRM-5. Three of these suggestions, SRM-1, SRM-2, and SRM-3 are discussed below. SRM-4 and SRM-5 are measures that the staff is currently utilizing to the extent possible and no further consideration is required. Table 2 summarizes the SRM recommendations.

TABLE 2. SUMMARY OF SRM DIRECTED PROCESS IMPROVEMENTS

SRM #	RECOMMENDATION	SECTION	COMMENTS
SRM-1	Waive Submission of Rulemaking Plans	3.1	
SRM-2	Waive CRGR and ACRS Reviews	3.2	
SRM-3	Release of Draft Information	3.3	
SRM-4	Assess whether measures in the SRM or RPIP can be applied to current rulemakings		The RPIP and the SRM direction have been implemented for current rulemakings when appropriate; the working group believes that continued implementation of these measures is warranted.
SRM-5	Continue use of Working Groups		This RPI has been implemented; the staff routinely uses working groups and steering groups for all but routine rulemakings.

3.1 SRM-1 Waive Submission of Rulemaking Plans

3.1.a Background

The following information is from the SRM dated May 31, 2006:

The staff may waive the development and submission of rulemaking plans at the discretion of the Director of NRR, and in consultation with the General Counsel. When the staff determines that a rulemaking plan is necessary, the staff should consider options to develop additional efficiencies, such as making the rulemaking plan more concise (perhaps no more than a few pages), or providing a rulemaking plan through informal mechanisms such as Commission technical assistant briefings.

3.1.b Assessment

The NRR Office Director waives the submission of rulemaking plans when it is determined that forgoing a rulemaking plan is the most efficient approach. However, since issuance of the May 31, 2006 Commission SRM, the NRR Office Director has not had an opportunity to exercise this Commission measure. The authority to waive the submission of rulemaking plans was not provided to other offices. FSME has eliminated rulemaking plans for specific rulemakings when approved by the Commission. This has been done on a case-by-case basis and is accomplished either by a Commission paper or Commission technical assistant briefings. In other cases, the Commission has directed the staff to go straight to a proposed rule. It would be more efficient and would provide additional flexibility if FSME had the same authority to waive rulemaking plans as NRR.

3.1.c Recommendation

The Commission should extend to the Director of FSME the authority to waive the development and submission of rulemaking plans in consultation with the General Counsel. This authority would provide additional flexibility and efficiencies to FSME.

3.2 SRM-2 ACRS and CRGR Review

3.2.a Background

The following information is from the SRM dated May 31, 2006:

The staff may waive review by the Committee to Review Generic Requirements (CRGR) at the proposed rule stage, and, notwithstanding 10 C.F.R. § 2.809 and the Memorandum of Understanding between the ACRS and the EDO, may waive review by the Advisory Committee on Reactor Safeguards (ACRS) at the proposed rule stage (as was done, for example, in the ongoing Part 52 rulemaking). Comments from CRGR should be limited to addressing, at the final rule stage, any public comments received relevant to backfit matters. Comments from the ACRS may be submitted to the Commission either during the comment period for the proposed rule, or following the close of the public comment period, but prior to issuance of the final rule. While the Commission grants the staff permission to waive review by both committees at the proposed rule stage, due consideration should be given to the merits of earlier engagement with one or both committees, if the staff determines that such engagement will result in a more efficient and effective process for a particular rulemaking. When committee reviews are waived, the staffs of both committees should continue to be

provided copies of the proposed rules and supporting documentation to keep them informed. The staff should work out suitable communication arrangements with ACRS to keep them informed of waivers of ACRS reviews at the proposed rule stage and to consider specific requests for earlier review opportunities. Nothing in this SRM should be construed as in any way discouraging open informal discussion of proposed rule documents with ACRS staff. The staff and ACRS should also work to coordinate schedules in order to enable timely and effective rulemaking.

3.2.b Assessment

The staff has been following this Commission SRM directive (to defer CRGR and ACRS review until the final rule) for recent rulemakings and finds that it effectively and efficiently accelerates the proposed rulemaking schedule provided that there are not significant technical or backfit issues. When there are technical issues and/or complex backfit issues, the staff believes it is more efficient to interact with ACRS and/or CRGR (or OGC if the Commission agrees with our recommendation which follows in this document that suggests elimination of CRGR from the rulemaking process). This is particularly important with technical issues so that staff can have the benefit of ACRS views at the proposed rule stage and thus is better equipped to sort out the technical basis supporting the rulemaking. Of course, if ACRS were involved during the development of the technical basis (see Section 2.1), it would be less important to inform ACRS at the proposed rule stage.

In the case of CRGR, the working group believes that it is not as important to interact with the committee at the proposed rule stage primarily because external stakeholder comments are used by the CRGR to assess backfit questions at the final rule stage. Overall, the working group finds that this Commission directive makes the rulemaking process more efficient by providing the staff greater flexibility in their use and timing of ACRS and CRGR interactions.

The working group believes there can be process improvements made regarding interactions with CRGR and ACRS. For rulemaking tasks, CRGR review has limited value, because rulemaking packages are subject to an extensive concurrence process which typically allows all offices to concur prior to CRGR review. The package includes a rigorous regulatory analysis that supports the rulemaking, and the legal perspective of backfit issues are adequately addressed by OGC with the support of the associated technical offices. This thorough vetting of the product significantly diminishes the opportunity for CRGR to add value; the same can not be said for any other products that CRGR reviews.

With regard to improving interactions with ACRS, the working group believes that ACRS review at the proposed rule stage can be eliminated for rulemakings that do not contain significant or controversial technical issues. Thus for routine rulemakings, staff should provide ACRS the package for informational purposes, optimally at the same time the proposed rule is issued for public comment. ACRS can review and comment on the proposed rule at its discretion and, if necessary, request a briefing. The ACRS would continue its practice of reviewing the final rule, and the staff would then address comments, if any, generated by the ACRS on the proposed rule package.

FSME currently provides ACRS and Advisory Committee on Nuclear Waste and Materials with an information copy, as appropriate, of proposed and final rules.

3.2.c Recommendations

Review by CRGR for rulemaking tasks should be completely eliminated.

Proposed rule packages should be provided to ACRS for comment, and ACRS should be briefed on proposed rules only as a result of an ACRS request.

3.3. SRM-3 Release of Draft Information

3.3.a Background

The following information is from the SRM dated May 31, 2006:

The NRR staff may routinely release draft rule text, statements of consideration, and the technical basis for public review, and hold workshops, if necessary, prior to submission of a proposed rule to the Commission. Draft rule text has been released on a case-by-case basis for past rulemakings (*i.e.*, rulemakings associated with 10 CFR Parts 26, 35 and 70), and is done for most rulemakings by NMSS, at least with Agreement States. The early release of draft rule text and supporting documentation in concert with workshops should reduce or eliminate the need for extended public comment periods (*i.e.*, those in excess of 75 days). The staff should notify the Commission of a planned release of draft rule text for public review prior to submission of the proposed rule to the Commission.

3.3.b Assessment

The staff has been following this Commission SRM direction for recent rulemakings when draft information is available for public review. In most cases, the information that was available for release to external stakeholders was draft rule language which enabled external stakeholders to provide feedback that staff considered prior to issuance of the proposed rule. In some cases (*e.g.*, 10 CFR 50.69) several versions of draft language were released. The staff believes that this interaction has improved the rulemaking framework, particularly the drafting of proposed language, in several ways. Receiving public feedback on draft rule language can direct the staff to eliminate efforts that would have been spent on less effective rule language. Thus, the earlier that this interaction occurs, the more likely that it will reduce the overall effort required to publish a proposed rule. If the staff can resolve public comments before a proposed rule is published, then stakeholders should have fewer objections to the proposed rule.

The staff believes that greater emphasis should be placed on the release of the draft technical basis, consistent with the discussion in Section 2.1. Interaction with external stakeholders on the technical basis is beneficial in identifying whether actual safety and security issues exist, the extent of such issues, and the best regulatory solutions for addressing the issues. Consequently, releasing a draft technical basis supports the development of both the technical basis and the regulatory analysis. Staff has been unable to exercise this aspect of the Commission's direction due to the lack of a sufficiently complete, draft technical basis that could be shared with stakeholders.

Although FSME routinely releases drafts to the Agreement States and the Advisory Committee on Medical Uses of Isotopes for review and comment, it does not routinely release information to other stakeholders. There have been specific cases where information has been released to other stakeholders and workshops held to obtain information (*i.e.*, rulemakings involving parts 35 and 70, specifically the recent rule “Naturally Occurring and Accelerator-Produced Radioactive Materials”). However, this has occurred with specific Commission approval, typically via the rulemaking plan. FSME would have more flexibility if it had the same authority to share draft information and hold workshops without prior Commission approval.

3.3.c Recommendation

The Commission should extend to FSME the authority to release draft rule text, statements of consideration, and the technical bases for public review and to hold workshops prior to submission of a proposed rule.

4.0 ADDITIONAL PROCESS IMPROVEMENTS

The May 31, 2006, SRM directed the staff to identify potential additional process improvements which have not been previously considered that could streamline the rulemaking process. The working group did identify two areas where it may be possible to gain further efficiencies. Those two areas are discussed below.

4.1 Petitions for Rulemaking (PRM)

In an effort to identify additional process efficiencies, the working group reviewed the NRC’s rulemaking petition process. PRM tasks are related to the rulemaking process since they become rulemakings when petitions are granted. In some cases, petitions may not be addressed in a timely manner due to prioritization and resource constraints. In other cases, the agency may receive a petition that is within the bounds of a rulemaking that is already underway. The working group reviewed other agencies’ PRM requirements for policy that could streamline the NRC’s PRM process. The working group believes that changes to 10 CFR 2.802 may make the handling of rulemaking petitions more efficient. One example of another agency’s petition procedures comes from the Federal Aviation Administration (FAA) regulations in Part 11 of Title 14 of the *Code of Federal Regulations*. Two explicit options are provided in the FAA’s petition process (in 14 CFR 11.73) that are not within the NRC’s requirements in § 2.802:

(c) If we have begun a rulemaking project in the subject area of your petition, we will consider your comments and arguments for a rule change as part of that project. We will not treat your petition as a separate action.

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(e) If we determine that the issues you identify in your petition may have merit, but do not address an immediate safety concern or cannot be addressed because of other priorities and resource constraints, we may dismiss your petition. Your comments and arguments for a rule change will be placed in a database, which we will examine when we consider future rulemaking.

The working group recognizes that the NRC may not be able to manage petition requests through a process identical to the FAA or other agencies. However, based on a cursory review of other agency petition handling requirements, it appears that an effort to more comprehensively review petition handling requirements may identify provisions that could make the NRC's petition process more efficient.

4.1.a Recommendation

The NRC should examine in more detail the petition handling requirements adopted by other Federal government agencies to identify provisions that would make the NRC's petition process more efficient while ensuring that petitions are handled in a manner consistent with the agency's openness objective and in compliance with the Administrative Procedure Act (5 U.S.C. 551, *et seq.*).

4.2 Regulatory Analysis

As discussed in NUREG/BR-0058 Revision 4, the principal purposes of a regulatory analysis are to help ensure that:

- (1) NRC's regulatory decisions support its statutory responsibilities and are based on adequate information concerning the need for, and consequences of, proposed actions.
- (2) Appropriate alternative approaches to regulatory objectives are identified and analyzed.
- (3) No clearly preferable alternative is available to the proposed action.
- (4) Proposed actions subject to the backfit rule (10 CFR 50.109), and not within the exceptions at 10 CFR 50.109(a)(4), provide a substantial increase in the overall protection of the public health and safety or the common defense and security and that the direct and indirect costs of implementation are justified in view of this substantial increase in protection.

The regulatory analysis process is not intended to be used to produce after-the-fact rationalizations to justify decisions already made, nor to unnecessarily delay regulatory actions. The conclusions and recommendations included in a regulatory analysis document are neither final nor binding, but are intended to enhance the soundness of decision-making by NRC managers and the Commission. Since the NRC is an independent agency, it technically is not required to comply with the executive order that directs government agencies to perform regulatory analyses (Executive Order 12866, as amended). NRC Office Directors have the authority to waive the regulatory analysis requirement. Nonetheless, the NRC "voluntarily" follows the executive order. This executive order was amended in January 2007, in part, to put more emphasis on regulatory analyses.

Stakeholders who would be subject to new requirements contained in a proposed rule generally want more rigor, not less, in the regulatory analysis (including the backfit analysis) of the proposed rule. As an example, the Nuclear Energy Institute (NEI) and Entergy, in their comments on the proposed power reactor security requirements rulemaking indicated that the NRC did not properly address all the new requirements in the proposed regulation, or properly account for the costs of the new requirements. NEI also recently commented to CRGR that it would like to see increased rigor to support backfit analyses. Reduction in the rigor of regulatory analyses (with the exception of the specific case discussed below) would likely result

in adverse and extensive comments (and associated net decrease in process efficiency) for actions that impose costs on licensees.

However, the regulatory analysis portion of the rulemaking process can be streamlined (in terms of being less rigorous or eliminated altogether) when 1) the agency does not require a regulatory analysis to determine that rulemaking is the appropriate approach, 2) there are trivial cost issues, 3) it is obvious that the rule involves significant cost benefits to licensees, or 4) there is little utility in using regulatory analysis to weigh various approaches for amending the rules (*i.e.*, relatively simple rule changes). One rulemaking for which it appears feasible to eliminate regulatory analysis is the updating of references in the *Code of Federal Regulations*.

Regulatory analyses do not appear to be needed to support routine (*i.e.*, not involving backfit issues), periodic updates to § 50.55a that incorporate, by reference, new Editions and Addenda of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (BPV) and the ASME Operation and Maintenance (OM) Code. The ASME BPV Code and OM Code are national voluntary consensus standards, and, as such, are required by the National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, to be used by government agencies unless the use of such a standard is inconsistent with applicable law or is otherwise impractical. It has been the NRC's practice to routinely review new editions and addenda of the ASME BPV and OM Codes and periodically update § 50.55a to incorporate newer Editions and Addenda by reference. New editions of the subject codes are issued every 3 years; addenda to the editions are currently issued yearly except in years when a new edition is issued. The NRC staff reviews ASME BPV and OM Code Cases, rules upon the acceptability of each Code Case, and publishes its findings in regulatory guides. NRC revises the regulatory guides periodically as new Code Cases are published by the ASME. The NRC incorporates by reference the regulatory guides listing acceptable and conditionally acceptable ASME Code Cases in 10 CFR 50.55a. Because Code Cases are alternatives to the provisions in NRC regulations and not interpretations, the NRC is required to incorporate them into its regulations to comply with the public notice and comment provisions of the Administrative Procedure Act.

4.2.a Recommendation

Regulatory analyses for routine rulemakings (*i.e.*, those for which backfit issues have not been identified) that involve updating references in the *Code of Federal Regulations* should be eliminated. Specifically, regulatory analyses are not needed to support the periodic updates to § 50.55a to incorporate, by reference, new Editions and Addenda of the ASME BPV and the ASME OM Code.

5.0 USE OF CONTRACTOR SUPPORT

In the May 2006 SRM, the Commission expressed concern with regard to the use of contractors to support rulemaking. This concern appears to center on both the level of dependency on contractors and on the manner in which the staff uses contractors to support its rulemaking efforts. The SRM provided the following direction:

Further, as part of the evaluation, the staff, in consultation with OGC, should address the feasibility, as well as the advantages and disadvantages, of reducing contractor dependence in the rulemaking arena.... Furthermore, the staff should address the necessary steps to ensure that, when contracting is needed, it is accomplished in a

manner that best serves the needs of the agency, *i.e.*, in the most efficient and effective manner possible.

Typically, the NRC staff relies on contractors to support the following rulemaking activities:

- Binning/sorting the public comments
- Supporting development of regulatory analyses
- Supporting development of OMB information collection analyses
- Supporting development of regulatory guides
- Supporting development of environmental assessments and environmental impact statements

Contractors are periodically involved on a limited basis with developing the resolutions to public comments, or in revising the rule language and supporting SOC to reflect the comment resolutions. Contractors generally are not used to develop regulatory positions, although contractors can be used to perform such tasks. Even in situations where a contractor is used in such a manner, the staff still reviews the contractor's input and takes ownership of the contractor's work. One situation where the staff may need to rely on a contractor is where the contractor contains specialized expertise that enables the staff to more efficiently develop the rule. The working group believes that the current contractor process, and the manner in which contractors are used, is serving the agency's rulemaking efforts in an effective manner.

With regard to whether it is feasible to reduce the staff's dependence on contractors in the rulemaking area, in all cases where contractors are used, the staff can perform the work contracted out, but in many cases it would consume more staff resources and often result in schedule impacts. Due to the nature of the rulemaking task, a single, resource-intensive task, for which that resource need disappears when the task is complete, can often best be addressed through contractor support since it is more interchangeable than using staff resources (*i.e.*, it avoids the need to reshuffle staff). Hence the use of contractors supports a more efficient rulemaking process where there tend to be peaks and valleys in workloads. Currently, NRR and FSME are resource-constrained in the rulemaking area, and a reduction in the use of contractors (assuming that rulemaking resources in NRR and FSME are not increased) would adversely impact rulemaking schedules.

In summary, the working group finds that contractor support for rulemaking has contributed to a more effective and efficient rulemaking process.

6.0 EARLY OFFICE COLLABORATION

In the May 2006 SRM, the Commission directed the staff to:

Examine ways to improve early collaboration with affected offices, particularly OGC and OIS, regarding the allocation of resources prior to the proposed rule stage, to determine the most efficient use of resources.

The SRM recognized the importance of early collaboration between offices on rulemaking tasks. The staff agrees with this insight, and the RPIP acknowledged the importance of collaboration through the development of recommendations that implement the use of working groups, comprised of members from the various offices [*i.e.*, RPI-34, RPI-35, RPI-36].

The working group recognizes that resource limitations in the offices which are vital to support rulemaking can slow the entire rulemaking process. Involving members of OGC, OIS, and ADM in rulemaking working groups enables these offices to consider the rulemaking schedule when coordinating resources to support the rulemaking. The working group continues to support this approach. NRR has improved its interaction with OGC on rulemaking tasks by re-instituting the OGC review tracking list. The tracking list provides OGC with advance notice of documents and packages that will require OGC review, enabling OGC to allocate resources more effectively. The same checklist enables NRR to monitor any delays with work under review by OGC. One of the critical tasks tracked is rulemaking packages. FSME has routine interactions with OGC that provide an opportunity to identify potential choke points and address any issues before they become a problem. FSME distributes its biweekly update of the FSME Rule Status Chart, which provides the status of FSME rulemaking activities and the next milestone, to OGC and ADM. The information in the Rule Status Chart can be used by OGC and ADM to refine their allocation of resources.

In summary, the working group finds that the current practices already result in early collaboration with OGC and OIS and further action is not necessary as long as the communication channels remain open.

7.0 CONCLUSIONS

The working group, consistent with the direction in the May 31, 2006 SRM, examined the rulemaking process in an effort to further streamline the process. This report assesses the previous RPIs that relate to process streamlining, and identifies additional actions to further improve the process.

In general, the working group has found that many of the RPIP recommendations have been implemented and that some efficiencies have been realized. For those that have not been implemented the reasons for not doing so remain valid. The working group has concluded that some additional efficiencies can be realized in the following areas:

1. Technical basis. While NRC's procedures call for an adequate technical basis to be developed before rulemaking commences, rulemakings are routinely undertaken without the technical basis being completed or with an inadequate technical basis. This causes rulemaking staff to revisit essential issues and re-write rulemaking documents during the review to accommodate an emerging technical basis and reflect consequential changes in policy direction. The net result is schedule delays and increased resource expenditures that are not consistent with the agency's commitment to regulatory efficiency. The working group recommends an increased focus on completion of the technical basis prior to initiation of rulemaking. To support this objective, the working group recommends that guidance on what constitutes a sound technical basis should be developed and included in the rulemaking procedures for each office.
2. Draft implementation guidance publication schedule. The working group believes that some efficiencies can be obtained if a greater emphasis is placed on issuing for comment draft implementation guidance in conjunction with issuance of the proposed rule for comment. The draft guidance can supplement the proposed rule and supporting SOC and provide additional information that can increase a stakeholder's understanding of the proposed provisions and convey what the Commission expects licensees to do to

comply with the proposed provisions. Draft guidance can help stakeholders offer more informed comments, and can actually result in fewer comments for staff to process since comprehensive guidance can remove some of the uncertainty associated with proposed provisions. The working group recommends that an increased focus be placed on the issuance of draft implementation guidance in conjunction with proposed rules.

3. Waiver of rulemaking plans. The working group recommends that the authority to waive the development and submission of rulemaking plans be extended to the Director of FSME in consultation with the General Counsel. This authority would provide additional flexibility to FSME.
4. Release of draft information. Although FSME routinely releases drafts to the Agreement States and the Advisory Committee on Medical Uses of Isotopes for review and comment, it does not routinely release information to other stakeholders. There have been cases where information has been released to other stakeholders and workshops held to obtain information (e.g., Parts 35 and 70, NARM). However, this has occurred with Commission approval, typically in response to rulemaking plans. The working group recommends that the authority to release draft rule text, statements of consideration, and technical basis documentation for public review and to hold workshops prior to submission of a proposed rule to the Commission be extended to FSME. This would provide the staff with additional flexibility to conduct a rulemaking in the most efficient manner.
5. ACRS interaction. ACRS review of rulemaking packages is required for issues within the Committee's scope. The Commission provided direction to streamline this aspect of the process in its May 31, 2006 SRM. The working group recommends that for rulemakings not involving technically complex or controversial issues, ACRS be provided the proposed rulemaking package for information rather than review. The ACRS would then perform its normal review during the final rule stage. The working group estimates that this recommendation may save up to 2 weeks of time in the overall rulemaking schedule, but it is not likely to reduce the technical effort required to gain Committee endorsement.
6. Eliminate CRGR review. The working group believes that CRGR review is valuable for many licensing actions but that it can be completely removed from the rulemaking process. Backfit issues can be handled instead by OGC in conjunction with the technical offices. The working group estimates that this may save as much as 2 weeks in the overall rulemaking schedule.
7. Regulatory analysis. Because of its status as an independent agency, the NRC technically is not required to conduct a regulatory analysis for each rulemaking. However, the working group does not advise elimination of the regulatory analysis except for a limited class of rulemakings (as explained below.) Wholesale elimination of the regulatory analysis would be in conflict with NRC's voluntary compliance with Executive Order 12866, as amended. It would certainly be inadvisable for any action where the NRC may be imposing additional costs on licensees since it would not be consistent with the agency's public confidence objectives, and it would increase the

number of adverse comments provided on the rulemaking which in turn would result in greater resources being spent to resolve those comments and concerns.

The regulatory analysis task can, however, be eliminated for certain routine rulemakings. Specifically, the working group recommends a regulatory analysis not be performed for routine (i.e., those for which backfit issues have not been identified), periodic revisions to § 50.55a that update by reference new editions of the ASME BPV and OM Codes. Additionally, it may be possible to relax the rigor of regulatory analyses that support rules that are voluntary, and that obviously provide alternative, cost-effective requirements. However, due to the infrequency of this occurrence, this potential efficiency is not likely to be used often.

The working group believes that the actions identified above represent the measures most likely to streamline the rulemaking process at this time. This is principally a result of the previous RPIs that have been implemented to date. The working group did examine the other major pieces of the rulemaking process not already addressed herein, and found:

1. The APA does not specify a minimum comment period. A reasonable time should be allowed that takes into consideration the complexity of the rule. Executive Order No. 12866, as amended, directs that the time should be 60 days for most rulemakings. The North American Free Trade Agreement (NAFTA) requires notification at least 60 days prior to adoption of a technical regulation and Executive Order No. 12889 of December 27, 1993, implementing NAFTA requires a 75-day comment period. The working group does not recommend that the NRC reduce the comment period for proposed rules as a means to streamline rulemaking. It would not only be inconsistent with the Executive Orders, but also inconsistent with the agency's openness objective.
2. The OMB information collection analysis is required by law, specifically the Paperwork Reduction Act, and hence is required to support rulemaking packages.
3. A backfit analysis is required by 10 CFR 50.109, 70.76, 72.62, and 76.76 and so it can not be deleted from the rulemaking process.
4. Direct final rules are being used by the NRC but are to be used in only limited circumstances (*i.e.*, if the rulemaking is non-controversial and the NRC does not anticipate any significant or adverse comment on the rule).

8.0 SUMMARY OF THE WORKING GROUP'S RECOMMENDATIONS

Technical Basis for Rulemaking

1. Continued emphasis should be placed on the development of a complete and adequate technical basis prior to the initiation of rulemaking.
2. Staff guidance should be developed that identifies what is required for a complete and adequate technical basis.
3. Emphasis should be placed on engaging internal and external stakeholders during technical basis development.

4. In the event that deficiencies in the technical basis are identified after a rulemaking has commenced, the rulemaking should be suspended until an adequate technical basis has been completed.

Concurrence Process

5. Managers reviewing rulemaking documents should continue to focus their review on technical and programmatic matters within their area of responsibility.
6. Technical staff should focus its review on matters that are germane to its technical areas of responsibility.
7. OGC's finding of no legal objection should be provided contingent upon its comments being incorporated into the rulemaking documents, if OGC specifies that its comments are of the nature that do not require further OGC review.
8. Efforts should be made to identify differing views earlier in the process through better information sharing.
9. Re-examine the new nonconcurrence process as applied to rulemaking to determine whether it can be simplified to remove the need to have people re-concur as a result of a nonconcurrence.
10. Additional guidance should be placed in LIC-300 and other rulemaking guidance documents that emphasizes the need for rulemaking PMs to follow up with managers reviewing rulemaking packages.

Training

11. The rulemaking LISTSERV, currently used by ADM to improve communication among the rulemaking staff, should be used more widely to promote available online training, solicit interest in specific training opportunities, and gauge interest in other rulemaking areas for which no NRC-specific materials exist.
12. Training should be provided to rulemaking PMs to apprise them of the RPIs that have been implemented into the process, and of any additional process improvements that have been implemented.

Timeliness, Resource Expenditures, and Internal Rulemaking Status Web Page

13. NRR should develop a more effective process to monitor the timeliness and resource expenditures associated with rulemaking tasks (*i.e.*, rulemaking task detailed schedule reports and rulemaking task resource expenditure reports).

Guidance Documents

14. Increased emphasis should be placed on issuing draft implementation guidance in conjunction with the issuance of a proposed rule for public comment.

Rulemaking Plans

15. The authority to waive the development and submission of rulemaking plans should be extended to the Director of FSME.

ACRS and CRGR Review

16. CRGR review of rulemaking tasks should be completely eliminated.
17. Proposed rule packages should be provided to ACRS for comment, and ACRS should be briefed on proposed rules only as a result of an ACRS request.

Release of Draft Documents

18. The authority to release draft rule text, statements of consideration, and the technical basis for public review and to hold workshops prior to submission of a proposed rule to the Commission should be extended to FSME.

Petitions for Rulemaking

19. The NRC staff should examine petition handling requirements adopted by other Federal government agencies to identify provisions that would make the NRC's petition process more efficient while ensuring that petitions are handled in a manner consistent with the agency's openness objective and in compliance with the APA.

Regulatory Analysis

20. Regulatory analyses for routine rulemakings that involve updating references in the *Code of Federal Regulations* should be eliminated.