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**OFFICIAL RECORDS TO BE MADE
PUBLICLY AVAILABLE IN ADAMS**

Rulemaking Process Improvement Task Force Summary Report

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Acronyms and Abbreviations

LIST OF ACRONYMS AND ABBREVIATIONS

ACMUI	Advisory Committee on Medical Use of Isotopes
ACNW	Advisory Committee on Nuclear Waste
ACRS	Advisory Committee on Reactor Safeguards
ADAMS	Agencywide Documents Access and Management System
ANPR	Advance Notice of Proposed Rulemaking
ADM	Office of Administration
APA	Administrative Procedure Act
CFO	Office of the Chief Financial Officer
CFR	Code of Federal Regulations
CIO	Office of the Chief Information Officer
CoC	Certificate of Compliance
CRCPD	Conference of Radiation Control Program Directors
CRGR	Committee to Review Generic Requirements
CTM	Chairman's Tasking Memorandum
DFR	Direct Final Rule
DOLLS	Document Logging and Location System
DQSR	Directors Quarterly Status Report
DRIP	Division of Regulatory Improvement Program, Office of Nuclear Reactor Regulation
DSI	Direction Setting Issue
EDO	Executive Director for Operations
FR	Final Rule
FTE	full time equivalent
GSA	General Services Administration
IMNS	Division of Industrial and Medical Nuclear Safety
LT	Leadership Team
MD	Management Directive
NMSS	Office of Nuclear Material Safety and Safeguards
NAFTA	North American Free Trade Agreement
NEI	Nuclear Energy Institute
NEPA	National Environmental Policy Act of 1969
NRC	Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
OAS	Organization of Agreement States
OCA	Office of Congressional Affairs
OE	Office of Enforcement
OFR	Office of the Federal Register
OGC	Office of the General Counsel
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
PA	Planned Accomplishment

PBPM	Planning, Budgeting, and Performance Management
PERR	Public Electronic Reading Room
PM	Project Manager
PMDA	Program Management, Policy Development and Analysis
PR	Proposed Rule
PROS	Professional Reactor Operator Society
Q&A	Questions and Answer
RAI	Request for Additional Information
RAP	Rulemaking Activity Plan
RCC	Rulemaking Coordinating Committee
RDB	Rules and Directives Branch, Office of Administration
RES	Office of Research
RGB	Rulemaking and Guidance Branch, Office of Nuclear Material safety and Safeguards
RISC	Regulatory Information Service Center
RMB	Records Management Branch, Office of the Chief Information Officer
RMP	Rulemaking Plan
ROCIS	RISC/OIRA Combined Information System
RPRP	Policy and Rulemaking Program, Office of Nuclear Reactor Regulation
SBA	Small Business Administration
SBREFA	Small Business Regulatory Enforcement Fairness Act
SECY	Office of the Secretary
SRM	Staff Requirements Memorandum
STP	Office of State and Tribal Programs
TAC	Technical Assignment Control Number
TBD	To Be Determined
TCF	Technical Conference Forum
TVA	Tennessee Valley Authority
WITS	Work Item Tracking System

Executive Summary

In October 2001, the Rulemaking Coordinating Committee established a rulemaking process improvement Task Force. The Task Force was a co-operative interoffice effort consisting of staff representatives from the principal rulemaking organizations within the U.S. Nuclear Regulatory Commission (NRC). The Task Force was chartered to perform a broad-scope review of the NRC rulemaking process and provide a report on its findings and recommendations.

As part of the review process, the Task Force collected data on rulemaking activities that received rulemaking numbers and/or were published in the *Federal Register* since 1995. (Earlier information was also collected but is not as complete.) Information was collected on the rulemaking plan, proposed rule, and final rule phases. A number of different sources were used, as no one source contained all the desired information; in fact, some of the information that was wanted on concurrence time, initiation date, and resource expenditure was not readily available. The Task Force also conducted meetings with key internal stakeholders. The Task Force met with Commissioner Assistants; the Executive Director of Operations (EDO); Deputy EDOs; Office Directors; Deputy Office Directors; Division Directors (or designees); Deputy Division Directors; Branch Chiefs; Section Leaders; and staff involved in rulemaking activities. The Task Force did not attempt a scientific sampling of the views of Agency personnel involved in rulemaking; rather interviewees were encouraged to express their individual opinions on all aspects of the rulemaking process. The Task Force also gathered some information from external stakeholders and other Federal agencies. It reviewed the legal foundation for NRC rulemaking and internal documents describing the rulemaking process. It also looked at the organizations and the administrative support aspects of the rulemaking organizations, such as planning, budgeting, and performance measures. The focus of the Task Force review was within the offices of Nuclear Material Safety and Safeguards and Nuclear Reactor Regulation, because these two offices conduct the majority of the rulemakings.

Overall, the Task Force found that NRC's rulemaking process is stable and functions reasonably well. This conclusion is supported by two simple observations--quality and output. The most obvious indicator of a process problem is poor-quality work. The quality of a rulemaking is a subjective characteristic, but, based on Task Force discussions with all levels of staff and management, there was no indication that rulemaking quality was an issue or concern. With respect to rulemaking output, NRC publishes around 23 final rules per year. This has been fairly consistent since 1995, although down from the 28 rule per year average from the early 1990s. Overall rulemaking output (final rules, proposed rules, rulemaking plans, and advance notices of proposed rulemaking) has actually improved slightly since the early 1990s, from an average of 50 rule products (1990-1994) to an average of 52 rule products (1998-2001). (Note that use of rulemaking plans was not initiated until 1995.) It would be expected that any serious process problem would have resulted in a general downward trend in the output of rule products.

Notwithstanding the general health of rulemaking, the NRC timeliness goal associated with rulemaking is often not met. The Agency has long-standing timeliness targets of completing a rulemaking within 18 months of approval of the rulemaking plan or within 2 years of initiation. The time necessary to complete a rulemaking has been gradually increasing. The average time from rulemaking plan approval to publication of the final rule has increased from 276 days in 1997 to nearly 1130 days in 2001. This is significantly above the Agency goal of 18 months (540 days) to complete a rulemaking after approval of the rulemaking plan. Data indicate that since 1995, approximately 26 percent of all completed rulemakings exceeded the target. If

those rules that are issued as direct final rules and those that are exempt from the Administrative Procedure Act are removed from the completions, the percentage of rules exceeding the target increases to 40 percent.

Many of the Task Force recommendations will not improve the timeliness, efficiency, nor effectiveness of completing an individual rulemaking, but will provide management better tools to manage the rulemaking process, thereby improving the overall efficiency and effectiveness of the Agency. The Task Force found that we do not maintain good data on which to make budget decisions. Management does not have a true handle on how much rulemaking costs the Agency. The Task Force discovered several problems in the areas of technical assignment control number management and discipline, scheduling, budgeting, and performance monitoring. The Task Force has developed draft prioritization criteria and draft performance measures for management consideration. The Task Force also collected data, on resource expenditure and timeliness, that can be used for making better estimates on schedule and budget in the individual rulemaking plans. Most of the recommendations in these areas can be implemented without Commission or EDO approval.

In addition, the Task Force made a number of recommendations that, if implemented, should improve the rulemaking process, including timeliness. The Task Force has recommended several process changes and enhancements to ease the concurrence process, improve Working Group function, improve communications, enhance stakeholder participation, and simplify rulemaking plans. Three key recommendations are: to create a rulemaking screening process, simplify the rulemaking plan, and engage external stakeholders earlier. One of the staff concerns is the initiation of rulemaking before the technical basis has been fully developed. Too often the staff is engaged in rulemaking at the same time the technical basis is being developed. This results in inefficient use of staff resources, driving up the cost of rulemaking, and increasing the perception that rulemaking takes too long. The time and effort devoted to technical basis development should not be in rulemaking space. The Task Force has recommended the development and use of a screening process to weed out those actions that lack a technical basis. Work on a rulemaking plan would not begin until the technical basis was in place.

The Task Force recommends reducing the scope and complexity of rulemaking plans within the bounds of the current procedures and processes. Rulemaking plans have become very elaborate and complex. We spend too many resources and take too long to complete a rulemaking plan. Rulemaking plans have become mini-rules. The staff should return to the basic concepts. Implementation of this recommendation should reduce both expenditure and time resources. Implementation would not require Commission or EDO approval.

The Task Force also believes that external stakeholders should be engaged before the completion of the rulemaking plan. Once the rulemaking plan has been approved, the Agency course of action has been set. External stakeholders, especially Agreement States, would like more involvement at the conceptual stage before the decision is made. Although engaging stakeholders earlier may result in more resource expenditures and increase the time line, the end result will likely be a product that is more readily accepted by the stakeholders. The same level and types of stakeholder involvement should not be used for all rules. Therefore, the Task Force has also recommended that criteria be developed to assist in determining when and how stakeholders should be engaged, including which tools are the most appropriate to use. Earlier stakeholder involvement will require Commission approval.

The Task Force has recommended the creation and use of a database and a rulemakers webpage. Both would be available on the internal web. The database is intended to replace

the various tracking systems and be used to create reports such as the rulemaking activity plan, the Regulatory Agenda, and the petition report. The webpage would contain various reference documents routinely used by rulemaking staff, a description of the rulemaking process, and other items that would be of use to staff and management.

The Task Force has made a number of recommendations, some of which should improve the process and ultimately the timeliness of the rulemakings. Other recommendations are secondary to the process but could improve rulemaking management, budgeting, tracking, and performance monitoring. A bullet form summary of task force recommendations is provided on the following pages. There is a reference to the discussion of each recommendation in the report.

The Task Force notes that the recommendations resulted from a combination of data analyses, interviews, and brainstorming discussions among Task Force members. Although some of the data collected for this report are incomplete, the recommendations do not rely on data alone but were made in conjunction with the experience and judgment of the Task Force members. The Task Force feels confident that these recommendation, if implemented, will benefit the rulemaking process, timeliness, efficiency, and management.

There is ample evidence that the rulemaking process, when executed by knowledgeable and experienced staff, is reasonably efficient. Although not a specific recommendation of this report, rulemaking management could improve the overall perception of rulemaking by communicating more rulemaking success stories.

The recommendations presented below are grouped into general categories for ease of consideration and use.

Process

Simplify rulemaking plans and focus on the basics. (Process Improvements, Rulemaking Plan; pages 82-83)

Revise the concurrence process for rulemaking actions to encourage empowerment of staff and other measures to reduce concurrence time. (Process Improvements, Concurrence Process; pages 83-85)

Create and/or use a rulemaking initial screening process. (Process Improvements, Rulemaking Initiation Screening; pages 79-80)

Do not initiate rulemaking related activities until after completion of the technical basis. (Process Improvements, Rulemaking Initiation Screening; page 80)

Consider centralizing the office of Nuclear Reactor Regulation rulemaking management within the policy and rulemaking program of NRR to ensure the most efficient use of rulemaking resources. (Organization of NRC rulemaking; pages 14-15)

Conduct a pilot where the Office of General Counsel (OGC) would have the lead for developing the rule package. (Process Improvement, Pilot Program; pages 86-87)

Conduct a pilot where an Agreement State or CRCPD/OAS would have the lead for developing the rule. (Process Improvement, Pilot Program; page 87)

Consider use of a shorter comment period for some proposed rules, if legally permissible. (External Stakeholders; page 65)

Public Participation

Engage external stakeholders at an earlier stage of the process. (Process Improvements, Earlier Stakeholder Involvement; pages 80-82)

Hold a pilot public meeting on rulemaking. (Process Improvement, Miscellaneous; page 87)

Develop criteria on enhanced public participation that would include criteria on what tool to use in various situations. (External Stakeholder Survey; page 65)

Develop a mechanism to allow stakeholders to provide comments by e-mail, with an attachment. Also consider providing a fax number for providing comments. (Process Improvements, Miscellaneous; pages 87-88)

Tracking

Develop a centralized rulemaking status web page (for internal NRC use only) that provides all essential rulemaking information and that could be used as a common feeder for reports. (Improvement of Internal Tracking and Reporting; pages 32-33)

Remove all rulemakings from the Chairman's Tasking Memorandum except those that are recognized as Agency-level high-priority, and are in direct support of the strategic plan. (Improvement of Internal Tracking and Reporting; page 33)

Reassess the purpose and function of the Rulemaking Activity Plan to streamline and improve its usefulness as an information and management tool. (Improvement of Internal Tracking and Reporting; page 33)

Training

Develop training material that could be used to help explain the rulemaking process for both internal and external stakeholders. (Internal Stakeholder Survey, Miscellaneous; page 54)

Develop regulatory analysis training (either internal or external) as required training for all rulemaking staff. (Internal Stakeholder Survey, Miscellaneous; page 55)

Develop training sessions for rulemaking staff on the clearance process and how to prepare an Office of Management and Budget supporting statement. (Internal Stakeholder Survey, Rule Package Content; page 52)

Planning, Budgeting, and Performance Management

Compile and maintain an accurate database on rulemaking resource expenditures and timeliness for all rulemaking activities. The database should be used in estimating schedules and budgets in rulemaking plans. (Budgeting for Rulemaking, Budget Details; page 40)

Develop performance measures that more accurately reflect rulemaking performance. (Performance Measures for Rulemaking; page 43 and Appendix C)

Develop a better TAC management process that includes TAC discipline. (Technical Assignment Control Numbers; pages 45-56)

Use planned accomplishment codes that are dedicated to rulemaking. (Budgeting for Rulemaking, Budget Details; page 41)

Analyze the items that comprise the expended rulemaking budget to ensure that only rulemaking activities are included. (Budgeting for Rulemaking, Budget Details; page 41)

Develop standardized criteria for prioritizing individual rules. (Prioritization of Rules; page 42 and Appendix C)

Guidance and Support

Develop Office of Administration and OGC rule checklists. (Internal Stakeholder Survey, Rule Package Content; page 52)

Develop a rulemaking package checklist. (Internal Stakeholder Survey, Rule Package Content, page 52)

Create a rulemakers' webpage. (Internal Stakeholder Survey, Miscellaneous; page 54)

Issue guidance documents for public comment as companions to the proposed rule. (Internal Stakeholder Survey, Rule Package Content; pages 51-52)

Complete Management Directive 3.54, "Collection of Information and Reports Management." (Rulemaking Process, Rulemakings with Collections of Information; page 25)

Clarify the practice or guidance on including the OMB supporting statement as an appendix to the regulatory analysis. (Rulemaking Process, Rulemakings with Collections of Information; page 25)

At the next revision of the office procedures include additional detail of a how-to-nature. (Internal Stakeholder Survey, Miscellaneous; pages 53-54)

At the next revision of the Regulations Handbook include more examples and explanations. (Internal Stakeholder Survey, Miscellaneous; pages 53-54)

Consider eliminating the publication of a separate notice for information collection requirements and revise the Statement of Considerations for the proposed rule to cover the essential elements. (Rulemakings with Collections of Information; page 26)

Working Group

Assign a Records Management Branch and ADM member to the rulemaking Working Group. (Process Improvements, Working Group Function; page 86)

Develop Working Group Member and Task Leader expectations and responsibilities. (Process Improvements, Working Group Function; pages 85-86)

Improve Working Group communications among members and management. (Process Improvements, Working Group Function; page 85)

Introduction

Performance management within the U.S. Nuclear Regulatory Commission (NRC) dictates that periodic self-assessments and program evaluations take place. Consistent with this policy, the NRC management responsible for conducting rulemaking activities in the offices of Nuclear Reactor Regulation (NRR) and Nuclear Material Safety and Safeguards (NMSS) determined the need for a programmatic review of the NRC rulemaking process to identify areas with potential for process improvements and/or enhancements. In support of this initiative, a rulemaking process improvement task force was chartered (see Appendix A for charter) consisting of working-level staff involved in rulemaking from NMSS, NRR, Office of the General Counsel (OGC), and the Office of Administration (ADM). No constraints were placed on either the breadth or depth of the review and thinking "outside the box" was encouraged to the extent that the statutes governing the rulemaking process allow. The principal objectives of this effort were to:

- Review the current NRC rulemaking process
- Identify areas of the process that may have potential for efficiency or effectiveness improvements
- Produce a report that summarizes staff findings and provides process improvement recommendations

The report is arranged into four primary areas of examination.

The first area involves the legal foundation for NRC rulemaking. A number of statutes require various mandatory rulemaking steps and elements that the staff is not at liberty to alter. However, there are aspects of the way NRC implements its rulemaking that go beyond the legal rulemaking requirements and are, therefore, amenable to change.

The second area involves the organization established by the NRC program offices to implement rulemaking. Such office-specific aspects of the rulemaking organization include not only the structure, control, and responsibility of the rulemaking personnel, but also how the organizational units budget, prioritize, and assess the performance of rulemaking efforts. In addition, the Task Force has identified possible performance goals for measuring and assessing the rulemaking process. Although each program office has designated personnel responsible for rulemaking activities, the majority of rulemaking occurs within NRR and NMSS. Therefore, this report only examines these office programs in detail.

The third area looks at the detailed steps of the rulemaking process. In general the NRC rulemaking process involves four significant steps:

- i. Identification of a need to conduct a rulemaking;
- ii. Development of a rulemaking plan;
- iii. Preparation of a proposed rule package and publication of the proposed rule; and
- iv. Preparation of a final rule package and publication of the final rule.

In addition, there are many details in each of these steps as well as other mandatory components of a rulemaking package that can make the process complicated and daunting to those unfamiliar with it. The detailed steps for each stage of the rulemaking process were examined to understand what is currently done and why.

The fourth area concerns pertinent rulemaking data that have been identified and accumulated for both quantitative and qualitative assessments of the rulemaking process. Qualitative data were obtained through staff surveys. Quantitative rulemaking data were obtained through historical reviews of previous NRC rulemakings and include such things as the number of rules processed, types, time frames, resource expenditures, etc. However, it should be noted that this data is not complete. Initiation dates, expenditure data, and actual concurrence time are the largest areas of missing information. The Task Force attempted to sort and analyze the data to determine if any revealing trends or apparent efficiency improvements could be deduced.

As a result of this assessment, the above information has been synthesized into a number of findings and recommendations that, if implemented, could result in overall rulemaking process improvements.

Background: Past Rulemaking Improvement Initiatives

Previous reviews of the NRC rulemaking process have been conducted to identify the factors that delay certain rulemakings and/or contribute to excess staff resource expenditures. In an attempt to better manage rulemaking activities and improve efficiency and timeliness, significant reforms to the rulemaking process were implemented in 1985, 1995, and 1998.

In 1985, the Executive Director for Operations (EDO) issued a memorandum on "Control of Rulemaking and Its Timeliness." The effort was directed to assuring that rulemaking was necessary, effective, efficient, of high quality, and timely. The same attributes that we try to meet today. With the initiation of this effort, all rulemaking initiation had to be approved by the EDO and schedules were developed for all ongoing and all future rulemakings. The effort was the impetus for the schedules and process now specified in NUREG/BR-0053. A goal to finalize rules within 2 years of their inception was put in place.

Before 1995, initiation of a rulemaking was difficult to determine. Entry into the rulemaking process was not always well-defined. Rulemaking was to have started when either a Commission Staff Requirements Memorandum (SRM) directed the staff to develop a rulemaking or the staff received approval from the EDO of a rulemaking initiation package briefly describing the rulemaking topic. However, the staff would often develop proposed rule packages without a great deal of forethought regarding the likelihood of ultimate success of the rule. Delays in rulemaking were attributed to inadequate definition of the problem the rulemaking was addressing, failure to anticipate legal or Agreement State implementation obstacles, inadequate information on cost-effectiveness, or inadequate consideration of how licensee compliance would be demonstrated. Planning and follow-through of the rulemaking initiation process was not well managed. NRC's goal for completing a rulemaking under this process was 24 months, but was often exceeded.

In 1994, the staff looked at the rulemaking process in detail and implemented a significant change in the hope of improving rulemaking time frames - the use of a rulemaking plan. The rulemaking plan was envisioned as an expanded version of the old EDO initiation package with the emphasis on preplanning. The elements of the rulemaking plan were a combination of an options paper and regulatory analysis. The rulemaking plan sought to define the regulatory problem, identify why NRC action is necessary, outline alternatives, and obtain early management consensus on the direction of the rulemaking. In addition, the rulemaking plan

drew heavily on the information contained in the regulatory analysis, such as assessing whether the rule would be cost-effective, meet applicable criteria for backfit, and satisfy the safety goals. The rulemaking would begin when the rulemaking plan was approved, and the new staff goal was to issue a final rule within 18 months from the approval date of the rulemaking plan.

In addition, major restructuring of the rulemaking organization occurred between 1997 and 1998 when responsibility for rulemaking was shifted from the Office of Research (RES) to the program offices (NRR, NMSS) and ADM. Concurrently, the Commission adopted performance goals as outlined in the Strategic Plan. In line with the performance goals, there is increased focus on stakeholder involvement in Commission activities. Many rulemakings now involve more enhanced public participation and increased use of information technology. In recognition of a mature industry, most rulemakings now include efforts to reduce unnecessary regulatory burden while maintaining safety. All these factors impact the rulemaking environment. This is the first comprehensive review of the rulemaking process since the restructuring and adoption of the Agency's performance goals.

Legal Requirements Regarding Agency Rulemaking

Administrative Procedure Act Requirements

Congress has placed certain minimum requirements for the conduct of rulemaking on all Federal agencies in Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 551 et seq.).¹ These are:

Notice

Notice of the proposed rulemaking must generally be published in the *Federal Register*. The notice must inform the public of the legal authority for the rule, the length of the comment period, and the manner in which comments may be submitted.² The notice must also include either the terms or substance of the proposed rule or a description of the subjects and issues involved. The notice of the substance of the rule must be adequate to obtain meaningful participation from the public and to fairly apprise interested persons of the issues to be determined in the rulemaking. This means that the notice must disclose in some detail the

¹Rulemaking governed by Sec. 553 of the APA is frequently referred to as "informal" or "notice-and-comment" rulemaking. Sections 556 and 557 of the APA mandate different, and more extensive, procedures for "formal" rulemaking, which is triggered only where a statute other than the APA requires a rule to be made on the record after opportunity for Agency hearing. Formal rulemaking is rarely used and is not further discussed here.

²The 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. 12,866 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. 12,889 of December 27, 1993, implementing NAFTA, requires a 75-day comment period.

thinking that has prompted the proposal and must also identify and make available technical studies and data the agency has used to support the rule. Courts have viewed failure to make supporting studies available as depriving the public of the opportunity to provide meaningful comment requiring re-notice of the proposed rule. If the final rule is different in some significant way from the proposed rule, the question of whether the notice was "adequate" may arise. The agency must demonstrate that the proposed rule sufficiently alerted the public to the possibility of the change made in the final rule. A frequently applied test is whether the final rule is a "logical outgrowth" of the proposal and comments.

Opportunity for written comment

The Agency must provide the public an opportunity for written comment. The objectives of this requirement are to enable the interested public to participate in the rulemaking and to educate the Agency so that the final rule will be the product of a fully-informed decision-making process. The agency also has the discretion to provide an opportunity for oral comment (e.g., by holding a public meeting as part of the rulemaking process). If the Agency does so, comments made at the public meeting should be treated in the same fashion as written comments.

Statement of basis and purpose

Section 553(c) of the APA provides that, after comments are received and assessed, the Agency must incorporate into the final rules adopted "... a concise general statement of their basis and purpose." This statutory language should not be read too literally. The statement of basis and purpose (sometimes referred to as the "Statement of Considerations" or the "Supplementary Information" section of the final rule) has become the primary document used by courts in deciding the validity of challenged rules. Thus, it is particularly important that this statement provide a clear and reasoned explanation for the action taken in the rule as well as for the decision not to take alternative actions. The statement need not respond to each individual comment but it must address the significant issues raised in the comments. Thus, there is no need to prepare a NUREG document to address minor comments not discussed in the statement.

Because of its importance, legal review of the final rule focuses on the adequacy of the statement of basis and purpose. The Supreme Court has articulated the following guidance for the content of this statement:

[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made. In reviewing that explanation, we must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. The reviewing court should not attempt itself to make up for such deficiencies; we may not supply a reasoned basis for the agency's action that the agency itself has not given.

Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29, 43 (1983) (quotations and citations omitted).

Publication at least 30 days prior to the effective date of the rule

Ordinarily, a final rule must be published in the *Federal Register* at least 30 days prior to its effective date. The purpose of this requirement is to give sufficient time to those affected by the rule to prepare for the new requirements or to take other action, such as requesting an exemption. There are important exceptions to the requirement for a 30-day preparation period: (1) a substantive rule that grants or recognizes an exemption or relieves a restriction; (2) interpretative rules and statements of policy; and (3) any rule for which the agency finds good cause (published with the rule) for excusing the 30-day period.

Abbreviated rulemaking procedures

“Good cause” exceptions

The APA provides for exceptions to the usual requirements for prior notice and an opportunity to comment where an agency for good cause finds (and includes the finding in the rule) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.³ Courts have warned that these exceptions will be narrowly construed and only reluctantly countenanced. The Attorney General has interpreted the meaning of these exceptions. Notice-and-comment rulemaking is “impracticable” where it would impede the agency from performing its statutory functions, such as taking measures necessary to correct an ongoing safety problem; it is “unnecessary” where there is no public interest, such as changing the addresses of agency officials; it is “contrary to the public interest” where advance notice would defeat the public interest, such as the issuance of price controls, where issuance of advance notice would defeat their purpose. Case-specific findings are needed to establish that there is good cause for dispensing with notice-and-comment procedures. These APA exceptions are primarily applied to two different types of rulemakings: emergency rules and very minor rules in which there is no public interest. To use an exception for an emergency rule, the agency should be able to demonstrate the existence of a safety or health problem which must be addressed immediately. Although the APA does not require a post-promulgation comment period when a good cause exception is used, NRC’s rules require that the Agency provide a 30-day post-promulgation comment period when good cause is based on prior notice being impracticable or contrary to the public interest. 10 CFR 2.804(e).

Direct final rules

The direct final rule (DFR) process is a technique for expediting the issuance of noncontroversial rules. The process may be used where the agency can articulate a reason for believing that the rule is noncontroversial and significant adverse comments will not be received. The rule cannot contain any new information collection requirements. The rule is issued as a final rule but with the proviso that if a significant adverse comment is received within a set time period (usually 30 days), the rule will not be allowed to take effect but instead

³The APA also generically excepts from the notice and comment requirements interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice, without the need for a finding of good cause. In addition, APA rulemaking requirements do not apply to matters involving a military or foreign affairs function of the United States, or relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

will be treated as a proposed rule, with subsequent issuance of a final rule.⁴ As a legal matter, the DFR process is not explicitly sanctioned by any statute. Nevertheless, there are two legal theories that may be used to support the proposition that the DFR process is in substantial compliance (although not full compliance) with the APA and thus should be upheld by the courts. The first legal theory relies on the fact that the DFR process implicitly relies on the “unnecessary” good cause exception, even though an explicit finding of good cause is not made.⁵ The second legal theory relies on the fact that the DFR process substantially complies with the basic APA notice-and-comment requirements because notice is given of the terms of the rule (albeit for a final rule rather than a proposed rule) as well as an opportunity for comment, and a statement of basis and purpose is included at the outset (rather than, as contemplated by the APA, after the agency has assessed any comments).

Interim final rules

Interim final rulemaking is a process for issuing a final rule without prior notice and opportunity for comment, but with a post-promulgation comment opportunity. This process may only be used if the agency is able to invoke the good cause exception because notice and comment are “impracticable” or “contrary to the public interest.”⁶ By inviting comment, the agency is indicating that it may revise the rule in the future based on the comments it receives; meanwhile, however, the rule is final and effective. This may be an appropriate process to use when an emergency dictates that a final rule be published as quickly as possible but the agency wants to preserve the opportunity to refine the rule in the light of any comments received. NRC’s rules require that a 30-day post-promulgation comment period be provided for any rule adopted under the good cause exception where the basis is that notice and comment is impracticable or contrary to the public interest. 10 CFR 2.804(e)(1). For any post-promulgation comments received, NRC must publish a Federal Register notice containing an evaluation of the significant comments and any revision of the rule made as a result of the comments and their evaluation. 10 CFR 2.804(f).

Other Legal Requirements

National Environmental Policy Act

The National Environmental Policy Act of 1969 (NEPA) requires each Federal agency to prepare an environmental impact statement on each major Federal action significantly affecting the quality of the human environment. The intent of the act is to build the consideration of environmental aspects of proposed actions into the decision-making process of the agency.

NRC must assess the environmental impact of each proposed regulatory action and include a statement concerning the environmental impact in the Supplementary Information section of the

⁴Criteria for determining a significant adverse comment are in the *NRC Regulations Handbook*, NUREG/BR-0053, Rev. 5, Supplement 1.

⁵Agencies generally use DFRs for generic types of rules which, in their experience, do not tend to generate adverse comments, but they do not make case-specific findings that there are good causes for dispensing with notice-and-comment procedures.

⁶The process may also be considered if another exception to the APA requirements for notice and comment applies, such as the exception for interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.

preamble to each proposed rule. Unless a proposed rule is covered by a categorical exclusion defined in 10 CFR 51.22(c), the NRC staff prepares an environmental assessment on the proposed amendments. If NRC completes an environmental assessment and finds that the proposed rule is not a major action significantly affecting the quality of the human environment, an environmental impact statement need not be prepared. However, in such cases NRC must prepare and publish a finding of no significant impact in which NRC explains why it believes that the action will not have a significant effect on the quality of the human environment.

If the proposed rule is not eligible for a categorical exclusion, and NRC finds through its environmental assessment that the proposed rule is a major action significantly affecting the quality of the human environment, the NRC staff prepares an environmental impact statement on the proposed rule. The staff also prepares an environmental impact statement if the proposed rule involves a matter that the Commission has determined should be covered by an environmental impact statement.

Consultation with Agreement States

In order to fulfill a commitment made to the Council on Environmental Quality, NRC also consults with the States on environmental issues before issuing a final environmental assessment and documents the consultation in the environmental assessment. The EDO has approved an NRC procedure for consultation with the States during the preparation of an environmental assessment for a rulemaking action.

Environmental Justice Considerations

In a letter dated March 31, 1994, from the Chairman to the President, NRC voluntarily agreed to carry out the measures set forth in Executive Order 12898 that each Federal agency should make the promotion of environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, or activities on minority populations and low-income populations. NRC stated that these considerations applied primarily to its efforts to comply with NEPA and that it would address environmental justice aspects as part of its considerations under NEPA. In practice, in most cases, NRC will not conduct an environmental justice review for an environmental assessment that results in a finding of no significant impact. However, in certain cases, NRC may conduct an environmental justice review for an environmental assessment for a proposed rule and determine that a finding of no significant impact is appropriate.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires that each Federal agency consider the impact of their rulemaking on small entities and evaluate alternatives that would accomplish regulatory objectives without unduly burdening small entities or erecting barriers to competition. With respect to NRC regulatory actions, this primarily applies to regulations that would affect byproduct, source, and special nuclear material licensees.

The requirements of the Regulatory Flexibility Act apply to each rule subject to notice and comment rulemaking under the APA, which includes each proposed rule developed by NRC. If NRC believes that a proposed rule will have a "significant economic impact on a substantial number of small entities," the staff prepares an initial regulatory flexibility analysis. This analysis, or a summary of the analysis, is published in the *Federal Register* for public comment along with the proposed rule. The regulatory flexibility analysis may be combined with other analyses, as long as it meets the requirements of the Regulatory Flexibility Act. NRC's

Regulatory Analysis Guidelines (NUREG/BR-0058, Rev. 3, July 2000) require that factors necessary to evaluate the economic impact of the proposed rule on small entities be addressed in the regulatory analysis that considers the costs and benefits of the proposed rule. Comments received on regulatory flexibility issues are addressed in the statement of considerations for the final rule.

If NRC determines that a proposed rule will not have a significant economic impact on a substantial number of small entities, it may dispense with the preparation of an initial regulatory flexibility analysis. The Commission must certify this to be the case, and both the certification and the factual basis for the certification must be published in the proposed rule, which must invite comment on the Commission's decision to dispense with a regulatory analysis. Public comment opposing the Commission's certification must be addressed in the final rule document. If adverse comment is received, the statement of considerations preceding the final rule must either justify the Commission's decision to reaffirm its initial certification, or include a regulatory flexibility analysis.

Regulatory Flexibility Agenda

The Regulatory Flexibility Act also requires NRC to prepare and publish a semiannual regulatory flexibility agenda listing rules under development that may have a significant economic impact on a substantial number of small entities. The agenda is required to state the objectives and legal basis of each such rule, discuss its expected impact on small entities, and provide a schedule for completion of each action.

NRC meets this regulatory flexibility agenda by submitting data for inclusion in the Office of Management and Budget's (OMB's) *Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda)*, published in April and October of each year.

Section 610 Review

The Regulatory Flexibility Act also requires agencies to periodically review each agency rule which has a significant economic impact on a substantial number of small entities. NRC regulations which could have a significant impact on a substantial number of small entities (byproduct, source, and special nuclear material licensees) are amended fairly often, and consequently subjected to regulatory flexibility analysis relatively frequently. Therefore, it has not been necessary for the NRC to develop a schedule for Section 610 review of its standing rules.

National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995 directs Federal agencies to reduce their use of in-house standards in favor of greater reliance on voluntary standards developed by private, consensus organizations and used in manufacturing, commerce, industry, and educational institutions. The preamble of each proposed rule or interim final rule must contain a statement that requests comment and contains appropriate information concerning NRC's use of voluntary standards.

If the rule uses a voluntary consensus standard, it must contain a statement that identifies the standard. If the rule proposes to use a Government-unique standard instead of a voluntary consensus standard, it must contain a statement that identifies the standards and provides a preliminary explanation for the proposed use of a Government-unique standard instead of a voluntary consensus standard. If the rule proposes to use a Government-unique standard and

no voluntary consensus standard has been identified, it must contain a statement to that effect and invite interested stakeholders to identify any appropriate voluntary standard and explain why it should be used. Comments submitted in response to this invitation must be considered by the staff in the formulation of the final regulation and addressed in the preamble to the published final rule.

Paperwork Reduction Act

The Paperwork Review Act of 1980 established OIRA (Office of Information and Regulatory Affairs) in OMB to review and approve or reject Executive branch agency information collection requests. The Paperwork Reduction Act of 1995 broadened that mandate, assigning to OMB the duty of coordinating federal information policy for all Executive branch agencies, including the independent agencies like NRC. The purpose of the Act is to decrease the paperwork burden on individual citizens, regulated communities, small businesses, and other government entities, as well as minimizing the cost to the Federal government of collecting and disseminating information.

The Paperwork Reduction Act requires independent agencies such as NRC to comply with all OMB regulations governing information collection. Under the act, NRC may only collect information that—

- Serves specific Commission purposes,
- Meets a specific Commission need,
- Maximizes practical utility, and
- Does not unnecessarily duplicate available information.

NRC must obtain OMB approval whenever the agency directly or indirectly requires 10 or more persons or organizations to collect information, e.g., via written report forms, application forms, telephone surveys, or electronic data collectors; record-keeping and/or reporting requirements; or third-party or public disclosure requirements. OMB evaluates the information collection and determines whether it meets the standards established in the 1995 act.

Small Business Regulatory Enforcement Fairness Act

The Congressional review provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) requires Federal agencies to provide Congress with an opportunity to review agency rules. The Act's definition of "rule" is broad enough to capture most of the NRC's generic, non-adjudicatory actions. However, compliance with the Act should not be an onerous burden because most of the agency's generic actions can become effective as soon as they are sent to Congress for review. Under the Act, OMB is responsible for the determination of whether a rule is "major." The Rules and Directives Branch (RDB), ADM, coordinates the OMB review of each NRC regulatory action to determine if the action is considered a major rule under the Act.

OMB Review

SBREFA requires Federal agencies to provide Congress with an opportunity to review agency rules. For each final rule, NRC is required to submit a report to Congress containing a copy of the final rule, a concise general statement of the final rule (including a statement indicating whether the action is a "major" rule), and the effective date of the final rule. The report is to be submitted to each House of Congress and the Comptroller General before the rule takes effect.

The report must be accompanied by any other relevant information required by another act or by an Executive Order. This information would include any cost-benefit analyses, regulatory flexibility analyses, Paperwork Reduction Act statements, and any environmental assessments or impact statements related to the rule.

The effective date for all "major" rules promulgated after March 1, 1996, may be no earlier than 60 days after the date of congressional receipt of the required material or publication of the final rule in the *Federal Register*, whichever is later.

With limited exceptions, all final agency rules, policy statements, and agency documents interpreting agency requirements are defined as "rules" for purposes of the act. OMB is responsible for the determination of whether a rule is "major." In order to comply with SBREFA, NRC must submit to OMB a brief description of each final rulemaking action, along with a recommendation as to whether the action is a "major rule" as defined by the act. The lead office uses information in the rulemaking plan and the draft regulatory analysis to make this determination and create the OMB submission.

On a monthly basis, each program office involved in rulemaking forwards a compilation of final actions to RDB, which functions as the NRC's SBREFA liaison with OMB. RDB forwards the list to OMB for consideration and coordinates with OMB on the determination of whether any action is considered a "major rule." If OMB review of an action results in a change in the determination of an action as a "major rule," RDB informs the lead office and the Associate General Counsel for Licensing and Regulation.

Any Federal Register notice either required or routinely prepared for an action covered by the Act must contain a statement as to whether the action is a major rule, and the notice must confirm that NRC has verified this determination with OMB. The statement must be included whether the Federal Register notice publishes the text of the final action in its entirety or simply announces the availability of the final action.

Congressional Review

The SBREFA legislation also established special procedures for Congressional disapproval of agency rules. When a final action is being readied for publication, the NRC staff prepares standard Congressional review forms for submittal to the Speaker of the House, the President of the Senate, and the General Counsel of the General Accounting Office. The standard forms are prepared for the signature of the Director, Office of Congressional Affairs (OCA) and transmit to Congress the information for each action required under SBREFA. Copies of the draft forms must be included in the concurrence package for the final action.

When the final action is submitted for signature and publication, the submittal package must include completed forms ready for signature and three copies of each of the required enclosures. OCA transmits the forms and enclosures to Congress. Though final actions, in the absence of Congressional disapproval, become effective 60 days after the publication of the rule, SBREFA allows Congress to act at any time to overturn an agency rule. An agency rule overturned after Congressional review cannot be re-proposed in anything like its original form.

Backfit

A rulemaking may impose a "backfit" as this term is defined in NRC regulations; e.g., 10 CFR §§ 50.109, 72.62, 76.76. A backfit generally imposes new requirements on a licensee beyond the requirements in effect at the time the license was issued. The Commission has determined

by regulation that if a rulemaking imposes a backfit, a separate analysis must be undertaken to determine whether a backfit is warranted. Accordingly, all rulemakings must be examined to determine whether a backfit is imposed and, if so, a backfit analysis must be completed.

NRC Rulemaking: Organization and Process

Organization of NRC Rulemaking

Rulemaking was transferred from RES to the program offices in fiscal year 1998. With the transfer, the program offices (primarily NMSS and NRR) became responsible for their own rulemaking activities. ADM became responsible for the rulemaking infrastructure (rulemaking website, Rulemaking Activity Plan, rulemaking guidance documents, etc.). NMSS and NRR implemented their responsibilities using different methods. NMSS established the Rulemaking and Guidance Branch (RGB) within the Division of Industrial and Medical Nuclear Safety (IMNS). RGB is responsible for and has the lead for all rulemaking activities within NMSS. RGB works with the responsible program division to develop rule packages. RGB assigns a Task Leader who is responsible for the rulemaking under development. The program division provides a Working Group member or members to assist RGB in the development of the rule package and concurs in the package. Although each NMSS Division has some budget allotted to rulemaking and guidance development activities, the major share of the rulemaking budget is with RGB. RGB is responsible for budgeting and prioritization. RGB currently has 26 members, with 17 FTEs devoted to rulemaking.

The rulemaking structure established in NRR after the transfer is quite different. NRR has a hybrid organization. NRR has established the Policy and Rulemaking Program (RPRP) (formerly the Generic Issues, Environmental, Financial and Rulemaking Branch) as the focal point for all NRR rulemaking activities. Under the current NRR structure some rulemakings are conducted with RPRP staff in the lead; some rulemakings are conducted by the cognizant technical organization, with RPRP staff providing advice and assistance; and other rulemakings are conducted by the cognizant technical organization, with very little interaction with RPRP staff (e.g., license renewal and future reactors). As in NMSS, the Task Leader is responsible for completion of the rulemaking, coordination of concurrences, etc. RPRP concurs on all rulemaking activities. The lead division ensures that the rulemaking activity is budgeted and prioritized. RPRP currently has 30 members, 17 of which have rulemaking as their primary responsibility.

In ADM, RDB supports rulemaking activities. It is responsible for reviewing rulemaking actions to ensure compliance with various acts and to ensure actions are consistent with current regulations and other authorization statements of Agency policy. RDB provides central coordination and oversight for the NRC rulemaking program. RDB currently has 7 FTEs devoted to rulemaking and supporting activities.

In OGC, the Rulemaking and Fuel Cycle Division supports rulemaking activities for all offices. OGC provides legal advice and support, reviewing each rulemaking action for legal sufficiency. OGC typically assigns an attorney to the Working Group. The Rulemaking and Fuel Cycle Division consists of nine attorneys with 3.5 FTEs devoted to rulemaking support.

The Rulemaking Coordinating Committee (RCC) was established in May 1998 in response to suggestions intended to ensure that the NRC rulemaking process remains consistent among

the program offices (OIG/98E-04, "Additional Measures Needed To Enhance NRC's Rulemaking Process). The RCC is chaired by ADM and consists of Senior Executive Service managers and Section Chiefs from the primary offices involved in rulemaking: NMSS, NRR, and OGC. The primary focus of the RCC is to ensure consistency in methods used to develop and promulgate rules and to facilitate initiatives for improving all aspects of the rulemaking process. The RCC approved the Task Force charter.

The Records Management Branch (RMB) in the Office of the Chief Information Officer (CIO) is responsible for reviewing rulemaking actions, to ensure compliance with the information collection requirements of the Paperwork Reduction Act. RMB is responsible for coordination with OMB on all paperwork reduction activities.

Other offices within NRC are responsible for their own rulemaking activities. However, since these offices perform very few rulemakings, they do not have specific groups dedicated to rulemaking activities. RES provides support in the development of the technical basis, if needed. RES is also involved when changes are made to the regulatory analysis guidelines.

As stated above, before 1998, the majority of NRC's rulemaking activities were centralized within RES. Based on recommendations in Directions Setting Issue (DSI) paper 22, assessing RES, the Commission directed the staff to transfer responsibility for rulemaking from RES and into the Program Offices (NRR, NMSS, and ADM) in COMSECY-96-066, dated March 28, 1997. The purpose of this rulemaking reorganization was linked to much larger issues encompassing the role and scope of NRC's research program. Commission records related to COMSECY-96-066 suggest that the Commission believed that overall rulemaking efficiency could be improved by moving all rulemaking activities back to the Program Offices because of the clear stake and direct interest the Program Offices have in enhancing the Agency's regulations. In addition, the Commission noted that the direct experience of the Program Offices provided a better understanding of the problems and shortcomings of existing regulations.

The effect of this reorganization on the Agency overall rulemaking efficiency is difficult to gauge. The rulemaking output since the early 1990s has routinely fluctuated with an apparent sharp drop-off this year. There is no indication that the reorganization affected rulemaking output. The length of time required to complete a rulemaking has generally increased since the early 1990s. However, there is no indication that the reorganization is the cause of the increase. It is more likely due to increased stakeholder participation.

Another efficiency measure is the total full-time equivalents (FTEs) dedicated to rulemaking activities. Based on information contained in SECY-97-220, "Implementation of DSI 22 (Research)," dated September 30, 1997, RES applied approximately 30 FTEs per year to rulemaking activities. ADM devoted about 4 FTEs to rulemaking related activities. Although some rulemaking activity was conducted by the Program Offices before 1998, the amount was probably not significant and, is estimated to have been on the order of 3 FTEs per year for each office (NRR and NMSS). Therefore, before 1998, the total rulemaking effort for ADM, RES, NRR, and NMSS is estimated to have been around 40 FTEs.

As discussed in the budget section of this report, the current rulemaking FTEs for the Offices of NRR, NMSS, and ADM is now on the order of 46.5 FTEs. This represents a relatively minor increase (approximately 16 percent) in resources applied to rulemaking and may have occurred even if rulemaking had been left in RES. There may be rule-specific factors that have caused the greater rulemaking expenditures. Complicated rulemakings like the recently completed Part 35 effort on medical use of byproduct material and the rulemakings related to risk-informing

Part 50 have consumed a large amount of resources. In addition, other factors such as additional Commission involvement and directives for increased stakeholder participation may also increase resource expenditures.

In summary, the reorganization of rulemaking from RES to the program offices does not appear to have resulted in obvious benefit in overall rulemaking efficiency. However, because RES did not maintain expenditure data on individual rulemakings and the exact office expenditure on pre-1997 rulemaking activities is unknown, that actual efficiency is unknown.

It is not obvious that a decentralized rulemaking organization is preferable to an organization where all rulemaking activities are consolidated. Organizational structure is certainly a factor affecting efficiency of any process. Of the counterpart agencies that responded to the rulemaking survey, only one of the four had a decentralized rulemaking process comparable to NRC's. That particular agency was also the least efficient in processing rulemakings based on the measures requested by the survey. However, it is hard to draw any conclusions based on the limited data. Because of the differences between NRR and NMSS rulemaking organizations, the post-1997 rulemaking data were examined to determine if there were any advantages of one Program Office's organizational structure over the other.

It is recognized that the nature of the licensees being regulated by NRR and NMSS are vastly different (along with the related technical and policy bases for the applicable regulations). Regardless of the differences in these regulatory areas, both Program Offices would be expected to encounter a relatively equal share of complex technical and policy issues related to any given rulemaking. Therefore, a comparison of the total rulemaking work-product outputs from each Program Office following the reorganization does not seem unreasonable. A rulemaking work-product output generally involves any one of three different items, depending on the completion stage of the rulemaking. These products are either: (1) a rulemaking plan, (2) a proposed rule, or (3) a final rule. Another product that NMSS often uses is a DFR. For the purpose of this comparison, a DFR was judged to be the equivalent of a final rule output even though DFRs are generally simpler than an ordinary final rule.

The work-product output for each Program Office since the 1998 reorganization compares as follows:

	<u>Rulemaking Plans</u>	<u>Proposed Rule</u>	<u>Final Rules or DFR</u>	<u>Total Products</u>
NRR	23	18	19	60
NMSS	14	25	46	85

By this comparison, NRR had 30 percent less output. Even more revealing is the labor rate (work-product per FTE) associated with this output. Since NMSS uses approximately 17 FTEs annually for rulemaking versus NRR's 22, the labor rate favors NMSS efficiency even more. Specifically, NMSS has a labor rate that is 45 percent lower than NRR's.

It should be noted that about 20 percent of the NMSS work products are DFRs, most involving amendments to the codification of dry spent fuel storage cask certificates of compliance (CoC's). The CoC amendment DFRs are somewhat structured and streamlined rulemakings. They are processed without the need of a rulemaking plan and are subjected to a much reduced concurrence and approval process, relative to ordinary notice and comment rulemaking. Even so, a DFR is still subjected to most of the rulemaking administrative processing requirements to which every other rulemaking is subjected. The processing of the

DFRs would probably require significantly more effort if it were not for the familiarity and experience of the staff involved. In addition, NMSS is to be credited for devising an efficient method of processing these specialized rulemakings that reduce concurrence related hold-ups and management reviews. Even if the DFRs were not counted in the above comparison, (which makes no real sense but permits the remaining work products to be considered as more directly comparable), NMSS output would still exceed NRR's by 11 percent and the NRR's labor rate would still be higher than NMSS by 30 percent.

There should be some caution in reading too much into this comparison. Many reasons unrelated to organizational structure may contribute to making NRR rulemakings inefficiencies (such as rulemaking complexity, stakeholder involvement, or additional industry/NEI comments and arguments directly to the Commission after the close of the comment period and subsequent Commission direction to address late industry positions). Nonetheless, there is a compelling argument that NMSS rulemaking is more efficient than NRR's.

As noted, NMSS has a centralized rulemaking organization where the rulemaking staff has the lead for all rulemaking activities originating in its Program Office. NRR has a hybrid organization where: (a) some rulemakings are done with the rulemaking staff in the lead; (b) other rulemakings are conducted by the cognizant technical organization, with the rulemaking staff acting in more of a consultation role; or (c) within certain divisions of NRR, rulemaking is conducted almost autonomously, with very little interface with the primary rulemaking staff (e.g., license renewal and future reactors).

The ostensible advantages from a centralized rulemaking organization within the program office are many:

- Establishes a cadre of qualified and experienced staff who become very familiar with the rulemaking process and whose primary duty is rulemaking project management;
- Avoids a learning curve on generic mechanics of the rulemaking process;
- Centralizes rulemaking expertise and supporting resources;
- Provides for greater fungibility in the application of resources to alternate rulemaking activities, when needed;
- Provides for continuity and consistency among rulemaking initiatives;
- Enables stronger management focus on rulemaking issues and should facilitate quicker resolution; and
- Provides ownership of rulemaking efforts and establishes a single point of accountability for rulemaking performance.

The disadvantages of a centralized rulemaking organization within the program office include:

- The ability to control and dictate the management of specific rulemaking activities without regard to the priority or resources needed in other Agency rulemakings; and
- Competing work responsibilities for Working Group members in the technical organization.

In summary, the data accumulated since the rulemaking reorganization of 1998 would indicate that NMSS is generally more efficient in processing rulemakings than NRR. The primary difference between the two Program Offices is the centralization of rulemaking responsibility in NMSS and, with regard to certain categories of rulemaking (those related to cask CoCs), a substantial streamlining of the management review and concurrence process. Since the rulemaking process is complicated and intricate, it is difficult for any organizational staff (whose primary duties are not rulemaking-related) to learn and efficiently process a

rulemaking—especially when such staff personnel may perform this process only once or twice during their careers at NRC. There are advantages to having dedicated staff whose mission is focused on the rulemaking process and whose skills will be honed with time and experience. Furthermore, it is believed that the best model for a rulemaking organization is a project management model where the rulemaking staff aggressively plans, schedules, and conducts rulemaking, with a sense of ownership and mission. The Task Force recommends that NRR consider centralizing rulemaking management within the policy and rulemaking program to ensure the most efficient use of rulemaking resources.

The Rulemaking Process

General Description

Rulemaking can be complicated and daunting to those unfamiliar with the process. For many of the staff and external stakeholders, rulemaking is a black box. NRC rulemaking, like that of other agencies, is a deliberate process intended to ensure that all aspects of any regulatory change are fully analyzed before the change goes into effect. On a high level, the NRC rulemaking process, like that of other Federal agencies, is constrained by legal requirements, described above, that impose various mandatory steps that the staff is not at liberty to alter. However, most of the internal process steps related to preparation and handling of a rule package can be changed.

It is the policy of the NRC to develop quality rules that are consistent with the requirements of all applicable laws and regulations. It is also NRC policy to constantly strive to increase the efficiency of its rulemaking process. Regulations specific to NRC rulemaking are addressed in 10 CFR Part 2, Subpart H, "Rulemaking." Subpart H governs the issuance, amendment, and repeal of regulations.

Management Directive (MD) 6.3, "The Rulemaking Process," describes the organizational responsibilities for rulemaking and the delegations of authority. The objectives set in MD 6.3 are :

To ensure that schedules for rulemaking actions are established and met.

To ensure coordination among offices and the efficient use of staff resources during the development of rulemaking actions.

To ensure that Agreement States are provided an opportunity to comment on draft rulemaking plans and rulemaking actions.

To ensure maximum opportunity for the full and robust participation by the public and stakeholders in rulemaking proceedings.

In addition to MD 6.3, the "NRC Regulations Handbook," NUREG/BR-0053 provides guidance for the staff who prepare, review, and coordinate rulemaking items. The handbook contains procedures, requirements, and background information considered essential to those who develop or review rulemaking actions. Both NRR and NMSS have also issued implementing procedures that provide more detailed information for initiating, conducting, and managing rulemakings. NRR issued NRR Office Instruction LIC-300, "Rulemaking Procedures," and NMSS issued Policy and Procedure Letter 1-63, "Preparation and Review of Rulemaking Packages." Guidance for preparing regulatory analysis is provided in NUREG/BR-0058,

"Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" and NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook." MD 3.54, "Collection of Information and Reports Management," contains guidance on preparing OMB clearance packages.

As stated in the Regulations Handbook, the Agency goal is to complete a rulemaking action within 18 months of approval of the rulemaking plan.

Steps in the Process

Although the basic steps in rulemaking are the same, each office implements the steps in a slightly different manner. There are also variations of this basic rulemaking process, such as direct final rules and APA exempt rules. Most rulemakings involve four significant steps:

- Identification of a need to conduct a rulemaking;
- Development of a rulemaking plan;
- Preparation of a proposed rule package and publication of the proposed rule; and
- Preparation of a final rule package and publication of the final rule.

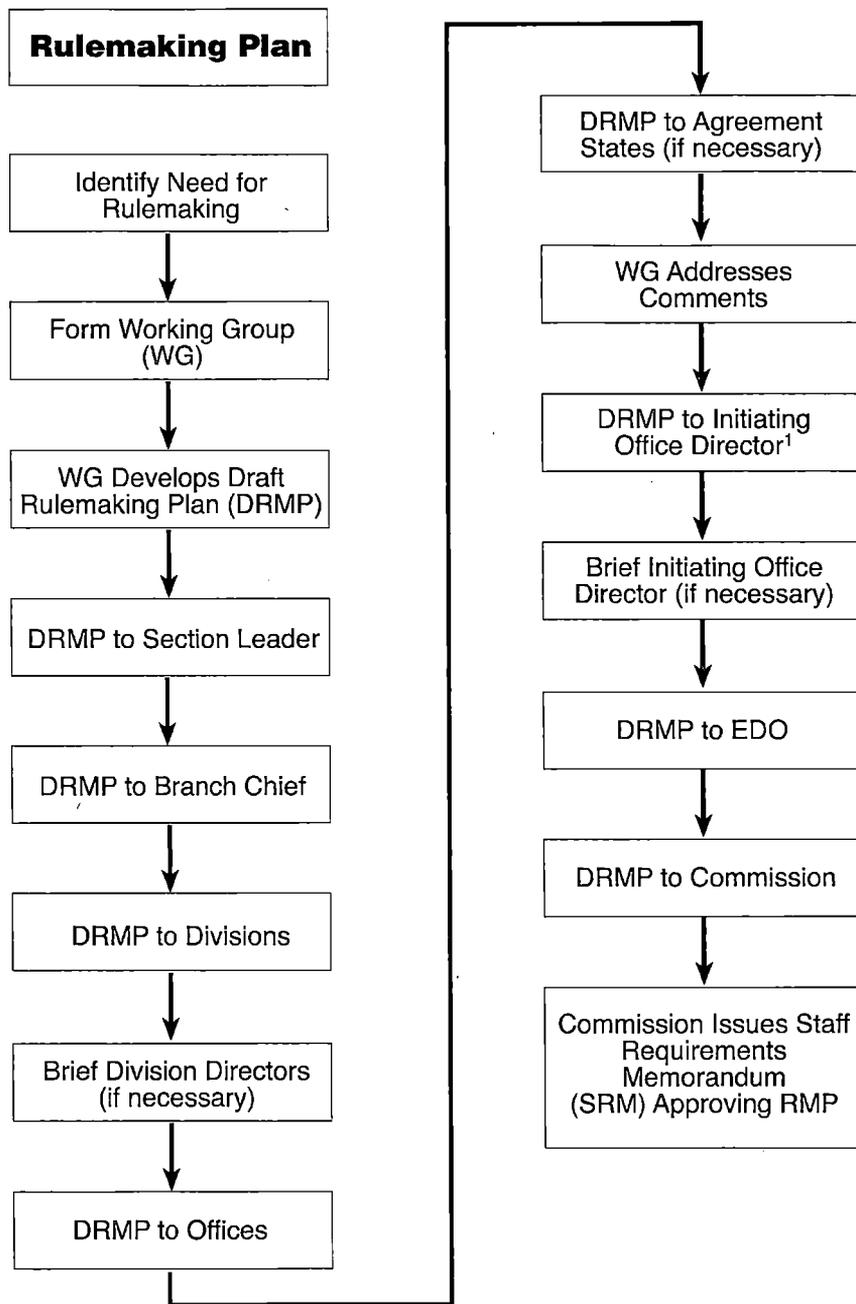
Following is a simplified description of NRC's rulemaking process. Simplified flow diagrams of the rulemaking process are presented in Figure 1. The process begins with a need for rulemaking having been identified and has several possible end points, the most common being the publication of a final rule in the *Federal Register*. The steps NRC follows in the process are many, consistent with the APA, and developed with opportunities for stakeholder participation.

Identifying the need for a rulemaking. The need for rulemaking may be identified within NRC either through a Commission directive, or through NRC staff initiation. External initiations result from Congressional mandate or a petition for rulemaking submitted to the Commission. Under the APA, citizens may petition Federal regulatory agencies to amend their regulations, and agencies are required to take such petitions under consideration. NRC's process for resolving petitions for rulemaking is described at 10 CFR §§ 2.802, 2.803 and in Part 15 of the Regulations Handbook. When a petition for rulemaking is submitted, ordinarily the petition is published in the Federal Register for comment. After the comment period, a determination is made whether to grant or deny the petition. If the determination is to grant the petition, a rulemaking proceeding is initiated, usually with the development of a rulemaking plan. When Congress mandates that a rulemaking be conducted, NRC would proceed directly with the development of a proposed rule.

The Commission can direct the staff to proceed with the development of a rule, this is usually accomplished through the issuance of a SRM. The SRM would indicate whether to prepare a rulemaking plan or proceed directly to a proposed rule. Staff-initiated rulemakings can occur in a couple of ways. In NMSS, the requesting organization prepares a user-need memo that indicates the proposed priority for the rulemaking and should provide sufficient technical basis for the rulemaking. If the technical basis is not developed, the programmatic division should send a user-need memo to RES, requesting it to develop the technical basis. In NRR, a manager suggestion may initiate rulemakings. The idea may or may not be presented to the NRR Leadership Team (LT) for approval.

Creation of a Working Group. The lead division assembles a Working Group from the respective offices and divisions within NRC that would have involvement with the rule in its development, including a member from OGC. For those actions involving Agreement States, the Working Group may include an Agreement State representative or a member from the

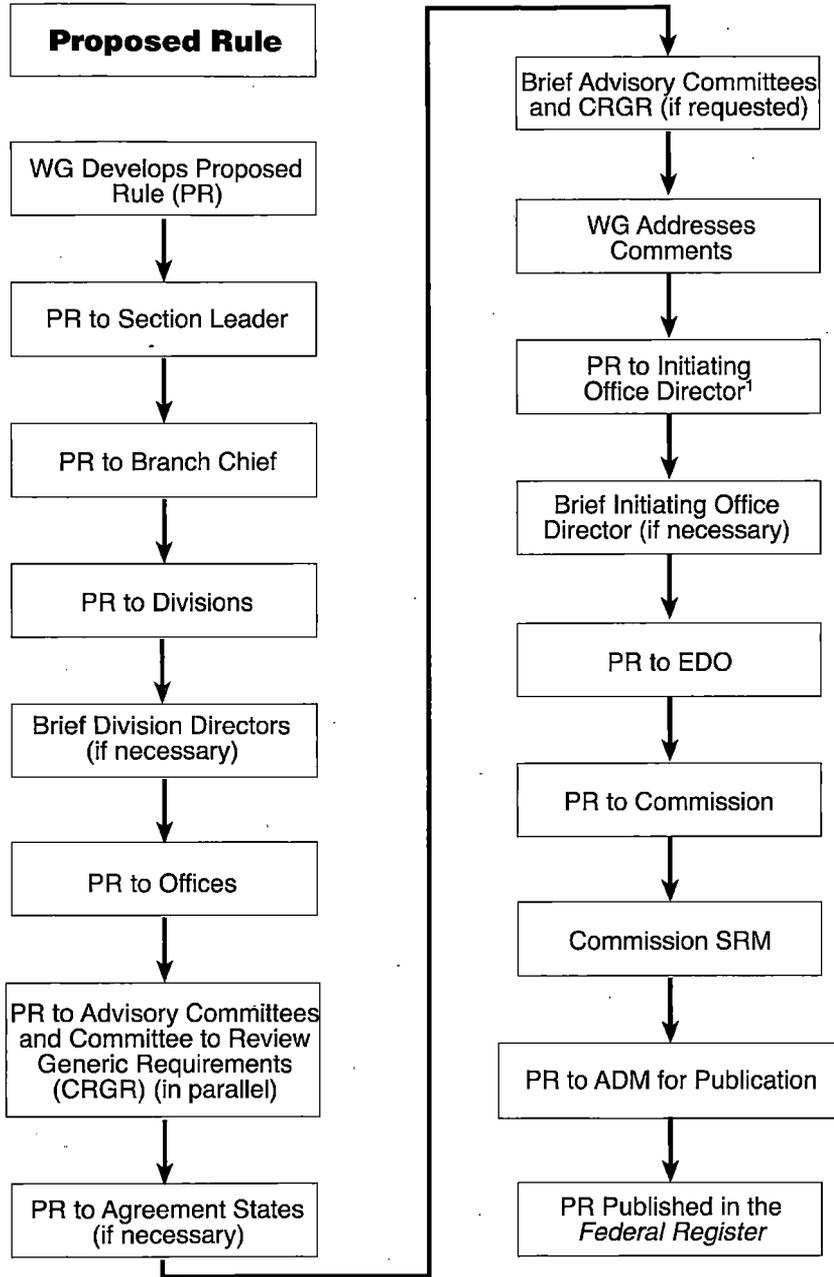
Rulemaking Process



¹ Packages may also need to go to the Section Leader, Branch Chief, and Division Director depending on the comments received and initiating office guidance.

Figure 1. Simplified Rulemaking Process Flow Diagram.

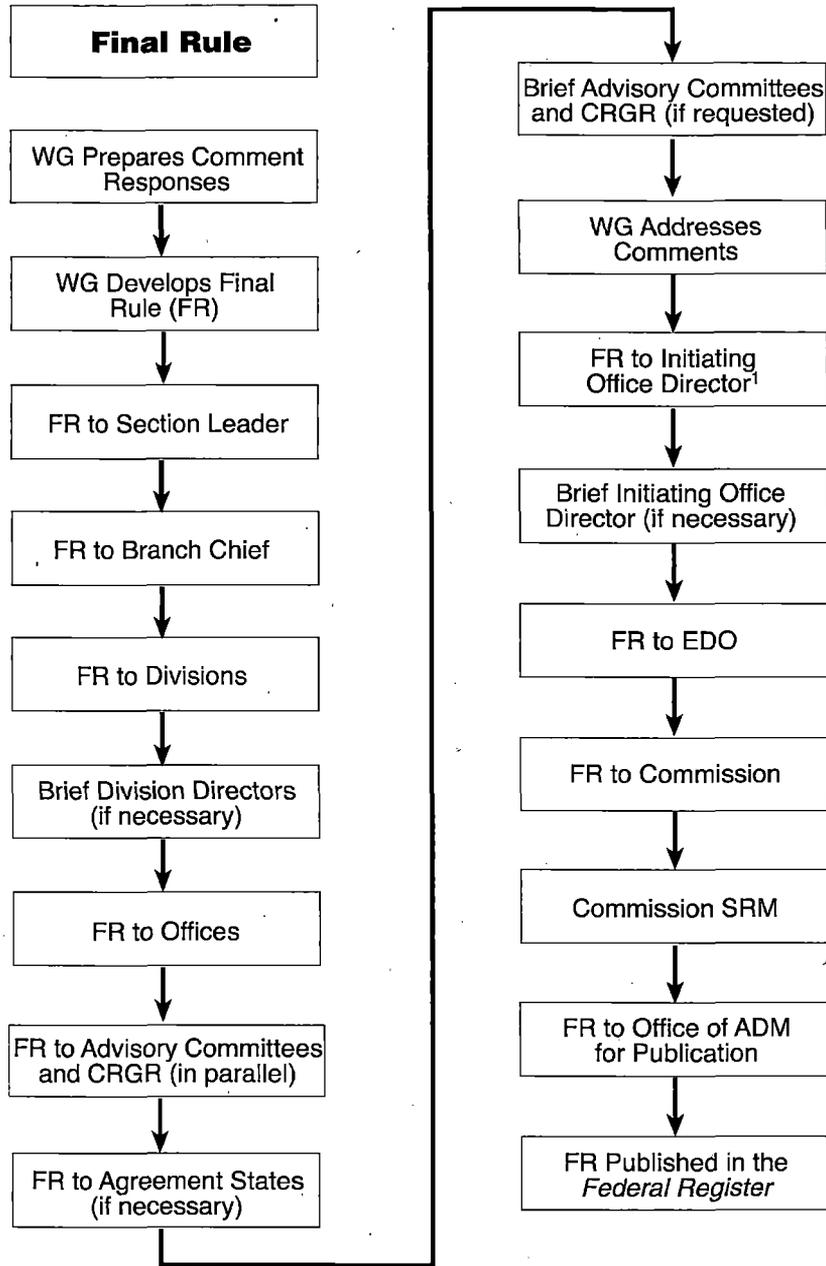
Rulemaking Process (cont'd)



¹ Packages may also need to go to the Section Leader, Branch Chief, and Division Director depending on the comments received and initiating office guidance.

Figure 1. Simplified Rulemaking Process Flow Diagram (Cont.).

Rulemaking Process (cont'd)



¹ Packages may also need to go to the Section Leader, Branch Chief, and Division Director depending on the comments received and initiating office guidance.

Figure 1. Simplified Rulemaking Process Flow Diagram (Cont.).

Office of State and Tribal Programs (STP). The Working Group responsibilities are outlined in MD 6.3 and in the NRR and NMSS office procedures. The Working Group is responsible for:

- Assessing the scope of the rulemaking action, identifying the tasks necessary to complete the rulemaking action, and developing schedules and resource estimates for completing each stage of the action;
- Preparing the rulemaking and supporting documents;
- Keeping management informed about the rulemaking's progress;
- Keeping the rulemaking on schedule; and
- Facilitating the concurrence process.

In addition, a steering committee may be used for rulemakings that involve matters of urgency or complex and controversial issues. The use of a steering committee helps to ensure that senior management is routinely and fully involved, and policy objectives are effectively represented, from the earliest stages of a rulemaking to completion. A key factor in the effectiveness of the steering committee is the delegation of authority to steering group members to deliver the views and concurrence of the participating offices. The steering group is responsible for:

- Providing guidance and direction to the Working Group;
- Mediating major issue resolutions; and
- Resolving significant questions of policy.

Development of a rulemaking plan. The APA does not require a rulemaking plan. It is a step NRC policy imposes. The rulemaking plan is intended to provide a preliminary outline of the scope and impact of the contemplated action sufficient to determine that the rule is needed and desirable. The intent of the rulemaking plan is to obtain Commission approval for a rulemaking action before significant resources are expended on the project. The rulemaking plan is also intended to provide a framework for completing the rule action and to shorten the length of time necessary to complete a proposed rule. The rulemaking plan is also intended to provide a mechanism for obtaining early substantive input from the Agreement States.

The Regulations Handbook and MD 6.3 provide guidance on the required content of a rulemaking plan. The rulemaking plan should include a discussion of the following:

- Definition of the regulatory problem or issue to be resolved;
- Description of the preliminary concepts of actions needed to resolve the problem;
- An analysis of the legal sufficiency;
- Rationale that the rulemaking will be cost-effective and will meet backfit rule criteria, where applicable;
- Resources necessary to complete and implement the rulemaking; and
- Schedules for preparing supporting documents and completing the proposed rule.

The office procedures provide instruction on the processing of the rulemaking plan. Although there are differences between NRR and NMSS, the basic steps are the same. The Working Group develops the rulemaking plan. The draft plan is circulated for review and concurrence by successive levels of management (sections, branches and divisions) of the lead office. Once the appropriate divisions within the lead office have concurred, the rulemaking plan is issued for inter-office concurrence. MD 6.3 establishes 20 days for inter-office concurrence. The offices typically included are Office of Enforcement (OE); CIO; Chief Financial Officer (CFO); ADM; OGC; NRR; and NMSS. STP is included for materials rulemakings. The Office of Nuclear Security and Incident Response is included for rules on security or safeguards matters. The

advisory committees are provided a copy during the office concurrence process, to decide if they want a briefing on the plan. For rules that potentially impact the Agreement States, the Agreement States are given the opportunity to comment on the plan during or after office concurrence has been completed. Depending on the nature of the Agreement State comments, the rulemaking plan may be reissued for office concurrence. After the Working Group resolves any comments received during office concurrence, the rulemaking plan receives final intra-office concurrence and is provided to the EDO. The Commission approves or denies the rulemaking plan for any rulemaking that is not under the authority delegated to the EDO or the CFO. For rulemakings under the authority of the EDO or CFO, the final rulemaking plan is provided to the Commission via a negative consent paper. In practice, the staff waits for an SRM on all rulemaking plans. After Commission approval, the rulemaking plan is posted on the RuleForum webpage.

With the exception of Agreement State review, the rulemaking plan stage does not involve any external stakeholder interactions because of its pre-decisional nature. The exception is when an Issues Paper or an Advance Notice of Proposed Rulemaking has been issued before development of the rulemaking plan. These documents currently require Commission approval before publication in the *Federal Register* to solicit stakeholder input.

Preparation and publication of the proposed rule. If the Commission approves going forward with a rulemaking, the Working Group prepares and assembles the proposed rule package, including the supporting documents. A proposed rule package typically consists of the Federal Register notice that contains the Statement of Considerations and the proposed rule language, an environmental assessment, a regulatory analysis, a Commission Paper or a memo to the EDO, Congressional letters, a press release, a backfit analysis, the OMB package (supporting statement and Federal Register notice), and any guidance documents. If the EDO is signing the rule, the package would also contain the authority statement for the EDO's signature and an entry for the weekly report to the Commission. The OMB package is provided to CIO and may not be part of the package going to the EDO or Commission.

There may be stakeholder interactions during the preparation phase. The rulemaking plan and/or Commission direction would establish the types and the timing of any stakeholder interaction. The draft proposed rule is circulated for review and concurrence by successive levels of management (sections, branches and divisions) of the lead office. Once the appropriate divisions within the lead office have concurred, the proposed rule is signed out by the Program or Division Director and issued for inter-office concurrence. MD 6.3 establishes 20 days for inter-office concurrence. The advisory committees are provided copies during the office concurrence process, to decide if they want briefings on the proposed rule. Sometimes, these committees will pass on reviewing the proposed rule, waiting instead to learn what comments the stakeholders had and inviting the staff to make a presentation at the final rule stage. Otherwise, a presentation may need to be made to one of the committees. For rules that potentially impact the Agreement States, Agreement States are given the opportunity to comment on the proposed rule during or after office concurrence has been completed. After the Working Group resolves any comments received during office concurrence, the proposed rule receives final intra-office concurrence and is provided to the EDO. The EDO signs those proposed rules for which he has been delegated the authority. Note that the CFO has also been delegated the authority to issue rulemakings relating to matters under his/her purview. All other rules are provided to the Commission for approval. For some rules, the staff may hold a Commission briefing or a briefing for the Commissioner Assistants. After Commission approval, via a SRM, the proposed rule is sent to the Office of the Federal Register for publication for public comment.

The proposed rule is published for public comment in the *Federal Register*. The comment period usually lasts for 75 days, although the notice indicates that "Comments received after this (the indicated) date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date." The proposed rule and supporting documents are placed on NRC's rulemaking website. The public may upload any comments electronically and can view any comments that have been made. NRC may also hold one or more public meetings, during the public comment period, to obtain stakeholder input.

Preparation and publication of the final rule. At the end of the public comment period, the public comments are summarized and the Working Group prepares responses to the comments. The Working Group assembles the final rule package, including the supporting documents. A final rule package typically consists of the Federal Register notice that contains the Statement of Considerations and the rule language, an environmental assessment, a regulatory analysis, a Commission Paper or a memo to the EDO, Congressional letters, a press release, a backfit analysis, the OMB package (supporting statement and Federal Register notice), and any guidance documents. If the EDO is signing the rule, the package would also contain the authority statement for the EDO's signature and the notice to the Commission (formerly called the daily staff note). The OMB package is provided to CIO and may not be part of the package going to the EDO or Commission.

There may be additional stakeholder interactions during preparation of the final rule. The rulemaking plan and/or Commission direction would establish the types and the timing of any stakeholder interaction. The draft final rule is circulated for review and concurrence by successive levels of management (sections, branches and divisions) of the lead office. Once the appropriate divisions within the lead office have concurred, the Program or Division Director issues the final rule for inter-office concurrence. MD 6.3 establishes 20 days for interoffice concurrence. The advisory committees are provided copies during the office concurrence process to decide if they want a briefing on the final rule. A presentation may need to be made to one of the committees. Agreement States are given the opportunity to comment on the final rule during or after office concurrence has been completed. After the Working Group resolves any comments received during office concurrence, the final rule receives final intra-office concurrence and is provided to the EDO. The EDO signs those final rules for which he has been delegated the authority. Note that the CFO has also been delegated the authority to issue rulemakings relating to matters under his/her purview. All other rules are provided to the Commission for approval. For some rules, the staff will make a presentation to the Commissioner Assistants or the Commission. After Commission approval, via a SRM, the final rule is sent to the Office of the Federal Register for publication.

Issuance of an advance notice of proposed rulemaking. Occasionally, the staff may issue an advance notice of proposed rulemaking (ANPR) or an issues paper to solicit stakeholder views before making a recommendation to go forward with a particular rulemaking action. The Working Group develops the ANPR. The concurrence and review process is the same for an ANPR or issues paper as it is for a proposed rule. The ANPR or issues paper is published for comment, in the *Federal Register*, usually for a 75-day comment period. The staff may conduct a public workshop during this period to solicit and discuss comments. The staff, through the Working Group, analyzes and resolves the public comments in the preamble to the proposed rule or in the rulemaking plan. Based on the comments, NRC may decide to change course or to terminate the rulemaking action.

Alternative Rulemaking Processes. The staff has developed unique processes for some rulemakings. In NMSS, a streamlined process for issuance of rulemakings related to CoCs for

spent fuel storage has been developed. The need for and time allowed for inter-office and intra-office concurrences has been significantly reduced. Concurrence authority for these rulemakings has been delegated to managers and staff at the branch level.

ADM uses a simplified process for issuance of corrections to a published rule.

Congressional Oversight

Under the Atomic Energy Act of 1954, NRC is required to keep the Congress informed of its activities. NRC notifies Congress whenever the agency submits an advance notice of proposed rulemaking, a proposed rule, or a final rule to the Office of the Federal Register for publication. The lead office drafts a letter, for signature by the Director OCA, describing the action that the agency is undertaking. Identical letters are prepared for the Chair and the ranking minority member of each of the House and Senate Committees charged with overseeing NRC—the Subcommittee on Energy and Air Quality under the House Committee on Energy and Commerce, and the Subcommittee on Transportation, Infrastructure, and Nuclear Safety under the Senate Committee on Environment and Public Works.

These letters are forwarded to RDB for review when the rulemaking package is sent for office concurrence, and to SECY or the EDO, as appropriate, as background information to the rulemaking package submitted for final approval. When the approved package is submitted to RDB for publication, RDB forwards the letters to OCA for final review, concurrence, and signature. OCA transmits the letters to Congress along with a copy of the Federal Register notice for the proposed or final action. On occasion, as the substance of a rulemaking warrants, letters will be sent to additional Congressional oversight committees. This occurs, for instance, in the case of the annual fee recovery rule, when Congressional committees with appropriations oversight are notified, as well as the standard oversight committees.

Rulemakings with Collections of Information

When a proposed rule under development would impose new, alter, or delete existing information collection requirements, NRC must obtain OMB approval. RMB manages the coordination with OMB. The process for obtaining OMB approval is described in MD 3.54, "Collections of Information and Reports Management". MD 3.54 was last revised in July 1989 and is significantly out of date. A revision is currently in preparation and is available in ADAMS as draft MD 3.54, "Collections of Information and Reports Management" (ML020590284). RMB has indicated that staff should be using this draft revision. The Task Force notes that very few staff personnel are aware of the new revision, or that RMB would like the staff to use the draft.

NRC may not submit for publication in the *Federal Register* a proposed rule that contains a new or amended information collection requirement until the clearance package necessary to obtain OMB review and approval has been approved by RMB and transmitted to OMB. The OMB clearance package that the staff must develop (in conjunction with a proposed rule that contains new, amended, or deleted information collection) provides the information needed by OMB to evaluate compliance with the Paperwork Reduction Act. The clearance package prepared by the staff consists of two items: (1) a Federal Register notice (separate and independent of the Federal Register notice for the proposed rule) that requests public comment on the information collection aspects of the proposed rule and, (2) an OMB supporting statement documenting the increase or decrease in information collection burden as a result of the proposed rulemaking. The OMB supporting statement must identify each specific information collection, address its need and use, and provide burden estimates for any new,

modified, or discontinued information collection. (The specific format and content of the supporting statement are shown in Exhibit 3 of draft MD 3.54.)

If the information collection requirements in the proposed rule represent insignificant changes in burden, a Federal Register notice and supporting statement are not required. Instead, an NRC Form 670 (from INFORMS) is completed by the staff and approved by RMB. The form is provided to OMB and, if OMB agrees that the information collection burden change is insignificant, no additional clearance action is needed. If the proposed rule does not impact information collection requirements, then no interactions or approval from OMB is necessary.

In order to facilitate the clearance process, NRC staff will generally, with the assistance of the office information management coordinator and working with RMB staff, develop the clearance package necessary to obtain OMB approval. This is typically done at the same time the proposed rule is being developed. For significant rulemakings, CIO wants the requesting office to submit the draft information-collection package to RMB no less than 5 weeks before the requested CIO concurrence date. (Significant rulemakings are those that: (a) completely revise 10 CFR Parts; (b) are major and move, revise, and renumber existing sections; or (c) have more than 20 pages of regulatory text or 10 pages of regulatory text consisting primarily of information-collection requirements.) Information-collection packages associated with other rulemakings should be submitted at least 2 weeks before the requested concurrence date.⁷ Per RMB guidance, the final OMB clearance package and the Federal Register notice for the clearance package should be submitted to RMB no later than the date a rulemaking is sent to the EDO for review.

When the OMB clearance package has been finalized and approved by RMB, it is submitted to OMB for review in coordination with the publication of the proposed rule. The clearance package must be submitted in adequate time to ensure receipt by OMB no later than the date the rule is sent to the *Federal Register*.

RMB facilitates the process of public comment on information collection requests by forwarding a copy of the clearance package to ADM for posting on NRC's RuleForum web site. The package is also posted on the information collection section of NRC's web site (<http://www.nrc.gov/public-involve/doc-comment/omb/index.html>).

OMB has 60 days from receipt of a clearance package to make a decision regarding approval of the information collections. If OMB approves the information collections contained in a proposed rule, and there are no significant changes made to these information collections in the final rule, the information-collection approval process is complete.

A revised information-collection package must be submitted to OMB for approval for information collections that OMB does not approve at the proposed rule stage, or those that change significantly between the proposed and final rule. The OMB clearance package used for the proposed rule may be used, but it should include all changes between the proposed and final rules as redline/strikeout changes. The reasons for the changes should be described. Additionally the package must specifically address each comment received on the information

⁷The timeframes for CIO review referenced in this paragraph are longer than those currently in MD 3.54. CIO plans to revise the timeframes in MD 3.54, to be consistent with those in the paragraph above. Note that in practice, staff may not be able to meet the 5 week date because the rule package, which the OMB package is based, may not be complete.

collection requirements. Promulgation of the final rule is delayed while the information collection review process is repeated.

OMB has up to 60 days to make its approval decision, and the final rule may not be published until OMB approval is obtained. Office staff should obtain a Commission affirmation vote (or EDO approval, if the rule is to be signed by the EDO) on the final rule, but not publish it until OMB's comments or approval decision are received. On occasion it is necessary to make changes to the final rule, based on OMB changes. When this occurs, any rule changes should be provided to the Commissioners' Assistants via a C-note or to the Commission via a memorandum. Depending on the change, the Commission may need to reaffirm its earlier vote. In the event that an information collection request is disapproved, the Paperwork Reduction Act allows independent agencies, such as NRC, to override the OMB Director's decision. A majority vote of the Commission is needed to countermand an OMB paperwork decision. No final rule containing an information collection requirement may be published until either OMB clearance is obtained or the Commission acts to override OMB disapproval.

Although OMB may grant a 3-year approval for information collection requirements contained in a new 10 CFR Part or completely revised Part, it generally grants approvals for rules that modify or delete information collection requirements to the same clearance expiration date as the currently approved clearance extension.

The Task Force recommends that MD 3.54 be completed. The Task Force also notes that the draft revision to MD 3.54 indicates that a copy of the OMB supporting statement should be an attachment to the proposed rule package. The NRC Regulations Handbook and the NRC Regulatory Analysis guidelines note that the OMB supporting statement should be included as a stand alone appendix to the regulatory analysis. This is not consistent with current practice. Specifically, the supporting statement is not generally included with the proposed rule package because the clearance package is often prepared during the lull time during office concurrence and between submission of the proposed rule package to the EDO's office and affirmation by the Commission. Neither MD 6.3 or the office procedures instruct the staff to provide the supporting statement as part of the rule package to the EDO or Commission. The Task Force recommends that the inconsistency between staff practice and guidance documents concerning inclusion of the OMB supporting statement as part of the proposed rule package be clarified. In making this clarification, the Task Force recommends that consideration be paid to the fact that the rulemaking process may well take longer if the OMB supporting statement must be prepared and finalized for inclusion in the rulemaking package, rather than being prepared during the lull time during office concurrence and between submission of the proposed rule package to the EDO's office and affirmation by the Commission.

The Federal Register notice for the proposed rule contains a Paperwork Reduction Act Statement alerting the public to the paperwork requirements contained in the rule and inviting additional comment on the information collections. The Task Force notes that the information contained in the Paperwork Reduction Act Statement is very similar to the information provided in the separate Federal Register notice requesting comments on the information collection requirements of the proposed rule. The Task Force questions the need to duplicate the information collection request for comments in both the proposed rule and a separate notice on information collection. The Task Force understands that other agencies routinely rely only on the proposed rule Paperwork Reduction Act Statement to solicit comments for OMB. The Task Force recommends that RMB consider eliminating the need for publication of a separate Federal Register notice for information collection requirements and enhance the Paperwork Reduction Act Statement in the proposed rule Federal Register notice to cover all essential elements needed to adequately solicit public comments for OMB.

Agreement State Review

Section 274 of the Atomic Energy Act of 1954 provides a statutory basis under which NRC relinquishes to the States portions of its regulatory authority to license and regulate byproduct materials (radioisotopes); source materials (uranium and thorium); and certain quantities of special nuclear materials. The mechanism for the transfer of NRC's authority to a State is an Agreement signed by the Governor of the State and the Chairman of the Commission, in accordance with section 274b of the Act.

By Commission direction, STP works with other program offices to provide Agreement States with early and substantive involvement in NRC rulemaking and other regulatory efforts. An Agreement State representative may serve on a Working Group. If a proposed rulemaking might affect the Agreement States, the lead office provides a copy of the draft rulemaking plan to STP, after offices have concurred in the rulemaking plan (may occur during office concurrence) and after the EDO or the CFO provides a copy of the draft rulemaking plan to the Commission via a C-note. STP provides a copy of the draft rulemaking plan to the Agreement States by placing it on a special, password-protected section of the Technical Conference Forum (TCF) web site (<http://techconf.llnl.gov>) dedicated to issues of interest to Agreement States. The Agreement States are notified by e-mail of the posting, and are allowed 45 days in which to submit any comments. States may upload their comments to the Technical Conference site or submit them directly to the program office contact. If a rulemaking plan is not required, STP notifies the Agreement States that a rulemaking action is being developed.

At the same time, the lead office notifies, through the Technical Conference Forum, the Conference of Radiation Control Program Directors (CRCPD) Council Chair that is responsible for suggested State regulations.

After consulting with the appropriate NRC offices and OGC, the lead office revises the draft rulemaking plan in response to comments submitted by the Agreement States and the CRCPD. The Commission paper must address Agreement State comments or contain an attachment that indicates the staff's disposition of Agreement State and CRCPD comments. If significant comments are received from the Agreement States, the rulemaking plan may have to be resubmitted for office concurrence.

If the rulemaking plan is approved, the lead office informs the Agreement States of the staff's intention to proceed with the development of a proposed rule through the TCF. The lead office notifies the CRCPD Council Chair responsible for suggested State regulations of the plan's approval through the TCF so that the parallel development of a suggested State regulation could begin, if such an action is desired.

If the Commission does not approve the rulemaking plan, STP is informed of this fact by the lead office, which also notifies the CRCPD Council Chair responsible for suggested State regulations through the TCF.

If a draft proposed rule affects Agreement State interests, Agreement State involvement is also sought on preliminary versions of the draft proposed rule. Agreement State involvement may be sought through Working Group participation and posting preliminary versions of the draft proposed rule on the TCF for comment. Both the proposed and final rule are provided to Agreement States for a 30-day comment period prior to providing the rule to the EDO or Commission.

Review of Rulemakings by Internal and Advisory Committees

The Agency's internal rulemaking review process includes not only regular office and management concurrence procedures, but review by NRC committees with responsibilities in certain areas.

The Committee to Review Generic Requirements (CRGR) is charged with ensuring that proposed generic backfits to be imposed on NRC-licensed power reactors and selected nuclear materials licensees are appropriately justified. Draft copies of proposed and final rules that raise relevant backfit issues are submitted to the CRGR for review. The CRGR's primary responsibilities are to recommend to the EDO either approval or disapproval of the staff proposals of new or revised generic requirements, and to provide assistance to the NRC program offices to help them implement the Commission's backfit policy.

Coordination with NRC Advisory Committees

When a proposed rule is sent for office concurrence, the lead office forwards it to the appropriate advisory committee for review, in accordance with Program Office procedures. The advisory committees are the—

- Advisory Committee on Reactor Safeguards (ACRS)
- Advisory Committee on Nuclear Waste (ACNW)
- Advisory Committee on Medical Uses of Isotopes (ACMUI)

ACRS is statutorily mandated by the Atomic Energy Act of 1954, as amended. The ACRS advises the Commission on the adequacy of proposed reactor safety standards.

ACNW was established by the Commission in June 1988 to provide independent technical advice on agency activities, programs, and key technical issues associated with regulation, management, and safe disposal of radioactive waste.

ACMUI advises NRC on policy and technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis and therapy. The ACMUI membership includes health care professionals from various disciplines who comment on changes to NRC regulations and guidance.

The lead office formally documents and responds to any consensus comments or recommendations from the appropriate advisory committee concerning the rulemaking action. The staff analysis and response to these comments must be presented in the "Supplementary Information" section of the proposed or final rule, as appropriate.

If an individual committee member participates in a rulemaking apart from a committee, the comments received from the individual are maintained as part of the rulemaking record. By mutual agreement, the lead office may meet with one of the advisory committees, at any time during the rulemaking process, to discuss the staff's rationale for the rulemaking.

External Organizations Involved in NRC Rulemaking

The key outside agencies that NRC rulemaking staff work with on a regular basis are the Office of the Federal Register, which publishes official government documents; OMB, which coordinates Presidential oversight of Federal regulators; and the Regulatory Information Service Center, an arm of the General Service Administration (GSA) which assists OMB in collecting and maintaining data on agency regulatory activities.

The Office of the Federal Register

The Office of the Federal Register (OFR) publishes the official texts of Federal laws, Presidential documents, administrative regulations and notices, and descriptions of Federal organizations, programs and activities. As the publisher of the daily *Federal Register*, the OFR establishes standard formats, systems of reference, style templates, and publication procedures for agency rulemaking documents. Because it also publishes the annually revised Code of Federal Regulations (CFR), the OFR monitors agency rulemaking actions to ensure that new regulations or changes in existing regulations are correctly codified. The OFR's legal division rules on agency requests to incorporate documents into the CFR by reference, and the OFR maintains a library of all such documents for public inspection. Federal regulatory agencies are required to comply with all OFR regulations and procedures (codified in 1 CFR).

ADM is charged with reviewing rulemaking documents destined for publication in the *Federal Register* to ensure that they meet all OFR requirements. RDB is the Agency's liaison to the OFR. RDB works with the OFR's daily issue staff to insure that Agency documents are published error-free and in a timely manner. RDB also coordinates with the OFR's legal staff in the processing of rulemakings that involve the incorporation by reference of various documents in NRC's regulations.

The Office of Management and Budget

OMB is authorized both by statute and by Executive Order to implement Presidential oversight of the Federal regulatory agencies. Independent agencies, such as NRC, are subject to the OMB paperwork approval process, must participate in parts of the Government-wide regulatory planning and review process, and are required to comply with SBREFA requirements. OMB also has responsibility for administering the Data Quality Act of 2001, which imposes new information quality review and reporting requirements on Executive-Branch and independent agencies. OMB issued final data quality guidelines for agencies in January of 2002; NRC has established a data quality review and reporting process in compliance with the OMB guidelines. These guidelines became effective October 1, 2002.

OIRA is charged with administering these oversight processes, and NRC offices work with OIRA staff to ensure that NRC rulemakings comply with OMB paperwork reduction requirements. RDB coordinates with the OIRA desk officer who handles SBREFA clearance of NRC rules. RMB works with OIRA staff to shepherd NRC's information collection requests through the OMB clearance process.

The Regulatory Information Service Center

The Regulatory Information Service Center (RISC) is part of the GSA. RISC was created in June 1981 to facilitate the development of, and access to, information about Federal regulatory and deregulatory activities. RISC publishes the semiannual *Unified Agenda* and the annual *Regulatory Plan*, and administers the RISC/OIRA Combined Information System (ROCIS), the

database used to generate these documents. The NRC liaison to RISC is the RDB, which submits NRC contributions to the ROCIS database *via* a web-based interface and works with RISC to resolve any difficulties that arise concerning NRC rulemaking data.

The Small Business Administration

In compliance with the Section 605(b) of the Regulatory Flexibility Act, RDB provides the legal staff of the Small Business Administration (SBA) with a copy of each of NRC's published proposed rules. This submission demonstrates to the SBA that NRC has met the regulatory flexibility analysis requirements of the act with respect to the rule in question, and affords SBA the opportunity to comment on the small business impacts of the rule. The SBA's Chief Counsel for Advocacy sends a comprehensive yearly report to Congress assessing Agency compliance with the Regulatory Flexibility Act.

The SBA also approves NRC's Agency-specific size standards for small entities in 10 CFR 2.810. The NRC uses these standards when determining, in compliance with the Regulatory Flexibility Act, whether a rule is likely to have a significant effect on a substantial number of small entities.

Tracking, Reports, and Information Systems

There are a variety of systems used to track NRC's rulemaking commitments and activities. Some of the systems are well-established, Agency-wide tracking systems. Rulemaking is just one of many different activities tracked by these systems. Other tracking systems have been developed for use at intermediate management levels—but are less formal and patterned to the particular styles and interests of the manager in charge.

In addition to the tracking systems, an assortment of status reports is issued on Agency rulemaking. These reports provide descriptions of the rulemaking along with status, milestones, and progress. Some of these reports are mandated by the Commission or external Government agencies. Other reports appear to have been developed principally for management oversight and monitoring of rulemaking.

Tracking Systems

The highest-level commitments tracked by NRC are tasking items from the Commission. These are tracked by the Office of the Secretary of the Commission (SECY) using the Secretariat Tracking and Reporting System. A subset of this system, the Commission Tracking System, tracks (among other things) the commitments from SRMs. There are an enormous number of Commission action items tracked by SECY, of which rulemaking is only a small part. Rulemaking activities are typically captured by this system because most rulemakings are sent to the Commission for action and result in SRM directions at the rulemaking plan, proposed rule, and final rule stages.

Similarly, the EDO has its own tracking system to track work items due to the EDO—which would encompass any Commission SRM items, including those related to rulemaking. This tracking system, known as the Work Item Tracking System (WITS), is used by a majority of the offices in NRC (except those that report directly to the Commission), and is updated weekly.

In addition, the EDO also tracks certain high-visibility activities in a tracking system called the Chairman's Tasking Memorandum (CTM). The CTM is updated on a monthly basis and lists milestones for activities of interest to the Commission, along with brief discussions and

comments. The CTM is also provided as an attachment to the NRC monthly report to Congress on licensing and regulatory duties. Some rulemaking efforts are highlighted in the CTM; however, the criteria or basis for reporting on rulemaking progress in the CTM is uncertain and appears to be at management's judgment rather than by Commission request. The need to include rulemaking updates in the CTM is questionable and is a good candidate for elimination. Based on the original EDO guidance for preparing this report, the CTM appears to have grown beyond its original intent and may be reporting on items for which it was not originally intended.

Both NRR and NMSS have systems for tracking WITS items. NRR uses an identically named, but independently maintained and updated WITS tracking system. The NRR WITS tracking system duplicates the EDO WITS items assigned to NRR. In addition, the system lists "green ticket" items that track important NRR correspondence due to the EDO or Commission, and "yellow ticket" items which track internal NRR commitments and actions. NRR rulemaking actions are captured in the NRR WITS system in a fashion identical to the EDO system. Essentially, the NRR tracking system duplicates the EDO WITS system for NRR-specific actions with the addition of yellow and green ticket items. NRR rulemakings do not typically receive NRR yellow tickets (nor EDO green tickets). The NMSS WITS system is set up in a similar manner; NMSS has "blue tickets" instead of "yellow tickets". Unlike NRR, NMSS does issue tickets for EDO WITS items. NMSS also uses DOLLS which stands for Document Logging and Location System. DOLLS is used to track (locate) items that require action by either the NMSS Office Director or Deputy Director. The item is logged into the system when the action goes to the front office for review.

Each NRR division has its own customized tracking system that is updated per division needs. Most of these systems are still based on WITS, but will only track those actions that the division is responsible for. Rulemaking actions are generally captured in these division-level tracking systems to the extent that a given division has the lead for a rule. The RPRP of NRR, having general responsibility for NRR rulemaking, uses its own customized rulemaking inventory and status tracking tool. The content and maintenance of the RPRP tracking system is at the discretion of the program director. Within NMSS, IMNS uses a system called DRAT to track those items that not only have a WITS and NMSS ticket, but also items that are not being tracked by EDO or NMSS. In addition, NMSS provides a weekly report to the EDO that contains a listing of all actions, including rulemakings, that will be going to the EDO in the next 6-week period.

Internal Reports

Rulemaking Status Report (NMSS)

The primary tool within NMSS to keep track of rulemaking activities is the Rulemaking Status Report. This report contains information on status of each rulemaking activity, major milestone due dates, pertinent history, and Working Group members. It is maintained by RGB and updated biweekly. This report provides the feeder information for the NMSS Operating Plan. RGB is in the process of initiating a Microsoft Project master list of rulemakings that can monitor the major milestones of most NMSS rulemakings. The master list will be used by the RGB managers to better monitor the branch's activities. However, work on this project has been on hold for some time due to higher priority items. RGB may want to consider completing this project.

Director's Quarterly Status Report (NRR)

The principal NRR report on rulemaking activities is the Director's Quarterly Status Report (DQSR). This report provides an assortment of information on NRR activities, including rulemaking. Details on each NRR rulemaking, including the purpose, background, schedule, progress, problems, Working Group, and resource expenditures are provided. This report is updated quarterly and is used as a source for other reports, such as the rulemaking activity plan (discussed below). The report, which is issued by the Division of Regulatory Improvement Programs (DRIP), has been in existence for a number of years and continues to evolve to suit the current needs of the NRR management.

Rulemaking Activity Plan (ADM)

The Rulemaking Activity Plan (RAP) provides a description of rulemakings that are currently being conducted and those that are being considered for future action. The RAP only includes those rules from ADM, NMSS, NRR, and the annual fee rule conducted by CFO. Rules conducted by other offices such as CIO, OGC, and the Office of International Programs are not included in the RAP. This annual report, submitted to the Commission each March, is intended to ensure that the staff incorporates Commission policy direction into contemplated rulemakings at an early stage of rule plan development, before significant resources are expended. The report also provides a mechanism for determining whether previously initiated rulemakings should continue, be redirected, or be terminated, based on benefit and cost. The RAP includes schedules (target completion dates) for all active rulemakings and priorities (high, medium, or low) for all ongoing and planned rulemakings, to allow for the effective allocation of resources in a manner consistent with Commission policy. Individual rulemakings are currently grouped into one of the following six categories.

- Active rules;
- Rules that are being planned;
- Rules that have been placed on hold;
- New Petitions and Petitions being resolved;
- Rules that have been terminated; and
- Rules that have been completed (EDO or Commission approved for publication)

RDB is responsible for maintaining and updating the RAP by compiling information on rulemaking activities supplied by the Program Offices. The Program Offices review the draft RAP in January, which is revised in accordance with Program Office direction. The final RAP is then reviewed by the Directors of ADM and the Division of Administrative Services, before being sent to the EDO for ultimate transmission to the Commission by the end of March. This document has on occasion been made public, although it is intended for internal use only.

EDO Report on Petitions (ADM)

To ensure the consistency of rulemaking activities in the Program Offices under the authority of the EDO, a semiannual report on the status of petitions for rulemaking is prepared for EDO review. This report contains an entry for each petition received, pending, or resolved during the 6-month reporting period. Each entry includes a summary of the substance of the petition, a status report on the resolution process, a timetable for achieving final disposition of the petition, and an explanation for any schedule slippage that has occurred since the last report. These entries are written by RDB and submitted to the Program Offices for review. RDB compiles and submits the report to the Deputy Executive Director for Management Services for approval, signature, and transmittal to the EDO.

Historical Compilation of NRC Regulatory Activities (ADM).

The "Historical Compilation of NRC Regulatory Activities" includes: final rules; proposed rules; ANPRs; documents relating to rulemaking actions; documents relating to petitions for rulemaking docketed by NRC under 10 CFR 2.802; policy statements; memoranda of understanding; systems of records; and selected general notices. The compilation contains a complete historical record for NRC's proposed and final rulemakings. The collection of documents for each 10 CFR Part spans various periods. Some of the documents go back as far as March 4, 1947.

NRR and NMSS Operating Plans.

Both NRR and NMSS issue annual operating plans that provide output measures and targets for rulemaking activities in these offices. Both provide quarterly updates to their operating plans. In addition, NRR provides monthly updates to its resource utilization for all its planned accomplishment (PA) codes, including rulemaking PA codes, in a data compilation known as the "Rainbow Report." Additional discussions on the planning, budgeting, and performance management process and how it relates to rulemaking are provided later in this report.

Improvement of Internal Tracking and Reporting

The problems associated with multiple tracking systems and periodic reports are generic and not unique to rulemaking. Specifically: (1) there is often duplication of information; (2) duplicated information is not consistently updated or captured in a uniform manner; and (3) maintenance and upkeep of the tracking systems and reports can become a resource burden. There are reasonable arguments for considering broader-based process changes for Agency commitment tracking systems, involving the capabilities of modern information technology, but such recommendations are beyond the scope of this report. Several recommendations have been proposed that may improve the usefulness of data tracked, as well as consolidating and clarifying the information reported. These recommendations are aimed at reducing duplication of information tracked and reported as well as improving rulemaking monitoring by management. Overall, there is no indication that the current rulemaking tracking systems or reports are adverse to the efficiency of the rulemaking process or directly affect the quality or timeliness of rulemaking. However, considerable effort is expended to maintain these systems, effort that would be better utilized if directly applied to rule activities.

The following generalizations can be made concerning the tracking systems used by SECY, the EDO, NRR, and NMSS (and to some extent even further down through the NRC organizational structure):

- The systems basically are duplicative;
- Each system appears to use different software that is technically obsolete and does not take advantage of the current state-of-the-art in information technology (e.g., the EDO WITS items cannot be accessed or viewed electronically by NRR and NMSS personnel and, therefore, outputs are transmitted and distributed by paper);
- A task force on Agency tracking systems issued a report on March 14, 2001, identifying the functional requirements for an Agency-wide tracking system. The functional requirements would support rulemaking tracking efficiency

The NRC Regulatory Agenda, the RAP, the NRR DQSR, the NMSS rulemaking status report, and the semiannual status report to the EDO on petitions for rulemaking, all provide duplicative information (to some extent) on rulemaking and petition status. The Task Force recommends

that the RCC consider development of a centralized rulemaking status web page (for internal NRC use only) that provides all essential rulemaking information currently provided in:

- The RAP,
- The NRR DQSR,
- The NMSS rulemaking status report, and
- The EDO report on petitions.

The web page would be used as a common feeder for any of the external rulemaking reports that are currently mandated. In addition, the information could also be used to generate specialized internal reports for the Commission or for other management purposes if it is determined that the web page is not sufficient for that purpose. This could result in the removal of a large amount of information that is periodically collected and distributed in the RAP, DQSR, and NMSS rulemaking status report. Another advantage to this approach would be the establishment of a single-source location for most relevant rulemaking status information to enhance NRC internal communications and awareness of rulemaking activities. Well-defined functional requirements and format constraints could be implemented to ensure consistency and sufficiency of the information. Routine updates could be mandated procedurally to ensure the information is maintained up to date.

The original guidance for the preparation and content of the CTM has been obtained from the EDO and dates back to August 1998. A principal instruction for the CTM from the 1998 guidance stated:

I specifically am requesting you to identify, define, and prioritize those areas which support our long term performance goals and which will receive short-term attention. This set of activities should be based on what is already underway and should concentrate on areas where considerable progress can be made. It is important to concentrate on areas where considerable progress can be made. It is important that a manageable set of high priority areas be identified for short-term actions....

The CTM, as it exists today, is very lengthy, and does not appear to conform with the original expectations of a manageable set of high-priority, short-term actions. The Task Force recommends that all rulemakings be removed from the CTM except those that are recognized as Agency-level high priority and are in direct support of the strategic plan. Implementation of this recommendation may require Commission or EDO approval.

Although the RAP contains a significant amount of useful information on Agency rulemaking activities, it is presented in a manner that is difficult to extract or synthesize. Many aspects of the Commission's original intent for developing the RAP may no longer be relevant or useful to the Commission. ADM is actively working to revise the format and organizational structure of the RAP. The revisions are intended to reflect the changed purpose of the RAP from a decision-making vehicle to an information paper. The anticipated changes will remove unnecessary and repetitive material, facilitate ease of use and maintenance, and improve readability. In making those changes ADM should consider how the current RAP meets the original objectives. The Task Force recommends that the purpose and function of the RAP be reassessed to streamline and improve its usefulness as an information and management tool. Implementation may require Commission or EDO approval.

External Reports

Unified Agenda (ADM)

The Regulatory Flexibility Act requires that agencies publish semiannual regulatory agendas describing regulatory actions that are under development. Executive Order 12866, "Regulatory Planning and Review" and OMB memoranda implementing section 4 of that Order, establish minimum standards for agencies' agenda, including specific types of information for each entry. The Unified Agenda helps agencies fulfill all these requirements.

The Unified Agenda provides information in a uniform format, about regulations that the government is considering or reviewing. The Unified Agenda is published in the *Federal Register* each spring and fall. The Unified Agenda includes rules from all Federal regulatory agencies.

The Regulatory Agenda (ADM)

In conjunction with the agency's twice-yearly *Unified Agenda* submissions to OMB, RDB prepares and publishes a semiannual brochure, the *NRC Regulatory Agenda* (NUREG-0936). This agency brochure includes all the rulemaking entries submitted for inclusion in the Unified Agenda, as well as an entry, supplied by the appropriate Program Office, for each petition for rulemaking being processed by NRC. The *NRC Regulatory Agenda* is made available to both NRC staff and stakeholders, and provides a convenient overview of all the Agency's current rulemaking activities. The public is invited to comment on any rulemaking or petition featured in either agenda.

Regulatory Plan (ADM)

The Regulatory Plan, required by Executive Order 12866, is prepared by RDB, signed by the Chairman, and sent annually to OMB by June 1. The Regulatory Plan contains a statement of the Commission's regulatory priorities and a description of the most significant proposed and final rules that NRC expects to issue during the upcoming fiscal year. OMB shares each agency's plan with other agencies and solicits comments on them. All agencies' plans are also provided to Congress. Each agency's Regulatory Plan is included in the fall edition of the Unified Agenda of Federal Regulatory and Deregulatory Actions.

The Role of Information Technology in NRC Rulemaking

NRC releases several hundred documents to the public each work day, many of which concern the Agency's rulemaking activities. The Agency employs information technology to make information about NRC rulemaking available to the public and to offer the public opportunities to participate in and comment on NRC rulemaking activities.

NRC's Public Web Site

NRC's public web site gives stakeholders online access to most publicly available documents, links site visitors to Agency rulemaking documents open to public comment, and affords users the opportunity to submit comments online. The site also lists upcoming public meetings and webcasts, including any associated with rulemaking, along with archived webcasts and transcripts of past public meetings. The web site enables NRC to quickly and effectively

communicate information about ongoing rulemaking activities to the variety of public, industry, and Government stakeholders with an interest in the Agency's rulemaking agenda.

The Public Electronic Reading Room

Featured on the Agency's public web site is NRC's Public Electronic Reading Room (PERR) (<http://www.nrc.gov/reading-rm.html>), which contains the documents most pertinent to NRC regulatory activities. Many of these documents are included in the PERR's list of Basic References or in its Document Collections. The list of Basic References links visitors to the full text of frequently requested regulatory reference documents, such as NRC regulations in 10 CFR Chapter 1. The Collections of Documents by Type provide index pages for Commission Papers, NUREG-series publications, and Regulatory Guides.

Online Library of Public Documents in ADAMS

Other publicly available documents connected with rulemaking, such as Federal Register notices, environmental assessments, and regulatory analyses, are stored in the Agencywide Documents Access and Management System (ADAMS), which can be accessed via the public web site (<http://www.nrc.gov/reading-rm/adams.html>) using NRC's on-line document retrieval system. Members of the public may download software that enables the user to search the ADAMS library for publicly available Agency documents and view them online. Users may also download copies of public documents available in ADAMS.

The Interactive Rulemaking Forum

In an effort to further public access to, and participation in, its rulemaking activities, NRC has developed the RuleForum (<http://ruleforum.inl.gov>), an interactive rulemaking web site. The site may be accessed directly or *via* a link on NRC's home page (<http://www.nrc.gov>). The text of Federal Register notices and supporting documents for all Agency rulemakings open to public comment—including proposed rules, DFRs, and petitions for rulemaking that have been noticed in the *Federal Register*—are posted on the RuleForum site. After approval, rulemaking plans are also posted on the RuleForum site. The site offers the public the opportunity to learn about proposed NRC rulemaking actions and to submit official comments online.

The RuleForum site is maintained by the RDB, with technical site support provided by contract with the Lawrence Livermore National Laboratory. RDB posts each proposed rule, DFR, and petition for rulemaking on the web site when the comment period for the action opens. At Commission direction, draft rulemaking language noticed in the *Federal Register* is posted on the site as well. Background files on posted rulemaking actions including a wide array of supporting documents, related public notices, and meeting transcripts, are made available for viewing or downloading from file libraries. A separate (access-limited) web page is available for posting rulemaking documents for Agreement State input.

The RDB web site manager also downloads public comments submitted *via* the site and forwards them for docketing by SECY. The site features a library of all public comments submitted in response to each posted document, including comments received by NRC via the web site and those submitted through traditional channels. These libraries are normally open to the public, providing interested stakeholders with an opportunity to view the full range of responses from the public, the States, special interest groups, and the regulated community.

RDB has been working on a redesign of the RuleForum webpage over the past year. The new page was recently implemented (September). The changes should improve the utility of the

webpage. Because of the pending change, the Task Force chose not to evaluate the then current page, other than to note that it was difficult to locate recent postings.

The Technical Conference Forum

The TCF web site (<http://techconf.llnl.gov>) was created to facilitate public input on NRC issues related to the development of draft rulemakings, draft guidance documents, and other initiatives. The site lists topics that are open for discussion and provides a library of available documents relevant to each topic. Visitors to the site can obtain background information about a given conference topic, read recent news about the issue, view comments submitted by other visitors, submit a comment of their own, or learn how to contact NRC for further information on the topic. The site also features a searchable calendar of meetings and workshops associated with issues under discussion in all ongoing technical conferences. RDB manages the TCF site and provides assistance to program office staff employing the site.

As noted in the section on Agreement State Review, the TCF site includes a special, password-protected section dedicated to issues of interest to Agreement States. Access to this portion of the site is restricted to the States and to Program Office staff developing rulemaking actions affecting Agreement States. STP uses a ListServ list to keep Agreement States informed of new postings to the site.

Planning, Budgeting, and Performance Management

In applying business-like principles to its regulatory processes, the Commission's goal is to ensure that NRC is both effective and efficient in implementing its mission. The Agency has implemented a disciplined, integrated process to improve for planning, budgeting, and performance management usually referred to as the planning, budgeting, and performance management (PBPM) process.

The four major components of the PBPM process are:

1. Setting the strategic direction

The first step of the PBPM process is to establish the goals and objectives for the Agency and to decide how it will meet them. The products of this step are the Agency's Strategic Plan and Performance Plan. The Strategic Plan sets the strategic direction of the Agency and the Performance Plan establishes how those goals and objectives are met. On a Strategic Plan level, rulemaking is not specifically identified as a goal, measure, or strategy. However, it is understood that rulemaking is integral to the strategic plan in order to advance the implementation of risk-informed and performance-based regulatory approaches to reduce unnecessary regulatory burden. Because rulemaking is the process through which the NRC regulatory framework is maintained and modified, it is essential to supporting all four of the agency's strategic performance goals.

2. Determining resources and planned accomplishments

Using the direction established by the Agency's Strategic Plan and the Performance Plan, the second step of the PBPM process is to determine the resources and planned accomplishments required to achieve the objectives. The result of this step is the development of the annual Agency budget. The budget allocates the Agency's resources needed to achieve the goals and

objectives established in step one of the PBPM process and reflects the priority of these activities (at the planned accomplishment level). This step also includes the development of office-level operating plans.

Further information on the establishment of rulemaking resources on a program level, which is done in conjunction with the PBPM process, appears in the budgeting for rulemaking section below.

3. Measuring and monitoring performance

The PBPM process also involves the development of performance measures and targets. This enables the Agency to track the degree to which it is achieving its objectives. These measures are reported and assessed as output measures in the Agency's annual performance plans. Detailed performance measures and targets are defined and assessed in the office-level operating plans.

Further discussion on performance measures and targets for rulemaking appears in the section of this report on performance measures.

4. Assessing performance

The final step in the PBPM process is the assessment phase, which determines the performance and effectiveness of a given task (such as rulemaking) and compares the performance against established objectives. These assessments include annual program reviews, program evaluations, self-assessments, and internal and external audits. The results of the assessment phase form the basis for the reevaluation of the Agency's strategic direction, and the net cycle of the planning, budgeting, and performance management process.

The rulemaking process improvement effort documented in this report represents an example of a PBPM performance assessment activity.

Budgeting for Rulemaking

Budget Overview

The approximate annual resource expenditures for NRC rulemaking activities are 50 FTEs and \$1.25 million in contract dollar expenditures. The office breakdown is shown below.

NRR:	22 FTEs and \$500K	
NMSS:	17 FTEs and \$500K	
ADM:	7.5 FTEs and \$250K	
OGC:	3.5 FTEs	
<u>Total:</u>	50 FTEs	\$1250K

[Note that there are also occasional rulemaking-related expenditures in the offices of CFO, CIO, RES, OE, and STP, however, the resources are not significant enough to be included above]

Description of the Budget Process

The budget structure outlines the program and planned accomplishments for each strategic arena. The NRC budget is broken out into the four strategic arenas, plus two other budget centers. Specifically:

- Nuclear Reactor Safety
- Nuclear Materials Safety
- Nuclear Waste Safety
- International Nuclear Safety Support
- Management and Support
- Office of Inspector General

Each of these arenas is further divided into program areas. The programs consist of a number of planned accomplishment codes. The resources for each planned accomplishment code are summarized to define the total budget for each program. The planned accomplishment (PA) codes and associated budget programs and arenas for rulemaking are noted below.

Rulemaking directly supports all four of the NRC strategic arenas. The Task Force review did not include the international nuclear safety support arena. Rulemaking to support this arena would typically be conducted by the Office of International Programs. The rulemaking program level description for the three other arenas is summarized below:

<u>Arena</u>	<u>Program</u>	<u>PA Code</u>
Nuclear Reactor Safety -	Reactor Licensing	101-120
Nuclear Material Safety -	Nuclear Material Users Licensing and Inspection	201, 203
Nuclear Waste Safety -	Regulation of Decommissioning	301, 302, 303, 308

Description: These activities encompasses the preparation and issuance of rules including the technical resolution of issues into rules. It includes efforts for the concurrent development of guidance for new rules, implementation guidance and revisions that are necessary because of rule changes, and development of implementation guidance for rulemaking after the final rule has been issued.

All the planned accomplishments are ranked by the leadership teams in each office against the strategic plan performance goals (the four pillars). A score of 3 means the work is essential to achieving a particular goal; a score of 1 means the work will have little or no impact on a particular goal; a score of 2 is somewhere in-between.

For NRR, rulemaking is ranked at a total score of 8 (safety=1, public confidence=2, burden reduction=3, and efficiency/effectiveness=2). For NMSS, rulemaking is not specifically ranked. Resources are allotted for rulemaking activities considered high-, medium-, and low-priority.

Although the budgetary ranking of rulemaking provides some insights on management's perception of its value and importance, there is very little variation from year to year in the resources devoted to rulemaking. Typically, rulemaking is budgeted at a level of effort based on historic trends. If budgetary constraints in other Agency programs necessitate reductions in

rulemaking resources, the reductions are generally accommodated by making adjustments in the rulemaking schedules. Rarely is there any shedding of rulemaking activities, based on a lack of resources. Similarly, emergent new rulemaking is normal and expected and is usually coincident with the completion of older rulemakings. Therefore, emergent rulemaking is often not reflected by additional resources in the budget.

Budget Details

Since the NRC programmatic rulemaking resources are budgeted at the planned accomplishment level, the breakdown of effort on individual rulemakings and related tasks is not identifiable in the overall Agency budget estimate. The details of the specific rulemaking tasks and related budget assumptions are found in living budgeting documents maintained by the financial analysts for each office. For NRR, the details of program-based budgets work items are broken down within each planned accomplishment code (such as rulemaking) in a document referred to as the "Fat Boy." For NMSS, the comparable document is the C-3:

The rulemaking branches in each office budget rulemaking resources differently. Within NRR, RPRP generally shares rulemaking responsibility with the technical divisions in NRR. Therefore, NRR rulemaking resources are distributed throughout the office. When budgeting resources for future years, the existing NRR rulemaking inventory is itemized, together with anticipated emergent rulemakings, into a master list. Management judgement is then used to distribute available programmatic resources, as established in the President's Budget, to meet schedules and maintain progress in moving forward on all active rulemaking efforts. However, there is no correlation between budgeted resources assigned to a specific rulemaking and actual resources expended. In addition, resources are generally not allotted to specific rulemakings based on a prioritization or importance ranking. Although many (but not all) NRR rulemakings have a rating against the four pillars (as documented in the DQSR), the budgeted resources appear to be assigned in an ad hoc fashion, to ensure that the existing level of effort is sustained and milestone commitments are met. For NRR, this creates a fungibility problem, since rulemaking resources assigned to a technical division will not convey to other rulemaking efforts, when work is slowed, delayed, terminated, or completed on a specific rulemaking.

Within NMSS, RGB does not establish budgeted resources to complete specific rulemakings, with occasional exceptions. There is no simple relationship between resources estimated for a given rulemaking and actual rulemaking personnel, since rulemakings are matrixed. Currently, the rulemaking budget is divided into high-, medium-, and low-priority categories, with some FTE resources designated to each category. One individual typically will be assigned multiple rulemakings for which the schedules are offset for high levels of effort. In general, low- or medium-priority rulemakings are assigned to individuals who also have a high-priority rulemaking. The medium- or low-priority rules are worked while a high-priority rulemaking is in a static state, such as when it is out for comment or with the Commission for consideration. Some high-priority rulemakings may have more than one RGB staffer assigned. Occasionally, a specific rulemaking is a separate line item in the C-3. For example, the control of solid material activities is captured as a specific line entry. For NMSS, RGB has the bulk of the rulemaking resources; however each division budgets resources for technical support to rulemaking. Since most rulemakings being conducted within NMSS are assigned to RGB, there is greater flexibility for redirection of resources to other rulemaking, as management so determines to account for fact-of-life changes.

Resource requirements for specific rulemakings are estimated in the rulemaking plans. However, it is unclear how the resources estimates are established because accurate and reliable rulemaking resource data have not been previously determined. Furthermore, once

those resource estimates are made, there are no feedback, adjustments, or accountability on variances between the actual resource expenditures and the estimates on an individual rulemaking basis. Although overall NRR and NMSS rulemaking expenditures are tracked in each office's operating plan, there is no similar tracking of individual rulemaking efforts (although some limited budget and actual resource information is now routinely reported in the NRR DQSR). When rulemaking was conducted under RES (up to 1998), budget data on individual rulemakings were not collected. The Program Offices have only been collecting data on specific rulemaking activities since 1998. Additionally, management has not been routinely collecting and analyzing the data that are available. Theoretically, individual rulemaking resource expenditures should be obtainable from staff hour utilization records. Unfortunately, the Task Force found that the available data are limited. The data analysis section of this report provides a limited assessment of resources associated with rulemakings. As discussed elsewhere, the staff is not uniformly charging time to the technical assignment control (TAC) numbers established for rulemaking activities. The budget data collected by the Task Force should be used by the rulemaking groups to better understand the effort involved in rulemaking activities and to improve budget estimates in future rulemaking plans and budgeting activities.

Budgeting is an important part of the PBPM process and rulemaking budget details are important parts of rulemaking process efficiency and effectiveness. However, it is not clear that only rulemaking effort is captured in determining actual expenditure on rulemaking. A recent look at some of the items that were included in the line-item materials rulemaking activities expenditure for NMSS included several items that were not part of rulemaking. These items included MOX activities, fuel cycle licensing, SDMP policy resolution, DOE SAR upgrade review, and several other items that had no relationship to materials rulemaking activities. Additionally, some rules appear to be listed under the wrong program activity codes. Inclusion of non-rulemaking activities in the expenditures provides an inaccurate accounting. Care should be taken to only include rulemaking-related activities. For management and the Commission to make informed decisions on rulemaking activities, there needs to be a good understanding of the cost of the rulemaking process. This information does not currently exist. The budget estimates in most current rulemaking plans are not much more than educated guesses, and the expenditure data include non-rulemaking activities. Consequently, there is no method that can assure management that the rulemaking schedules can be met using the available rulemaking resources.

Additionally, and more directly relevant to rulemaking process improvements, accurate budgeting for individual rulemaking provides management an important tool to monitor the progress of the rulemaking activity. Specifically, resource expenditure significantly different than estimated at the outset of a rulemaking should be a red flag to management. Either not enough resources are being applied to the effort or the rulemaking has encountered challenges or issues that should be surfaced for management action.

It should be noted that rulemaking can be expensive. Simple rulemakings can cost over \$300,000 and complex rulemakings cost over \$1 million. The cost of the rulemaking should be a consideration in the cost benefit analysis of any proposed rulemaking action.

The Task Force provides the following recommendations related to the budgeting process:

Each office should compile and maintain an accurate database on rulemaking resource expenditures and timeliness for all rulemaking activities. The database should be used in estimating schedules and budgets in rulemaking plans. The data presented in Tables B.6 and B.7 in Appendix B could be used for this purpose until more accurate data can be compiled.

Note that to maintain an accurate database will require more TAC discipline than is currently practiced.

Each office should pay careful attention and care in the use of PA codes and the calculation of expenditures under the PA codes to ensure that the budget picture is accurate. The offices should consider having dedicated PA codes for rulemaking.

Prioritization of Rules

As part of NRC's PBPM process, the Program Offices assess the priority of all rulemakings relative to their contribution to the Agency's Strategic Plan goals and performance measures. The Task Force spoke to RGB and NRR concerning the prioritization of rulemaking activities. NMSS' current process prioritizes each activity against its primary and secondary Strategic Plan goal and scores it on a scale of 1 to 3 (3= highest impact on goal; 1=lowest impact on goal). The safety score is used to differentiate between high-, medium-, and low-priority items. NRR considers all four goals. The results of this prioritization process are considered in the RAP and in the operating plans. There are no criteria in place to determine if a ranking should be a 1, 2, or 3; it is a subjective judgment call. In addition, other considerations also determine the final priority and schedule assigned in the RAP, such as Commission direction, ticketed due dates, and stakeholder interest.

The overall resources budgeted for rulemaking can be separated into approximate groups:

High-Priority: Examples include those rulemakings that address new risk information, emerging technologies, major burden reduction, significant regulatory issue, major stakeholder interest, etc.

Medium-Priority: Examples include those rulemakings that address regulatory improvement, minor or deferred applicability, etc.

Low-Priority: Slight burden reduction, improved regulatory efficiencies, etc.

Petitions for rulemakings that may rank as low-priority in terms of safety or reducing unnecessary regulatory burden are not considered low-priority, so as to be responsive to the public and meet the timeliness goals of the Agency (petition resolved in 1 year). The petitions are promptly noticed in the *Federal Register* for public comment, and a Working Group is formed to resolve the petition within the one-year timeframe. However, once a decision has been made to grant the petition in whole or in part, the resulting rulemaking is ranked against other rulemakings, to determine the priority.

The current priority process appears to be very subjective. No criteria have been established for determining the numerical rankings (1, 2, or 3); the determination comes down to a judgment call and is open to negotiation when individual rule actions don't rank as high as desired. Within NMSS, the ranking does not consider all four strategic goals. In determining the initial safety ranking, NMSS arbitrarily determined that no more than one-third of the rules could be in the high, medium, or low categories. NMSS currently has nine high-priority rulemakings, nine medium-priority and three low-priority rulemakings. NRR currently has 12 high-priority, five medium-priority, and two low-priority rulemakings. Several of the low-priority rulemakings are currently on hold pending resolution of post-September 11 issues.

Reprioritization of rulemakings can result in additional resource expenditure, particularly for low-priority rulemakings. The process ends up being stop and go, which means that the staff stops working on the project for long periods of time. When the project is picked up again, time and resources are lost because the individuals must reorientate themselves on the project. Reprioritization also frequently results in the reassignment of a project. The new individual must then take additional time to become familiar with the project. This reduces the efficiency and effectiveness of the particular rulemaking, but enhances the efficiency and effectiveness of rulemaking overall, as long as reassignments and reprioritization do not occur too frequently for particular projects.

The Task Force recommends that standardized criteria be developed for the prioritization of rulemakings. Use of criteria should result in a more consistent prioritization that would be more objective than the current process. The criteria could be used as a tool for better management of Agency rulemaking resources. The criteria should address the four performance goals. The Task Force has drafted prioritization rating factors for consideration. These factors are presented in Appendix C.

Performance Measures for Rulemaking

The measuring and monitoring of performance are a key element in adapting the rulemaking process to the PBPM business model. The hierarchy for PBPM performance measurement consists of three levels: (1) the strategic plan level; (2) the performance plan level; and (3) the operating plan level. At the strategic level, rulemaking performance is not specifically measured. At the performance-plan level, rulemaking measures are only identified for the materials arena. The current (fiscal year 2002) measures include: (1) completion of the Part 35 rulemaking; (2) completion of at least one burden reduction rulemaking; and (3) reduction of paperwork and record keeping imposed on licenses by 25 percent, over 5 years. No output measures were included.

The performance measures for rulemaking used by NMSS and NRR in the current (fiscal year 2002) operation plans are limited in scope. NMSS uses three factors: (1) rules on schedule and any adjustments coordinated; (2) all rulemakings, guidance, and meeting summaries submitted for publishing in the *Federal Register* and/or on the website, as appropriate, within 15 days of completion of approved document; and (3) demonstrate OMB burden reduction. NRR measures the outputs, productivity, timeliness, and resources used. The criteria used for the measures are: (1) three rulemakings completed for which NRR has the lead (recently changed to indicate to be determined (TBD)); (2) a labor rate of no more than 600 average hours/rulemaking (recently changed to TBD); (3) 90 percent of CTM milestones met within 30 days of original schedule and 90 percent of other office rulemakings are reviewed within 4 weeks of receipt; and (4) the budget is within plus or minus 20 percent of the estimate. Both NRR and NMSS also provide additional rule specific performance measures:

NRR cites the specific rules that will be proposed or finalized in FY 2002
NMSS cites the schedule milestones for every rule-related activity it has underway.

The Task Force considered the measures used by both NMSS and NRR and determined that more realistic measures should be developed. The NMSS measure did not have any associated criteria to measure success or failure for timeliness. The NRR measure only considered those rules on the CTM and used the original schedule. Schedules are often changed for good reason and with the approval of Senior Management and/or the Commission; these approved changes should be taken into account in the criteria. Additionally, concurrence on rules originated by other offices should be provided within 20 days, as outlined in MD 6.3.

The metric should not exceed the timeframe provided in the management directive. NMSS does not consider concurrence in other office rulemakings in its performance measures. The use of 600 average hours/rulemaking as a single criterion ignores the fact that rulemaking is not a one size fits all. A complex rulemaking will require much more effort than moderate or simple rulemakings. Many rulemakings are budgeted at multiple FTEs. The use of a measure for publishing in the *Federal Register* is not a good measure for the overall success/failure of rulemaking. It should be noted that the operating-level performance assessments are reported monthly in NRR (via the Rainbow Report) and quarterly in NMSS. The current operating-plan rulemaking performance measures are not conducive to assessment at this frequency of monitoring, because the incremental units of accomplishment (a complete rulemaking) are too large. It is apparent that the performance measures currently used for rulemaking are minimal; not fully defined (as exemplified by the use of TBDs); unrealistic; and inconsistent between offices.

The current rulemaking performance measures and targets are deficient and need improvement. The Task Force recommends that better performance measures be developed and used for rulemaking activities. Performance measures have been drafted and are presented for consideration in Appendix C. In developing the performance measures, the typical categories of outputs, timeliness, productivity, and resources were considered, as well as quality.

Technical Assignment Control Numbers

Ideally, a unique TAC number should be opened on the initiation of each rulemaking activity. All staff effort associated with the rulemaking should be charged to that specific TAC number, regardless of the NRC office or organization expending effort on the rulemaking. At the completion of the rulemaking effort, the TAC number should be promptly closed. Since staff charges to the TAC are recorded as a function of the date, the TAC data for any given rulemaking could be used to determine, with a high degree of accuracy, the total effort associated with any phase of a given rulemaking. This resource expenditure data could then be used to assist management, work planning, and overall Agency budgeting in determining resource estimates for future rulemaking activities.

This ideal situation does not exist in practice. Reviews of utilization reports, interviews conducted with rulemaking staff of the principal offices involved in rulemaking, together with general experience and understanding of common work practices, confirm that staff involved in rulemakings do not rigorously adhere to a disciplined accounting of rulemaking effort against a unique TAC for a given rulemaking activity. For example, there are instances where the lead office, upon initiation of a new rulemaking, does not always open a new TAC number. Much effort may be expended in the early phase of a rulemaking activity with the staff charging time to a generic rulemaking TAC. NMSS and NRR generally open TAC numbers early in the rulemaking process, but not in all instances. Even so, technical support groups within NRR or NMSS often do not charge their efforts to specific rulemaking TACs and, instead, use pre-existing generic TACs. Even Working Group members do not always charge their time to the rulemaking TAC number. In fact, in at least one recent instance, a separate TAC was established by a Working Group member in a non-lead office. It was also noted that several offices do not charge the time for preparation and review of a rulemaking to the specific TAC number designated for this purpose, instead charging to a general overhead code. For example, ADM does not charge time to rulemaking-specific TAC numbers, instead charging its time to an overhead TAC number for generic rulemaking. ADM does collect information on page count that could be used as a rough estimate of effort. Staff from OE and STP indicated

that they usually open TAC numbers for any rulemakings initiated by their offices, but have not always charged time for review of other office rulemakings. Neither CFO or CIO charge review time to the rule-specific TACs. OGC does not charge time to the rule-specific TAC, instead using a generic code for the arena. However, OGC does collect the time expended on a specific rulemaking activity under its own system, WIDAD. Note that effective October 7, 2002, OGC discontinued the WIDAD system and has started tracking each specific rulemaking.

NMSS rulemaking procedures require that the Task Leader obtain a TAC number for his/her rulemaking activity when work is first initiated. However, in practice, this does not always occur. NRR rulemaking procedures do not address when rulemaking TACs should be opened. A finding from this study is that the NRR office rulemaking instructions are deficient in discussing control and management of TACs. The proper usage of TACs for NRR rulemakings is not based on rulemaking instructions but, instead, on project management instructions in the Project Managers Handbook. Rulemaking TAC discipline appears to decline for rulemaking staff without a Project Manager (PM) background; this is true for NMSS staff as well. Specifically, TAC management and discipline are well established for project management activities associated with fee-billable licensing actions, and the staff with PM backgrounds are likely to continue to exercise that discipline for rulemaking activities. This discipline appears to break down for staff that have little or no PM experience and have mostly worked on non-fee-billable activities (and therefore not subject to licensee scrutiny), such as most rulemaking.

The process for opening a TAC number is straightforward in NRR. NRR has an automated process to permit its staff to open new TACs. NRR has recently implemented a new Time, Resource, and Inventory Management (TRIM) system to interface with STARFIRE. The system permits the opening, searching, monitoring, and closing of TAC charges for NRR activities. However, it does not permit similar interface with TACs opened by other offices under non-NRR PA codes. Within NMSS, TAC numbers are opened by Program Management, Policy Development and Analysis (PMDA) staff. RGB staff sends a request by e-mail to the appropriate PMDA staff member, who then opens the new TAC number. Recent experience has shown that this process does not always work very efficiently; it has taken over 3 weeks to obtain a TAC number for an activity. Requests for utilization reports (staff charges) and closure of a TAC number also go through PMDA.

In theory, once a TAC has been opened, all time expended on the rulemaking activity would be charged to the specific TAC number. This would include time expended by all Working Group members and time expended during the reviews for office concurrence. In addition, meetings or workshops associated with the rulemaking would be charged to the same TAC. The TAC number should be obtained (opened) by the rulemaking Task Leader and provided to the Working Group members (generally at the initial meeting of the group). The TAC number should be included on the memoranda requesting office concurrence.

Once a TAC is established, it is often difficult for staff to locate and identify the correct TAC associated with a given rulemaking. TACs can theoretically be searched from the new STARFIRE time and labor system; however, the method and techniques required to perform a successful STARFIRE search are not intuitively obvious and in most cases result in user frustration and inability to obtain the desired TAC information. Even if the user can find a list of rulemaking TACs, in many cases, the title does not always provide an indication of the rulemaking for which the TAC number was issued. Neither NMSS nor NRR maintains a listing of rulemaking TAC numbers. Managers cannot run a utilization report for a specific rulemaking without the TAC number. The TAC number must generally be obtained from the Task Leader.

Until recently, staff hour utilization reports for specific rulemakings were not tracked and TAC numbers have not been routinely used to obtain and monitor rulemaking progress. NRR rulemaking management has now begun to track specific rulemaking effort using TAC data. However, because of the lack of TAC discipline and the failure of other offices to use TACs, it is recognized that the effort charged to a specific rulemaking TAC is likely to be an underestimate of the real resources expended on the rulemaking. NMSS does not currently routinely collect and use the staff hour information.

Notwithstanding recent actions to monitor specific rulemaking resource expenditures, management does not have a good historical data base on the effort expended to support previous rulemakings and, therefore, cannot provide accurate projection of the resources and effort that are needed for rulemaking activities. As part of the data collection efforts associated with this study, staff hour utilization reports were obtained for a number of the rulemaking TACs. This data review confirmed that many Working Group members do not charge to the specific rulemaking TAC number and, instead, resort to the use of a generic TAC—particularly staff outside the lead rulemaking office. It also appears that some staff members charge non-rule activities to the rule TACs. Other offices seldom charge their review time to the rulemaking-specific TAC number. More than one TAC is frequently opened for the same rulemaking. This practice not only exacerbates the confusion on determining the proper TAC to charge effort against, but also tends to obscure and mislead management oversight on the resources expended on a given rulemaking effort since many rulemaking resources may be charged to a TAC not being monitored. It was also observed that TAC numbers often remain open long after a rulemaking has been completed. In some instances, staff members charged time to efforts that had been completed for over a year.

In summary, the use of TAC numbers and TAC discipline were found to be deficient. Although these deficiencies do not impact the quality or the timeliness of rulemaking, they do impact the administrative aspects of rulemaking, including the budgeting process. The Task Force has several recommendations related to TAC accounting.

These findings related to TACs were discussed with both NRR and NMSS rulemaking management prior to the completion of this report. Both NRR and NMSS management took immediate steps to close TAC numbers for completed rulemaking actions. Both NRR and NMSS will benefit from the acquired rulemaking resource data provided in Appendix B. The data can be useful for budgeting of future rule activities.

The Task Force recommends that NMSS and NRR change their current practices relating to administration of staff work effort and resources expended on rulemaking using TAC numbers, and enhancement of overall TAC discipline. Some of the suggested changes should be incorporated into the *NRC Regulations Handbook* and/or the rulemaking procedures for each office. Other recommendations would result in a change of practice but may not need to be spelled out in a procedure. The specific TAC-related recommendations are:

- Effort on specific rulemaking activities should never be charged against generic rulemaking TACs;
- One and only one TAC number should be opened for each rulemaking activity, including minor rulemaking;
- Responsibility for opening the TAC number should be placed on the office that has the lead responsibility for the rulemaking. (Under normal circumstances Working Group members should not open a separate TAC for their office.)

- A rulemaking specific TAC should be opened as soon as a new rulemaking effort has been identified (initiation of a rulemaking plan; decision to grant a petition for rulemaking; upon direction of an SRM; or any other internal or external initiation);
- The title and description assigned to the TAC number should reflect the rulemaking action and should be opened under the appropriate PA code;
- A list of rulemaking TAC numbers should be maintained. For NMSS, the TAC number should be added to the rule status chart;
- All rulemaking Working Group members should be reminded to charge time to the TAC;
- The office concurrence memorandum associated with the rulemaking should document the official TAC number to help ensure that any non-Working Group staff providing effort related to the rulemaking (such as during concurrence review) will be aware of the TAC and use it appropriately;
- All activities associated with the rulemaking shall be charged to the TAC including:
 - meetings,
 - workshops,
 - policy papers, and
 - supporting documentation (regulatory analysis, OMB package, environmental reviews, etc.);
- Regulatory guidance developed as part of the rulemaking package should have a separate TAC when guidance development is routinely tracked under a different PA code;
- TACs should be promptly closed after the completion of the rulemaking activity;
- The time charged on a specific rulemaking TAC should be routinely monitored, collected, and reported by the responsible lead office as part of rulemaking performance monitoring; and
- The lead office should maintain a database of FTEs expended at the completion of the rulemaking plan, proposed rule, and final rule stages of every rule, so that the data are available for budget purposes. The database should also include any contract charges.

Data Analysis

Internal Stakeholder Survey

To determine, what, if any, problems existed, or were perceived to exist with rulemaking, and to help focus the Task Force effort, the Task Force conducted meetings with key internal stakeholders. The Task Force met with Commissioner Assistants; the EDO; Deputy EDOs; NMSS and NRR Office Directors; NMSS and NRR Division Directors (or designees); and selected Deputy Division Directors, Branch Chiefs, Section Leaders, and staff in both NMSS and NRR. The Task Force met with management and staff in ADM and OGC who are involved in rulemaking activities. The Task Force also met with selected managers and staff in other offices that have a role in rulemaking. The Task Force did not attempt a scientific sampling of the views of agency personnel involved in rulemaking; rather interviewees were encouraged to express their individual opinions on all aspects of the rulemaking process. Accordingly, this section presents an impressionistic composite of views held by the interviewees. The questions asked of each group were varied, as appropriate depending on the stakeholders' positions and roles in the rulemaking process. The questions focused on concerns with and recommendations on, the rulemaking process. Some of the concerns raised were specific to rulemaking. However, several concerns, such as concurrence and communication, are generic across the Agency.

Quality

One positive outcome of the stakeholder surveys is that there appears to be little to no concern over the quality of NRC rulemaking. The great majority of the stakeholders interviewed thought that the quality of NRC rulemakings was very good and that the quality should be maintained. Some stakeholders suggested that quality should be measured in some manner. Measures suggested for consideration were whether a final rule is withdrawn for some reason or if there is a need to go back and fix a rule that had been issued. At the working staff level, some concern was expressed that management doesn't seem to care a lot about the quality of a rule, only the timeliness. It was apparent from the discussions with management that quality does matter. These views need to be expressed to the staff, along with some discussion on balancing quality versus timeliness. These concerns indicate that communication between management and working level staff needs improvement.

Timeliness

One of the largest areas of concern was the timeliness of rulemaking. This topic probably had the largest diversity of views, with views ranging from good with no problems, to acceptable considering constraints, to the process is too slow and takes way too long. Several expressed views that they would like the process to move faster, but that they didn't see anything to fix. Many individuals identified that there is a lot of administrative time and down time where the rule activities are on hold. The view was that once we get down to business and actually work on the rule, the time is acceptable. Several upper managers expressed a desire to understand why a rule takes the amount of time it does. Several managers encouraged more use of direct final rules and EDO signature authority to speed up the process. It was also suggested that the EDO sign out all proposed rules. Senior managers expressed the view that managers should be held accountable for timeliness. There was no consensus view on how long a rulemaking should take; views ranged from 6 months to 3 years after approval of the rulemaking plan. Almost everyone stated that it depended on the complexity of the rule. Concern was expressed

that if a rulemaking takes too long or if there are long periods of time with no public notification of status, public confidence will lag and this could cause public relations problems. A couple of managers expressed concern that rulemaking is not responsive to the needs of the Agency, because the process takes so long. Several issues that impact timeliness were raised, including the concurrence process, the timing of the development of the technical basis, stakeholder participation, and schedules.

Concurrence

The concurrence process was raised as a concern to some degree by every category of internal stakeholder. Several, including the Commissioner Assistants, expressed concern over the amount of time the concurrence process takes, questioning the value-added of several of the layers of concurrence. The staff agreed that the layers of management review seriously slow down the process and may add very little value. The view was expressed that in some cases, the changes suggested by management reduce the quality of the package, because of incomplete, detailed understanding of the managers making the suggested changes. The concurrence process is definitely viewed as being very burdensome and time consuming. There were many complaints that the process is ineffective and that the same issues keep being rehashed. One of the concerns expressed at the staff level was that management kept changing its mind regarding the direction of the rule, even after apparent buy-in. This results in major rewrites and increases the time and resources needed to complete the action. Others raised concern that packages sit on managers' desks for long periods, due in part to other priority work. There was no consensus view on how long concurrence should take. Most thought that the time should depend on the complexity of the rule and the workload. Suggestions ranged from a couple of days to several weeks at each layer of concurrence. There were several suggestions to improve the concurrence process by getting earlier buy-in from managers, obtaining agreement up-front on how long a manager has for concurrence, parallel review by the section chief and branch chief, and empowerment of lower-level staff to concur based on the complexity/controversial nature of the rulemaking. Several managers and staff expressed the view that the staff should be empowered by delegating the concurrence authority as low as possible; others were obviously uncomfortable with the concept and expressed the view that the concurrence should be at the Division Director level. There were some questions on why certain groups needed to concur on a rulemaking package. The Task Force recognizes that concurrence is a generic problem for NRC and is not limited to rulemaking. The Task Force considered several suggestions to improve the concurrence process; the suggested improvements are specifically designed for the rulemaking context. These suggestions are discussed under process improvements.

Rulemaking Initiation

One area that impacts the perception of timeliness is the point in time that the rulemaking process actually begins. Many internal and external stakeholders hold the view that rulemaking begins when an issue is raised. However, many issues lack a firm technical basis when first raised and the rulemaking can not go forward until the technical basis is developed. In other cases, management may not have adequately thought an idea through before initiation of rulemaking. In many instances, stakeholders believe that rulemaking has begun, when the actual rulemaking may be a couple of years away or shouldn't be contemplated in the first place. The staff has debated the question of when rulemaking begins for some time. The view used to be that the rulemaking clock did not begin until the rulemaking plan was approved. Most individuals today support the view that rulemaking should begin with the initiation of the rulemaking plan development, but after the technical basis has been developed. Some individuals even believe that the technical basis should be fully vetted with the public before

initiation of rulemaking. This would provide an indication of stakeholder interest and support for a particular initiative. Several individuals were concerned about rules where the technical basis was being developed at the same time as the rule language. This type of process results in stop-and-go efforts with lots of redrafting, and is an inefficient use of staff resources. It is obvious that many managers view the time spent developing the technical basis to be a part of the rulemaking process; this adds to the perception that rulemaking takes too long. Staff should not develop a rulemaking plan until the necessary technical basis on which a decision will be based is complete. The Task Force believes that rulemaking should not begin until completion of the technical basis. Technical basis development should not be part of the rulemaking process. This concept needs to be communicated to both internal and external stakeholders.

Stakeholder Participation

The amount and timing of public participation is another area that can have significant impact on the timeliness of a rulemaking. The Commissioner Assistants indicated that more stakeholder participation is preferred and that the staff should not have to be told every time enhanced participation should be used. However, everyone acknowledges that enhanced public participation activities, such as public meetings, do tend to lengthen the timeline for the rule and result in the expenditure of additional resources. It was also noted that it can be difficult to engage the stakeholders and that we need a more effective process for involving and interacting with stakeholders. Public meetings are beneficial only if you can get the right people to the meeting and get them to participate in the process. The view was expressed that we do not get a cross-section of views during the comment period, but tend to get only the objections. We need to do a better job of engaging the public. Another issue raised was the timing of stakeholder involvement. Most stakeholder involvement occurs during the public comment period on a proposed rule. The staff is also, on a case-by-case basis, posting draft language on the RuleForum webpage for comment before publication of the proposed rule. However, Commission direction is typically set at the rulemaking plan stage. With the exception of Agreement States, no stakeholder engagement occurs until after Commission approval, because the staff is prohibited from discussing predecisional material with external stakeholders. Suggestions to improve public participation were to e-mail societies and other groups when placing material on the web, and to place redline versions of the rule on the web. The Task Force received several suggestions to consider other processes, such as e-mail or a web-based process for allowing public comment. The Task Force solicited public comment on the issue of public interaction for rulemaking. The results are discussed in the section on external stakeholders. The Task Force recommends that external stakeholders be engaged at an earlier stage of the process. This is discussed further under process improvements.

Rulemaking Schedules

Both staff and management expressed concern about schedules. Respondents stated that there is little to no flexibility in schedules. Schedules for rules are forced to be short, regardless of the complexity of issues or availability of resources. Adjustments (reductions in time) are always at the expense of the Working Group level, never management review time. The view was expressed that about two-thirds of a rulemaking schedule is slated for review and concurrence. Schedules are typically set by SRM or ticket-due dates and are often not based on staff input. Management does not appear to have a good handle on how to set due dates for various projects, work load, or necessary effort. The schedule ends up being set without a good understanding of the tasks that must be completed, the resources involved, nor the availability of resources. Normally the end date is predefined by management, which results in reverse engineering the schedule and its respective milestones to meet the predefined

completion date. Task Leaders and Working Groups are often not provided with adequate time to understand the issues involved in the project. Management is often reluctant to request extensions, even when one is obviously needed. It was noted that it is easier to get extensions on lower-priority, less controversial items. Several expressed the view that some rules should not have a due date, that these low-priority rules would be worked as time was available.

Initially, the major factor affecting rulemaking schedules is the resolution of technical issues. When these issues are particularly difficult, senior management (e.g., Risk Informed Licensing Panel, Leadership Team, Executive Team, Steering Groups) must get involved to reach resolution. This inserts considerable uncertainty into the process, both because of scheduling difficulties, as well as management reversing decisions or not making decisions. At the later stages of the process, the schedule is determined by the concurrence process itself. At this point it is up to staff management to review and concur on the package in a timely manner. This is difficult for these people given their workload, and the often considerable complexity of rulemaking packages. The view was expressed that the schedules should reflect more time for comment resolution. Apparently, both the staff and management need better guidance for estimating the time and effort needed to complete a rulemaking. Several of the recommendations made in this report, if implemented, would provide a better tool for making these types of estimates.

Rulemaking Plans

Rulemaking plans (RMPs) were another area where a large number of comments were received. Many individuals believe that we are not following the original concept of RMPs which was to look at an area in general. Large amounts of resources were not to be expended before approval of the RMP. The RMPs have become too elaborate and detailed and often contain proposed rule language; the RMPs have become mini-rules. In some cases, people think that the process has evolved into an impediment to timely initiation of rulemaking. One suggestion to simplify the rulemaking plans was to drop the regulatory analysis information and focus on the problem, the options, and a brief analysis of the options. There was clear support to simplify the RMPs. As a cautionary note, the Commissioner Assistants would like to see a better presentation of real alternatives. The view was that alternatives are not well-thought-out, and that real alternatives which offer good solutions are not presented. The discussions tend to be too focused, too biased to the staff's preferred alternative. In some cases, it may be appropriate not to present a preferred alternative (this should be run by the Commissioner Assistants in advance). The alternatives should be fully developed.

There were several questions as to why a RMP was needed. It was noted that we should explore areas where a RMP is not necessary. The routine ASME code update was provided as an example of where a RMP might not be necessary; another was for a topic where there has been a lot of Commission engagement. Another frequent concern about the RMP was the schedule provided in the RMP. Often the staff doesn't fully understand the effort necessary for a rule at the RMP stage, and either a generic schedule or an overly optimistic schedule is provided with the hope that it can be extended later. This is done to get the RMP through concurrence. There is a feeling that management would not approve a realistic schedule. When a more realistic schedule is prepared, based on the discovered complexities, real-life situations, stakeholder interest, or other conflicting priorities, it is too late to modify the schedule. The schedule has become locked in place and is nearly impossible to change. People think that we too often go into rulemaking with unrealistic or incompatible goals versus those held by industry or other stakeholders, which results in delays. Goals should be identified and stakeholder input verified before launching into rulemaking. The Task Force has looked at

the rulemaking plans and rulemaking initiation and has several suggestions to modify the current process. These are discussed under process improvements.

Cost

The Commissioner Assistants and senior management expressed concern over the cost of rulemaking and its impact on fees. Managers recognized that the cost accounting data are not in place to determine the true cost of a rulemaking. The view was expressed that for materials, rulemaking is the single most expensive item in the budget. There were questions on the items included in the rulemaking budget figure. Several individuals expressed the view that fees were becoming the driving force and that there should be more of a balance. The Task Force did look at available cost data for rulemaking. We did not evaluate cost from the standpoint of why rulemaking is costly. Data were collected that managers can use to better understand the cost of rulemaking. These issues are discussed in the sections on TAC management and budget.

Rule Package Content

Several concerns were raised in the area of rule content. The Commissioner Assistants and senior managers expressed concern over the regulatory analysis. These concerns included: the cost of conducting a regulatory analysis; the cost-benefit analysis having too many soft areas because of a lack of good data; and the difficulty of obtaining cost information from stakeholders. Several persons stated that the regulatory analysis needs to state where numbers originate and provide the basis for the numbers. There was a definite indication that the staff needs to look for ways to simplify and standardize the regulatory analysis, as well as improve the quality. Working level staff also expressed concern over the availability of hard cost data to support a rule; stakeholders are not always forthcoming in providing cost information and we are limited in our ability to solicit the information by OMB requirements.

Several individuals expressed concern over the amount of repetition in a rule package. The same information is in the Statement of Considerations, regulatory analysis, and environmental assessment. ADM staff notes that sometimes the staff uses different language in these documents and should be more aware of this when developing the various documents. A lot of frustration was expressed over the staff effort necessary to prepare a section-by-section analysis. OGC staff believes it important that the statement of considerations identify the reasons for changing each section and that, unless the responses to comments fill this purpose, a separate section-by-section analysis is needed. Staff frustrated by the effort did agree that the section is beneficial.

A couple of individuals raised the use of a question and answer (Q&A) format for rules (both in the Statement of Considerations and in the rule language). It is believed that the Q&A format makes the regulation easier to understand and use. If not feasible for the rule language (resources necessary to implement and buy-in being obstacles), it was suggested that the Q&A format be used in the Statement of Considerations. Many rules also have too many subsections that make it difficult to locate and understand a particular requirement. Concern was also expressed over the content of the environmental assessment. Environmental assessments to support a rulemaking are different from those to support a site-specific licensing action and should not have the same requirements.

One other area related to rule content was the availability of guidance documents related to a rule. It was noted that the Agency needs to do a better job of having the guidance documents available for comment with the proposed rule. External stakeholders shared this view. Current Agency policy is to have the guidance documents available for comment while the proposed

rule is out for public comment. However, in practice, this seldom happens. The guidance documents have the detailed information on how the staff plans to implement a rule. The Task Force recommends that the guidance documents be made available for comment as a companion to the proposed rule. It is recognized that preparation of these guidance documents may extend the schedule for a rule and require additional resources. However, it is believed that the benefit of having the guidance documents available with the proposed rule out weighs the cost of additional time for the rule. Development of the guidance can expose problems with the rule language that otherwise would not be discovered until later. The guidance documents can also help focus public comments. Schedules in the rulemaking plans should account for development of any guidance documents.

A concern at the staff level is the OMB clearance package. The staff feels that there is no good guidance on what needs to be in a supporting statement and that CIO staff has not been able to clearly articulate what is being sought. Rule staff feel that they are always in the "bring me another rock" mode, in dealing with CIO, and that a more efficient process is needed. It appears that communication between rule staff and CIO staff needs to be improved. The Task Force recommends that CIO complete the Management Directive concerning compliance with the Paperwork Reduction Act that has been in the works for years and that it conduct some training sessions for rulemaking staff on how to prepare an OMB clearance package. Although the concern was primarily related to the supporting statement, the training should also address the Federal Register notice.

The Task Force also received suggestions that development of checklists could be beneficial. OGC has a checklist that is used internally that perhaps could be shared with the rule writing staff. OGC also noted that the same standard issues keep coming up and noted that perhaps it could develop a list that addresses these issues. It was also noted that a list of what ADM needs in a rule package would be helpful. Staff also requested a checklist on rule package content. The Task Force agrees that these are good ideas and recommends that both ADM and OGC develop a checklist of things they look for and issues to be aware of and that both NMSS and NRR develop a checklist on rule package content.

Communication

Many people indicated the need for improved communication and coordination - between Working Group members, between staff and management, and between divisions and offices. Better communication up-front between management and the working staff would make the rulemaking process more efficient and effective. Management needs to articulate its expectations for the rulemaking and agree up-front on what is being fixed and how it is being fixed. If policy or management views change, the Working Group should be informed. Better alignment at the front end should result in less recycling at the back end and should have the benefit of speeding up the concurrence process. Working group members also need to do a better job of keeping management informed on particular rulemakings and taking their management's perspective back to the Working Group. The level of commitment of the Working Group member and his/her management was questioned. Management does not provide adequate time for the Working Group member to effectively participate. Some concern was expressed over the level of effort needed to brief management on a rulemaking issue. There are too many layers of briefs and prebriefs - it has become too big a production. It was suggested that we have more informal briefings. Several individuals were concerned that managers are managing to sound bites instead of an understanding of the issues involved.

Several individuals stated that the roles of RES and OGC need to be clarified. Many individuals in NRR also stated that the roles and responsibilities of DRIP versus the program divisions

within NRR need to be made clear. Task Leaders need to better communicate the milestones and schedules to Working Group members and management. The Task Leader needs to define the roles and responsibilities of the various Working Group members and communicate any redirection or changes to the other members to keep them informed. The Task Leader needs to communicate back to ADM and CIO on why particular comments are not taken. Some believed that OGC needs to do a better job of explaining to the Task Leader why edits are necessary from a legal perspective. The view was expressed that OGC involvement was occurring either too late in the process or at a superficial level when input is provided earlier. In discussions with OGC staff, OGC needs to see the initial drafts and near final drafts, but not necessarily all the drafts in between. The Task Leader needs to better communicate with the lawyer assigned to the Working Group when OGC input is necessary, and to raise legal issues as they come up.

A major concern was the availability of knowledgeable staff to participate on a Working Group. Concern was expressed that Working Group members frequently either don't show up for meetings or do not come prepared, and frequently don't deliver their input in a timely fashion. This is often because work on rulemakings is usually not given priority when work conflicts arise and these decisions are made without rule group input. In some cases, it may be because of the assignment of inexperienced people to the Working Group. Working Group members often do not bring their management's perspective to the table which results in issues being raised during the concurrence process instead of earlier in the process. The working Group member may also need to pulse the rest of his/her organization to better understand an issue or he/she may need to circulate a draft within the organization. Many times the Working Group member does not pay attention in the early stages of the project. Involvement occurs too late in the process, resulting in late raised issues that can have major impacts on the project. Many individuals felt this was especially true for the OGC member and because of this OGC is viewed as a bottleneck. All of these lead to an inability to meet the schedules established for the project and can result in a lower-quality product. It was suggested that a management to management understanding be established for members of Working Groups. Another suggestion was to develop a process for securing firm commitments from the technical staff to support rule activities (similar to the work request process used by the Division of Licensing Project Management in NRR). One area raised by the Commissioner Assistants was that interaction with the Commissioner Assistants be at an early stage when resolving major issues and comments.

Miscellaneous

A suggestion was made to create a rulemakers' webpage (and keep it up-to-date) that would contain the applicable Management Directives, the Regulations Handbook, office procedures, points of contacts, Rulemaking Activity Plan, etc. This would enable the staff to obtain from one location the necessary tools to complete a rule. Staff would like to be given the opportunity and time to review and comment on these documents when they are revised. Several individuals suggested the need for a database system that could be used to replace many of the reports currently used. A suggestion was made for ADM to keep a log of staff suggestions/complaints on the Regulations Handbook for consideration at the next update. (Note that ADM currently maintains such a log, however, staff are apparently not aware of this action.) Several suggestions were received to improve the rulemaking guidance documents - Regulations Handbook and office procedures. Several individuals requested more detailed information of a "how-to" and heads up nature. The rulemaking process is a complex process that contains many potential pitfalls where tasks not being completed at a certain juncture can result in major delays. It is very important to provide guidance on the time sequence of events, what has to be done, who must be involved, at what point this should be done, etc.--in other words, what it

takes to get a rule out the door. There were requests for good examples of various documents that could be used as a model. NRR staff requested better guidance for the use of the performance-based guidelines. There were requests for better examples of how to develop an action plan schedule (levels of concurrence, how long, etc.) For the NMSS procedure, staff requested that the milestones in the sample schedules be clarified. Additional detailed information on Agreement State related interactions should also be included in the NMSS procedure. There were several suggestions for more use of templates and the development of templates, with the caution to be careful as errors can creep in over time. Some concern was also expressed over the loss of creativity when using templates. There were several requests for more examples of environmental assessments, OMB supporting statements, and Commission papers. There was a request for a more detailed discussion in the Regulations Handbook on the section-by-section analysis; staff thought the current discussion was not self-explanatory. NMSS, NRR, and ADM should keep the above suggestions in mind when the next revisions of the various documents are prepared. The Task Force recommends that a rulemakers' webpage be developed. This is a tool that could greatly benefit staff and would not require a lot of resources to develop and maintain.

Several issues were raised that are not specific to rulemaking. These issues included training, corporate memory, staffing, administrative support, and interchanging of managers (knowledge level). Staff expressed concern that a lack of management familiarity with the subject matter with which their staff are involved can affect both the quality and timeliness of a product. Staff also expressed concern that current rulemaking managers have never written a rule and are not familiar with the process. The staff was concerned that due to the knowledge level you could not brainstorm issues with management. Some staff concern was also expressed over the knowledge level of rule writing staff, as well as management. If an individual doesn't understand the current regulatory base, how can they be expected to undertake rulemakings to change the structure.

At the staff level, there was concern over the lack of administrative support. Additional support was desired to help with such items as the care and feeding of the tracking systems, setting up public meetings, and simple searches for old Commission papers and Federal Register notices. The staff believes that too much time is spent on administrative work that does not advance the active rule work. Use of administrative staff to conduct those administrative type activities currently handled by GG-14s and GG-15s would make more efficient and effective use of technical staff time. Concern was also expressed that many of the administrative support staff are not familiar with the document formats and with the necessary ADAMS role. Staff was also unhappy with the administrative turnaround time for documents.

The Task Force explored the desirability of a short training session on rulemaking that provides an overview of how rulemaking is conducted. Overall, there was support for the idea, although the manner and target audience suggestions varied. Several individuals suggested a web-based training course that could be assessed by anyone interested in gaining a better understanding of rulemaking. Most managers saw some benefit from offering a training session, but not making it mandatory for all staff. However, Working Group members should receive some training so they have a basic understanding of the process that they are operating under. Senior managers expressed interest in a tool that explains the types of rulemakings and the associated constraints. The Task Force recommends that 'training' material be developed that could be used to help explain the process for both internal and external stakeholders. A better understanding of what is involved and the necessary steps to get there may help with the perception that rulemaking occurs in a black box and takes too long.

A lot of current rulemaking staff are either eligible or will soon be eligible for retirement. This will result in a significant reduction in the knowledge base. One of the more significant areas is regulatory analysis. This is one training area that management definitely needs to address, particularly in light of the problems identified in this area. The Task Force recommends some sort of training (either internal or external) on preparing regulatory analysis be developed and become required training for all rulemaking staff. Other areas management may want to consider for additional training of rule staff are project manager type training and training on environmental assessments.

There were many issues raised by the internal stakeholders that have merit but are not subject of a recommendation. Rulemaking management should carefully consider this section for other opportunities to improve the function of the rulemaking sections and/or branches.

External Stakeholders

NRC's Rulemaking Process Improvement Task Force solicited stakeholder input on the process the NRC currently uses to communicate during rulemakings with Agreement States and with the general public. The Task Force used a questionnaire for the Agreement States (STP-02-045), published a Federal Register notice (67 FR 37733; May 30, 2002) requesting external stakeholder input, and participated in a teleconference call with the Agreement States.

The Task Force received responses from 10 Agreement States (Arkansas, Illinois, Nevada, Ohio, Texas, Washington, Louisiana, Georgia, Maine, and Utah) and comments from five other stakeholders, including Mark Burzynski for the Tennessee Valley Authority (TVA); Robert Bishop for the Nuclear Energy Institute (NEI); Peter Vernig from the VA Medical Center in Denver Colorado (Vernig); Robert Meyer for the Professional Reactor Operator Society (PROS); and a private citizen. Their responses have been summarized by question, below:

At what stage(s) of the rulemaking process is interaction with the public most effective and beneficial? At what stage in the rulemaking process would the Agreement States like to become involved and to what degree?

Overwhelmingly, the majority of the commenters responded that Agreement States and other stakeholders should be involved in the rulemaking process as soon as possible. Texas stated that Agreement States should be involved after the NRC staff identifies the regulatory problem, but before the initial decision to do rulemaking. Texas noted that commenting on a rulemaking plan seems an efficient use of State resources because the NRC staff would have already outlined the regulatory problem and recommended rulemaking.

However, Vernig, Texas, and Ohio all noted that once a rulemaking plan is published, the perception is that the decision to do the rulemaking has already been made and that by the time NRC has developed a final rulemaking plan, many issues and philosophies are already "cast in stone" and it is difficult to veer from the "chosen" path. After the plan is complete, Ohio commented, much of the remainder is "wordsmithing." Vernig pointed out that there may be a need for published material describing the process and the stages of rulemaking at NRC.

Washington, Utah, Nevada, and Louisiana stated that the current NRC procedure of providing the draft Rulemaking Plan to the Agreement States for comment before Commission approval is appropriate, because it allows States to then decide if the proposed rulemaking will affect programs that a particular Agreement State implements, and they can choose to participate in

the process or not. Arkansas noted that when a rulemaking is not specific for NRC licensees and has an impact on the Agreement State program, Agreement State participation and input as soon as possible are critical.

Texas believes that with NRC's decreasing number of licensees, "NRC staff may not always be the closest to the regulatory issue." Texas supports the Alliance concept recommended by the National Materials Program Report, which addresses the need for joint State and Federal participation in the decisionmaking process.

Georgia states rulemaking plans should include only that level of detail that is necessary to present a rulemaking concept to the Commission and should not be elaborate and developed "rules-in-waiting." Maine argues that Agreement States, or at least a representative from the Organization of Agreement States (OAS), should be involved at the very beginning of the process; he further notes that the CRCPD has rulemaking groups to initiate rulemakings when the need arises, usually after a rule change by NRC. Maine believes if OAS and CRCPD are brought in early, Agreement States may be able to adopt regulations sooner than they do now.

TVA advocated the use of "scoping meetings," and PROS stated that the "...onset of the rulemaking process provides the most benefit of feedback." PROS added that "the period shortly before issuing a proposed rule is an ideal time to incorporate any PROS input that could preclude future challenges."

NEI stated that "...effective interaction with the public begins with NRC issuance of well-considered rule proposals and clearly written explanations in rulemaking documents," and found that beyond early interaction, "...there are many other instances in which it would be helpful to ventilate a more fully developed proposal prior to issuance of the final rule, and thus, such interaction necessarily would take place later in the process." NEI stressed the need for NRC flexibility regarding the form of public interaction in any individual rulemaking, noting that simple rulemakings may require only written comments, whereas rulemakings involving "...more complicated technical issues or significant policy revisions may need additional stake holder interaction through public meetings, RAls or other means."

When should Agreement States participate on NRC's working group? The working group is responsible for development of the Rulemaking Plan, the proposed and final rule, and all supporting documents. What is the best method to ensure that one Agreement State participant expresses the views of all Agreement States or should a single participant just represent their own State?

Comments from the States were split on the method of Agreement State participation.

Texas, Arkansas, Illinois, and Ohio agreed there should be one designated Agreement State representative for Working Groups, with these divergent specifications: Texas believed that Working Group representatives would need to be "trained" as to when it is appropriate to speak for all Agreement States, most Agreement States, or to represent the single State the representative is from. Arkansas stated the representative should express the views of all states, and that it would be especially useful if the participant has unique and special knowledge relevant to the rulemaking. Illinois stated that the representative should solicit and represent the majority view, and any minority view should be provided in a written statement. Ohio emphasized that Agreement State Working Group members should be chosen at the same time NRC members are chosen, so they can work as a team on the whole process. Ohio

seemed to best express the range of concerns accompanying the selection of one member to represent all Agreement States:

...the best any one individual from a state can do is to give "a state perspective" unless the individual is tasked to take rulemaking issues to a forum like RADRAP to get comments from all states (or those who want to respond) and bring this information back to the working group. Agreement state members should be charged with the responsibility of reaching out to other states so that there is better assurance that the state members are providing the state perspective and not their own. This may also be a topic to discuss at the OAS meeting: "What is the expectation/duties of the state participant on an NRC rulemaking working group?"

Louisiana stated that an Agreement State participant should represent the OAS, and should be provided with guidance reflecting a consensus position. Yet Louisiana also recognized that there can be a divergence of opinion from 32 Agreement States, and that a single participant representing his/her own state views might be in alignment with the majority of the Agreement States opinion, or, in a worst-case method, the single participant has an opposite view from the majority of Agreement States. Louisiana noted that it may be important at times to consult with non-Agreement States to get a broader view of State opinion on a rulemaking issue.

Maine also stated that a representative from both OAS and CRCPD should be on the Working Group and that there should be at least two (Agreement State) individuals on the group. Maine believes that the views expressed would be a collection of its respective organization's comments, and should be taken into account whether from each individual or from the State.

Utah, Nevada, and Georgia argued that States should participate in Working Groups when the proposed rulemaking impacts the States or when involving a controversial/high-profile issue. Nevada suggested that States be allowed to volunteer for Working Groups if they have applicable expertise or are specifically invited. Tennessee emphasized that physical participation in Working Groups for some States may not be possible because of budget constraints, and suggested that the Commission consider teleconferencing.

Washington believed that having representation from all Agreement States that have particular interest in specific rulemaking activities is best. However, where participation must be limited, there should be at least three Agreement States represented, from differing regions and program sizes; and further, these State representatives should be encouraged (but not "required") to poll other Agreement States to ensure representative views are brought to the Working Group.

Georgia expressed a similar viewpoint, noting that the diversity of needs of the various Agreement States require a single State participant to represent only its State.

Should Agreement State involvement be dependant upon various factors (i.e., the potential complexities of the rule, potential impact on States, particular State expertise, etc.)?

All but two respondents stated that Agreement States should be involved in all rulemakings that have the potential to affect their interests. The exceptions were Louisiana and Georgia, both of which stated that OAS should assign participants to Working Groups based on experience and an interest in the subject the Working Group would be addressing.

Texas, echoed by Ohio, and Arkansas, emphasized that the States themselves are often "centers of expertise"; Ohio elaborated that "state expertise on a topic could make the process go faster and smoother since the Working Group could benefit from state experience."

Arkansas commented that "the NRC is not always on the fore front [sic] of radiation protection issues," but stipulated that although Agreement State involvement depends on the complexity of the rule, impact on States, and expertise in the rule, there is also "...the consideration of participation time and a State's ability to pay expenses."

Utah noted that "...it is often difficult to balance priorities to have time to review a proposed rule, much less devoting resources to a Working Group developing a rulemaking plan and beyond." Illinois also cited factors such as resources of time and money as affecting State involvement in NRC proceedings, and notes that "...the NRC must recognize that it cannot demand state participation, or consider lack of participation to be equivalent to lack of interest."

Washington points out if the number of States desiring to participate exceeds the NRC ability to fund participation, then representation should be based on evidence of expertise, then potential impact to the state; additionally, Washington states that Agreement States wishing to participate at their own expense should be permitted to do so.

Ohio acknowledged that in NRC-only rulemakings State involvement would be minimal, and Maine stated Agreement States should be involved at all times except when rulemakings pertains to an NRC-only rule.

When the NRC is developing the rule without specific Agreement State support, what is the best method to provide Agreement States NRC products? And what products should the NRC provide (early drafts, drafts prior to going to the EDO/Commission, etc.)?

Texas and Ohio stressed that the majority of NRC rules shouldn't be developed without Agreement State input. Texas, Ohio, Georgia, and Nevada agreed with Arkansas, which stated that in the few cases without State input, such as reactor rulemaking, supplying Agreement States with any early drafts on an informational basis and all final drafts before going to the EDO/Commission would be appropriate, provided Agreement States have sufficient time to comment and NRC staff has time to consider the comments and revise the drafts throughout the process.

Arkansas also noted that rulemakings going to the EDO/Commission before going to the Agreement States often put NRC, particularly STP, in battle with the States, on compatibility issues.

There were several different methods proposed for distribution of early drafts. Illinois recommended the use of notices from STP to include early drafts and all later drafts. Louisiana and Maine both suggested early drafts be provided to OAS or CRCPD for review. Georgia wanted posting via a list server, and stated that the TCF could be used to notify States of a (dated) posting.

Utah commented that NRC has to decide which rules will be developed without support (such as simple changes to rules), and stated that the best method to alert Agreement States regarding NRC products is during the monthly OAS/NRC teleconference.

Tennessee stated it would not support using RADRAP for official discussions with the rulemaking review process.

Currently Agreement States can use the TCF to provide input to the NRC. Can this be improved and/or what other methods would Agreement States like to use to provide input to the NRC?

Agreement State responses to the TCF ranged from Ohio's positive comment that the TCF has been working, and it is easy to download drafts for review and comment, to Arkansas's response that the TCF is very difficult to use and access. Utah states that the TCF input is not user-friendly.

At the far end of the spectrum is Nevada's comment: "Don't know what TCF is?" Significantly, Washington believes additional "advertising" for the TCF is needed, including periodic reminders that certain topics are still under discussion. Currently, Washington points out, the TCF suffers from being "out of sight, out of mind."

Utah, Texas, and Arkansas stated that it is more effective to directly e-mail comments to a designated contact person, despite the drawback of not allowing other States to view each other's comments.

Texas and Utah noted increased use of commenting via the RADRAP, and Utah also supported the idea brought up at the teleconference of automating endorsement of comments from other States with a response comment form on the NRC STP web site.

Illinois backed using the TCF for technical exchanges of information and ideas, but stated that formal letters should be used for formal communications to NRC; Illinois also observed that the TCF is used to download information, but is not used by many States for posting comments.

Louisiana favored the use of notices to State Liaison Officers; Maine, and Nevada argued for commenting individually or collectively through the OAS and/or CRCPD.

Georgia and Tennessee recommended several formatting and procedural changes, including: the addition of the date of the posting; comment deadlines; a "thumbs up" feature to the existing reply options (without soliciting any additional comments); streamlining bullets or an outline format; and always sending a list serve notice of a posting.

How should the NRC treat comments from State officials that are not the official Agreement State comment?

A ballot count of the responses showed that five respondents (Washington, Arkansas, Georgia, Utah, and Maine) stated that all comments should be treated equally, and that five States (Texas, Ohio, Nevada, Illinois, Louisiana) believed some form of differentiation was necessary if the State official commenting is not the director of the Agreement State program.

Texas said NRC should "...identify the comments as to who they came from, whether that's the agency designated as the radiation control program(s) or another state official."

Ohio affirms that comments need to come from the Agreement State official for them to be characterized as comments from that particular Agreement State, but acknowledges that

comments from organizations/licensees within a State should be given equal status, and such entities be allowed to freely comment. Ohio states that NRC should verify such other comments with the Agreement State official.

Nevada pointed out that an Agreement State manager may not be aware of comments from other state officials such as Governors or State Liaison Officers, and noted that while they may be "official," such remarks should not be considered indicative of the Agreement State manager's opinions or input.

Illinois argues that the radiation control program director should be contacted on a case-by-case basis regarding such comments, unless offered in a public forum such as a workshop or an Agreement State or CRCPD meeting, in which case NRC should take those comments into consideration even if they are not followed up by a formal letter on State agency letterhead.

Louisiana states that the official Agreement State position should be determined by CRCPD or OAS.

How long should the Agreement States generally have to comment?

The respondents recommended comment periods ranging from 30 days to 90 days; Nevada stated that Agreement States should be given enough time to organize a teleconference among themselves, but did not specify a precise time period. Ohio indicated that the current comment periods are adequate. Utah and Louisiana recommended 30 days, but Utah added a provision to allow the opportunity to request more time to review complex, controversial, or high-stakes rulemakings.

Texas, Illinois and Georgia suggested 6 weeks/45 days, minimum; 90 days for long documents or for complex or controversial issues. Illinois stated that a review period could be shortened to 30 days in instances where the rule is a revision with highlighted changes from the previous version.

Arkansas and Maine recommended at least 60 days to comment on a rule, and Washington suggested at least 90 days for any major rules, noting that 60 days may be adequate, but "...in many instances that would be insufficient time for appropriate state staff review and consideration by state management."

When Agreement States identify a regulatory problem and have the expertise to develop a rulemaking, should Agreement States take the regulatory lead in the rulemaking process?

Six Agreement State commenters (Texas, Washington, Ohio, Louisiana, Georgia, and Arkansas) said that an Agreement State with expertise should take the lead in developing a rulemaking. Georgia warned that "...the NRC should not come back and reinvent the wheel."

Washington and Arkansas cautioned that the Agreement State must work closely with NRC to ensure compatibility, and that NRC will be the liaison to the Commission. Louisiana suggested that NRC might wish to form a Working Group to assist the Agreement State in developing the draft regulation.

Nevada asserted that although an Agreement State can't effect an "NRC rulemaking," it could proceed with a State rulemaking because of its own expertise and ability to move the process ahead. Illinois, on the other hand, noted that having the expertise is a:

...necessary but not sufficient condition to develop a rulemaking. Having the time and financial resources to do a rulemaking in a timely manner is also important. The rulemaking process in some states is not as elaborate as NRC's, and the work product might not have the backup information that NRC needs to adopt a similar rule.

Utah agrees with the summary of "States Taking the Lead in Rulemaking," as described in the summary of rulemaking teleconference notes. Maine stated that NRC should coordinate with CRCPD and the OAS on the prioritization of the rulemakings.

How should the NRC interact/coordinate with Agreement States regarding the setting of priorities for various rulemakings?

Texas and Washington endorsed use of the National Materials Program Working Group Report recommendations, which propose an implementation plan to enable NRC and the States to jointly establish priorities for regulatory issues. Washington adds that it would be helpful if NRC would send notification to Agreement States in advance of prioritizing rulemakings, and ask for Agreement States to provide information to NRC about the relative importance to the State of the proposed rulemakings.

Arkansas stressed the need for early Agreement State involvement in the process. Ohio suggested working out general schedules together, possibly at the Agreement States meeting in the fall or at the OAS meeting, and put on TCF for comment and finalization. Illinois and Louisiana also supported working through the OAS/CRCPD, and Utah recommended using the monthly OAS/NRC conference calls.

Nevada states that if "setting of priorities" equates to establishing levels of compatibility, Agreement States should be invited to participate.

Georgia recommends a coordinated effort between NRC and the States based on the Table Top model initiated by the National Materials Program Working Group at the Charleston, S. C. Agreement States meeting. Georgia also supports use of the OAS Executive Board. Georgia notes that there is a basic difference in philosophy between NRC and the States--States generally have compliance as the highest priority and NRC has enforcement as the highest priority.

One additional comment was submitted by Texas, explaining the recommendation of the National Materials Program Working Group that NRC and the States have a Standing Compatibility Committee. Texas claimed this committee is needed to provide a more objective designation of compatibility by persons not directly associated with the rulemaking and to prevent straying from the intent of the compatibility designation policy. Texas cited an instance where editorial changes in a 10 CFR Part 39 rule resulted in a questionable Compatibility Category designation.

How useful is the initiative by the NRC to place draft rulemaking language on the NRC Web site with or without the associated statement of considerations?

NEI, PROS, TVA, and Vernig all responded that the initiative is beneficial (when timely), but that NRC should include the Statement of Considerations whenever possible.

In addition to the use of the Federal Register and the NRC rulemaking Web site, what other forums would be effective in informing the public about rulemaking activities?--e.g., e-Mail, mailing lists, announcements on related Web sites, public meetings, or other suggestions.

TVA suggested that a new forum to inform the public about rulemaking activities might be a subscription service providing e-mail distribution of the Federal Register notice, similar to the service that the NRC is providing for distributing general communications. PROS states that all activities that impact an individual license holder should be communicated with direct correspondence to the PROS through linked announcements to the PROS website. Vernig states that NRC should develop e-mail lists just as it has traditional mailing lists for licensees and interested parties and send out notices of rulemaking activities electronically, though he also acknowledges that other methods such as fax and USPS might be preferred by some stakeholders.

NEI finds Federal Register notices and listings on the NRC web site to be adequate notification to anyone interested in NRC rulemakings, but notes NRC may opt to develop e-mail and/or mailing lists for categories of issues as a stand-alone communications effort, or alternatively, could choose a case-by-case approach in which an e-mail and/or mailing list is developed for a particular rulemaking. NEI cautions that NRC should not burden the rulemaking process with unnecessary communication efforts. The public citizen would like NRC to require advance public notice in local newspapers because publication in the *Federal Register* is not adequate notice. (Note that the commenter seemed to be primarily concerned with the CoC rulemakings.)

The general process used by the public to provide comments on rulemakings published in the Federal Register is to either mail the comments to the Secretary, U.S. Nuclear Regulatory Commission or use the NRC's interactive rulemaking Web site. In addition, public meetings are occasionally used for obtaining public comments for some rulemakings.

Are there any other methods that might be used to facilitate public comments on rulemaking activities? What method of public interaction on rulemaking activities is preferred? How useful are public meetings for communicating NRC rulemaking activities to all

TVA finds the current process generally sufficient, notes that the Rulemaking Web page is effective when postings are timely, but warns that methods such as dial-up conference calls might complicate and slow down the process by allowing the submittal of incomplete or anonymous comments. PROS, on the other hand, favors the use of advanced communications such as phone-bridge, which allows organizations to participate with minimal financial impact. Vernig believes NRC should encourage the use of e-mail by itself or with attachments, and notes that an interactive website may not be as attractive to commenters who may need more than one sitting to prepare their comments, and may not wish to store half-finished comments on someone else's server. NEI favors the use of public meetings with a variety of structures: limited statements by stakeholders, panel discussions with written questions, or workshop settings. For more complicated matters, NEI recommends using a limited request for information (RAI)-type process available to all commenters, and proposes the RAI process:

Be handled through mail, email, conference call;

Also could be posted on NRC website;
Have a short turn-around time;
Be limited to those who submitted comments to the original Federal Register notice; and
Be limited to existing issues.

NEI emphasizes that the purpose would be to ensure NRC understands the commenter's position or data so that NRC can make a more informed decision. NEI states that public meetings are not always the best method for providing information on rulemaking activities, and that a letter, e-mail, or conference call involving all commenters may in some rulemaking circumstances, be more effective. NEI states that a public meeting should also be a vehicle to communicate the status of the rulemaking and future activities needed for staff to complete its review. PROS states that workshops for issues that directly impact the NRC licensed operator provide a forum for an independent view of issues, and notes that meetings held before rulemaking provide the best forum, and those held before issuing a proposed rule provide for uniform implementation.

Vernig admits to ambivalence regarding public meetings, noting that, in cases when input is ignored, the meetings appear to be simply politic for the NRC. Vernig states meetings can be important when input is heeded and when used as an educational tool or to promote acceptance of new rules and changes. Vernig advocates holding some meetings (similar to a scoping meeting) early on in the rulemaking process, possibly at the point where a RMP has been approved. The public citizen objects to the time limits imposed on citizen comments at public meetings, particularly since staff is allowed unlimited time to respond.

Are published responses to public comments on proposed rules generally comprehensive, clearly written, and well-argued?

TVA, Vernig, and NEI state that quality of the responses vary; TVA explains that some are well-written and provide clear, well-argued insight as to the reasoning behind the response, others are too brief to fully explain the reason for the final decision. NEI and Vernig cited particular instances illustrating the shortcomings of NRC responses, including demonstrations of instances of failure by NRC to consider the merit of a comment.

Is the NRC's typical 75-day comment period for proposed rules sufficient?

TVA agreed that the 75-day comment period is usually adequate, but Vernig believed this question to be overly simplistic, ignoring the complexity and length of the rulemaking, which should govern the length of the comment period. Vernig states NRC needs flexibility regarding comment periods, should post changes on the website, and mail hard copies as close to the publication date as practical, noting Federal Register notices can take 2-3 weeks after the publication date to reach licensees.

NEI also supports flexibility, but states that the 75-day comment period, while necessary for complicated rulemakings, is not legally required, and for some rulemakings a much shorter comment period and completion schedule might be appropriate.

How can the NRC obtain better information and comments on the cost or benefit of a rulemaking under development--i.e., information used to create a regulatory analysis?

NEI states that NRC may be able to obtain better information on the cost or benefit of a rulemaking by making its requests for such information more specific. TVA recommends, for issues that will affect larger numbers of licensees, the use of scoping meetings or workshops where the affected licensees are able to participate in the development of possible solutions and provide greater insight on site-specific benefits and implementation costs.

Vernig cited several organizations to use as resources, including the Health Physics Society, Society of Nuclear Medicine, and the American Association of Physicists in Medicine.

Summary

The Task Force agrees with many of the commenters who stated that stakeholder involvement in the rulemaking process should be as soon as possible. This was also emphasized by the OAS and the CRCPD at the Commission meeting on August 21, 2002. But we also agree with the comment stressing the need for flexibility regarding the form of public interaction based on the complexity of the rulemaking. Also, we agree with the commenter noting that the RMP should only include a level of detail necessary to present a rulemaking concept. When the draft RMP is very detailed, some Agreement States believe that NRC has already made its decision, and therefore, their comments may not be well received. One commenter noted that if the rulemaking plans were less detailed, Agreement State participation at this stage would be less important as they could comment on a true draft document. As noted elsewhere in this report, NRC is devoting a significant portion of the total rulemaking effort during the RMP stage.

Many Agreement States want to be involved during the development of the RMP. Since many Agreement States may have expertise and/or experience exceeding that of NRC staff, they would like to provide their involvement at the earliest stages. However, how one or two representatives from Agreement States (or the OAS) would represent the entire Agreement State population needs to be further evaluated as there was a wide diversity in opinions amongst the commenters. Also, funding for Agreement State representatives could also present difficulties in competing against other State priorities. Agreement States also noted that when they have specific expertise, they be allowed to take the lead role in the development of a rulemaking.

The States that the National materials Program Working Group recommendations fully address when States can and should take the lead. Where States have established centers of expertise, NRC should take advantage of that knowledge. The worst situation, from the States's point of view, is when the States get out in front of NRC, develop a solution to a regulatory problem, commence rulemaking, and then subsequently get pushed out of the way when NRC belatedly steps in to address the problem. The States' efforts have been wasted, and NRC starts from scratch.

The States would like to see NRC follow their regulatory lead in cases where the States have already done the spadework. NRC should build on the States' work, instead of reinventing the wheel.

Many Agreement States believe that establishing rulemaking priorities in coordination with NRC would improve the rulemaking process. Various suggestions were provided, but techniques for implementation need further evaluation.

Another topic for further evaluation is how NRC should effectively communicate draft documents with Agreement States. Various methods of informing about, or providing

Agreement States with, such documents, include the NRC Web site; placing documents on the TCF; and the STP letters to Agreement States. States have mixed feeling regarding the usefulness of the TCF. Agreement States extensively use RADRAP and were surprised to hear that NRC staff does not generally monitor this site. Because of the potential benefits of more effective communication with Agreement States, NRC should continue to seek better communication techniques.

The Task Force believes a potential time saver for some rules deals with the length of time for public comments on proposed rules. As one of the commenters noted, the NAFTA requires a 60-day comment period for rules affecting Canada and Mexico. A related Executive Order requires a 75-day comment period. This 75-day comment period has become the "norm" for NRC rules. However, some NRC rules may not fall under NAFTA. The Task Force recommends that OGC consider use of a shorter comment period for some proposed rules, if legally permissible. Although many rules should allow for this type of comment period, there may be some rules where a 30-, 45-, or 60-day comment period is sufficient. Although this may not be a significant savings, it would allow the staff to make informed decisions instead of "practice as usual."

A tool that would be beneficial to the staff is criteria or guidelines for determining when to use enhanced public participation. Staff often question whether to use enhanced public participation and what is the most appropriate public participation mechanisms. The Task Force recommends that the offices (alone or together) develop criteria for using enhanced public participation. The criteria should include guidance on when different mechanisms are most effective. The different mechanisms include, but are not limited to, the following: an ANPR; Issues Paper; concept or draft rulemaking plan; draft language on the web; draft language in the *Federal Register*; use of e-mail lists for notification; workshops; town hall style meetings; Q&A style meetings; simple comment style meetings; explanation meetings; presentation at society meetings, presentation at conferences, Commission meetings, etc.

Historic Rule Data

The Task Force collected data on rulemaking activities that received rulemaking numbers and/or were published in the *Federal Register* since 1995. (Earlier information was also collected but is not as complete.) Information was collected on the RMP, proposed rule, and final rule phases. Sources of information included the RAP, rule status reports, rulemaking webpage, SECY papers, archived data collected by ADM, the *Federal Register*, rule files, the RIDS, and staff hour utilization reports. There was no one source that could be consistently relied on to have all the desired information. Information on how long a document was in the concurrence process was not readily available, because the concurrence page doesn't usually have the beginning date since the author generally reconcurs when changes are made. Initiation dates, TAC numbers, and individual rule expenditure data are other examples of data that was not readily available. There are holes in the information where it was not cost effective to continue the search. An ACCESS database was used to help analyze the data.

Different queries can be used on the database to gather a variety of information. Data can be sorted by office lead, type of rulemaking (safety, burden reduction, and other), priority, complexity, rule stage, etc. Table D.1 in Appendix D contains a listing of information contained in the database. Calculation queries were performed to obtain information on the number of rulemakings and the length of time to complete a RMP, proposed rule, and final rule (including the Commission review time). Tables containing data from some of the queries, an example query, and figures showing average and median times to complete various phases are also contained in Appendix D. The 2002 data presented in this report is through the end of July.

Rule Data

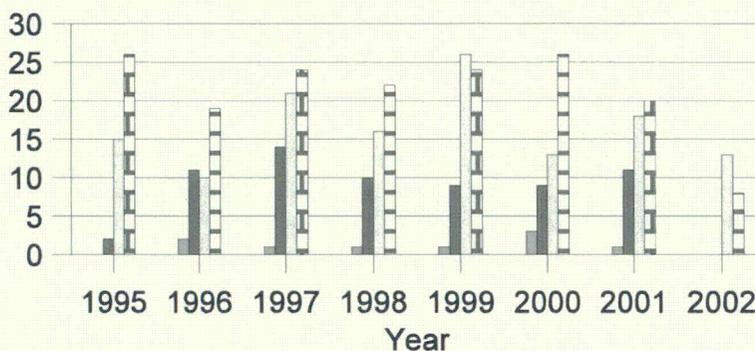
Data show that the total number of final rules NRC has issued per year has remained fairly consistent since 1995. The average number of final rules has dropped from 28.4 per year for the period 1990-1994 to 23 final rules per year for 1995-1997 and for 1998-2001. The number of rules completed by NMSS and NRR since 1998 show more variation. NRR experienced a peak of 11 final rules in 1999, probably because of an effort to complete rulemakings initiated by RES. NMSS showed a large peak in 2000 that can only be partially attributed to the CoC rulemakings for spent fuel storage casks. Table 1 shows the number of final rules by year for NRC overall and for just NMSS and NRR. If the trend for 2002 continues, the total number of rulemakings for 2002 will be less than half of the average of 23 rulemakings a year since 1995. This can only be partially explained by the redirection of effort to security issues.

Table 1. Number of Final Rules from 1990 to 2002

Calendar Year	Total Number of Final Rules	Number of NMSS Final Rules	Number of NRR Final Rules
1990-1994	142 (28.4 avg per year)	NA	NA
1995	26	2	2
1996	19	2	0
1997	24	0	0
1998	22	9	3
1999	24	7	11
2000	26	17	3

Calendar Year	Total Number of Final Rules	Number of NMSS Final Rules	Number of NRR Final Rules
2001	20	13	2
2002	8	5	1

Figure 2 shows the total number of each type of rulemaking action (ANPRs, RMPs, proposed rules, and final rules) for the Agency as a whole. The number of proposed rules shows the greatest variation over time. The number of proposed rules in a given year does not appear to track the number of final rules in the following year just as the number of RMPs does not seem to track the number of proposed rules in the next year. Although RMPs have been in place since 1995, the majority of final and proposed rules do not begin with a RMP. Reasons for not having a RMP include the use of a DFR; an APA exempt rule (no proposed rule either); or the Commission directing the staff to proceed with a proposed rule. If APA exempt rules and the direct final rules are removed from the total, the percentage of final rules that initiated from an RMP is less than 50 percent.



Number of Rulemaking Actions

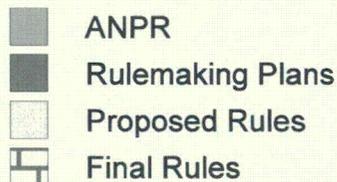


Figure 2. Total Number of Rulemaking Actions from 1990 to 2002.

Data were also obtained on the length of time taken for each rule stage. It is obvious from the data that the time necessary to complete a rulemaking has been gradually increasing. The average time from RMP approval to publication of the final rule went from 276 days, in 1997 to nearly 1130, days in 2001. This is significantly above the agency goal of 18 months (540 days) to complete a rulemaking. The median time experienced a slightly larger increase from 243 days in 1997 to 1309 days in 2001.

Final Rules

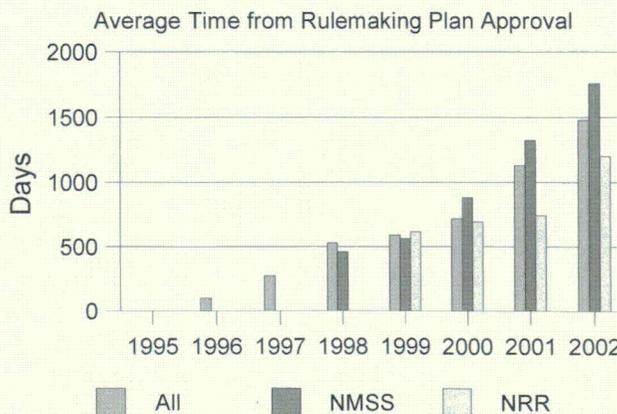
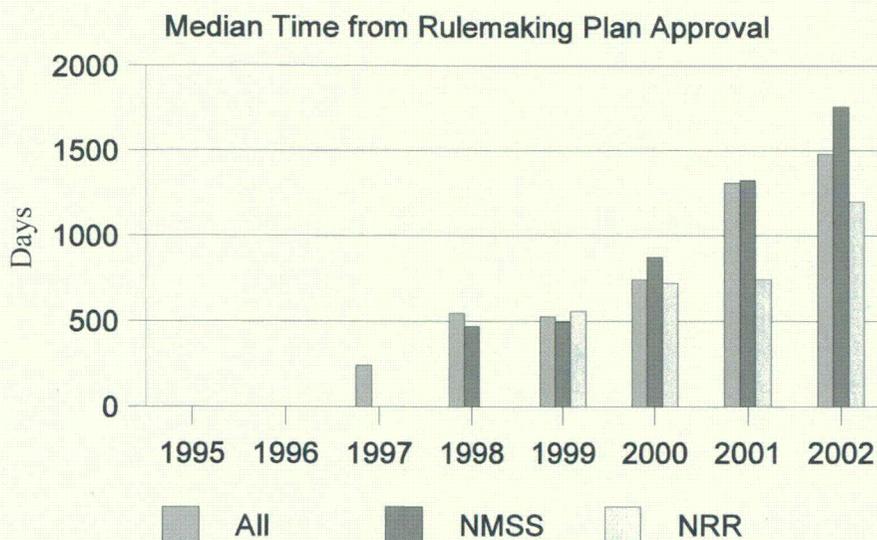


Figure 3. Average Time from Rulemaking Plan Approval to Final Rule Publication.

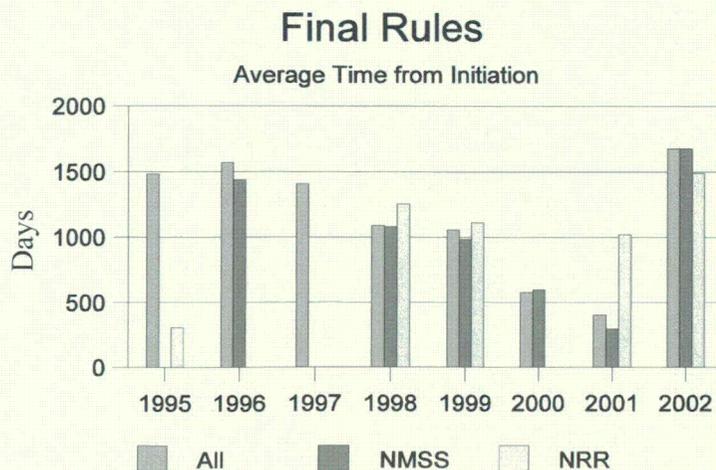
Final Rules



The data to date for 2002 show a continuing increase. Figure 3 shows a bar chart of the average time in days from 1995 to 2002 - the increasing trend is very apparent. The figure shows the average for all rulemakings and breaks those out that were developed by NMSS and NRR. The trend is apparent for both offices, as well as the Agency as a whole. Figure 4 shows the chart for

Figure 4. Median Time from Rulemaking Plan Approval to Final Rule Publication.

the median time. Medians are shown in addition to the average, to reduce the potential impact from a few rulemakings that might be considered outliers. In general, NRR is getting its proposed rules out more swiftly than NMSS, but is taking a little longer at the RMP stage. The time from the publication of the proposed rule to the publication of the final rule is about the same. The time from initiation to publication of the final rule was also calculated. It should be



noted that the initiation date for all the rulemakings was not available. All calculations are based on the data available. If additional information had been available, some of the time values may have been different. The overall time from initiation to publication shows a decreasing trend. Based on the information to date, there is a large increase for rules completed in 2002. This is in part because of the Part 35 multi-year rulemaking effort. In 2002, NRR exhibits a large increase in both the median and average time; this is based on only 2 rules. The overall average and median show a decrease in 2001.

Figure 5. Average Time from Initiation to Final Rule Publication.

Figure 5 shows the average time in days from the initiation of rulemaking to publication of the final rule; Figure 6 shows the median time. There are some apparent discrepancies in the data. For example, the average time from initiation for the years 2000 and 2001 is less than the time from approval of the rulemaking plan. This is because the initiation dates were not known for several of the rulemakings, and CoC rulemakings are streamlined and do not have a RMP. Although this makes absolute comparisons hard, you can view the general trends and it does point out the need for better routine data collection.

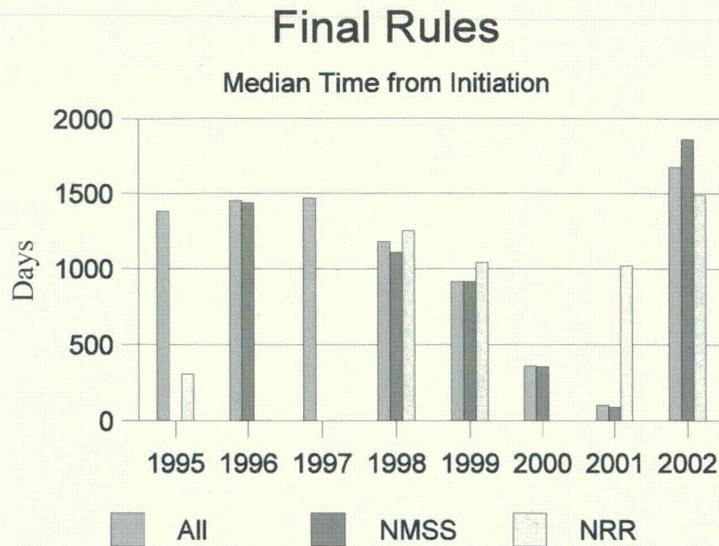


Figure 6. Median Time from Initiation to Final Rule Publication.

Figure 7 shows the average time for each phase of rulemaking (based on available data) for the years 1995 to 2000. One conclusion can be drawn from the data; RMPs are taking too long. The time is not reflected in a savings (timewise) on the proposed rules. The time to complete a proposed rule is also increasing. Each phase seems to be taking longer. The reasons are not obvious, but review and concurrence times appear to be a factor. For a typical final rule

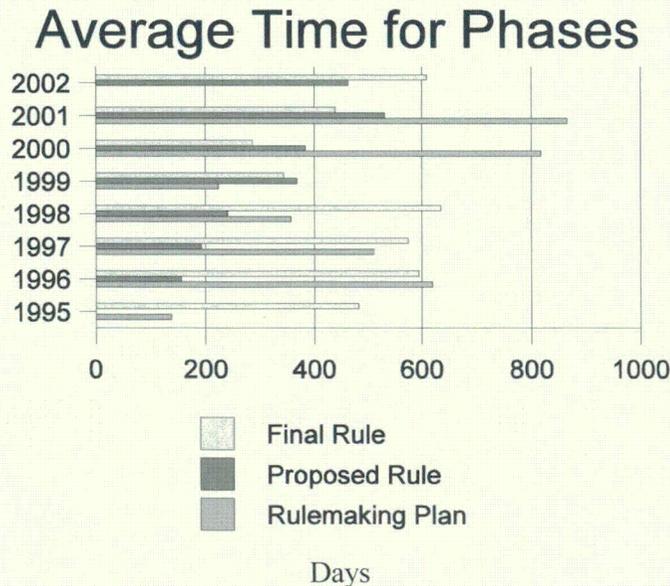


Figure 7. Average Time to Complete Rulemaking Phases.

package, about 60 percent of the scheduled time is for review and concurrence by the various management levels. This goes up when Agreement State and Commission review time are included. Agreement States are given 30 to 45 days (depending on the rule phase) for review and comment. If external stakeholders are provided time to comment on drafts, the percentage would further increase. Commission review adds on average about 2 months to each stage of rulemaking. Delays occur for the same reasons as determined in 1994 - redirection of approach, issues raised during later stages of concurrence, and diversion of staff resources to higher-priority rulemakings. Management availability also appears to be a factor in today's environment - no time available to review the package.

Expenditure Data

The Task Force obtained the resource expenditure data for the available rulemaking TACs. The information was gathered for the periods that would cover the RMP, proposed rule, and final rule. The assembled data is presented in Appendix B. The average expenditure for each phase of rulemaking was calculated for simple, moderate, and complex rulemakings for both NMSS and NRR. Figures 8 and 9 show the percentage of effort extended for each phase for

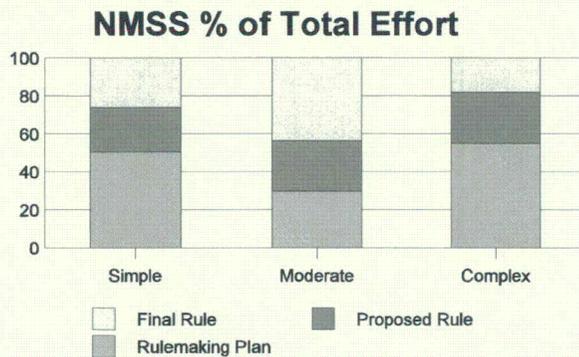


Figure 8. NMSS Rulemaking Effort by Stage.



Figure 9. NRR Rulemaking Effort by Stage.

NMSS and NRR rule efforts. As indicated by the bar charts, it appears that too much effort is being expended on the RMPs, particularly by NMSS. This supports the view expressed by many of the staff that RMPs have become too complex and burdensome. In part, this may be from charging the development of the technical basis to the rulemaking TAC versus tracking the charge separately. The RMP should not require more effort than development of the proposed rule. NMSS expends nearly the same effort on an RMP for a simple rulemaking as for a moderate rulemaking; NRR on average has expended more effort on a simple RMP than on a moderate level RMP. Figures 10 and 11 show the average total hours for each phase of rulemaking.

NMSS Average Effort by Stage

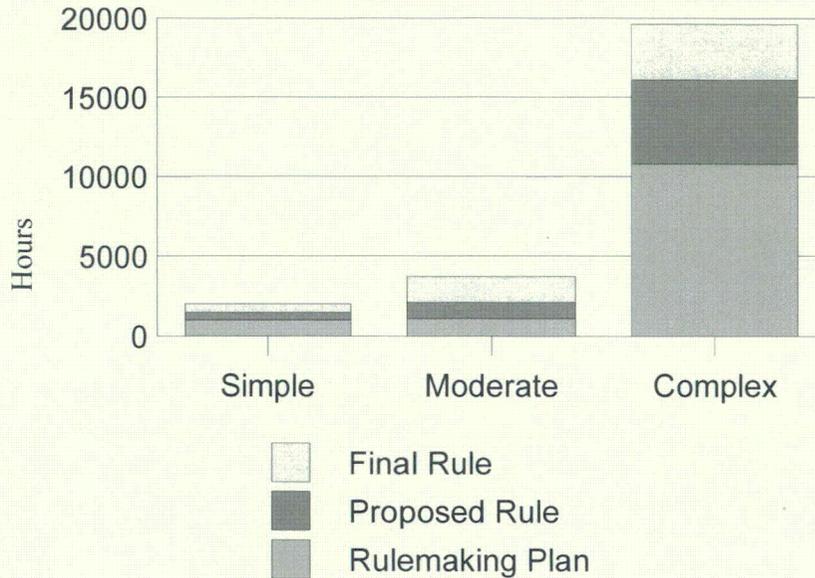


Figure 10. NMSS Average Total Effort by Stage.

NRR Average Effort by Stage

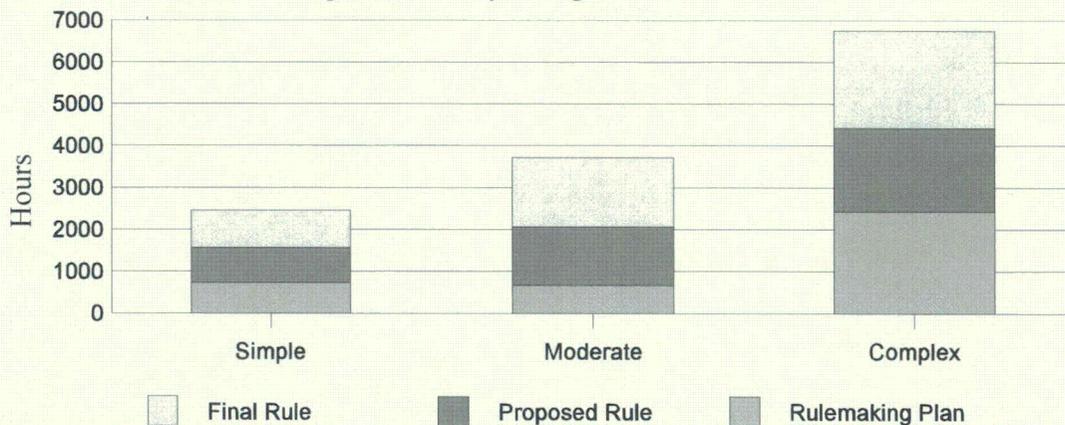


Figure 11. NRR Total Average Effort by Stage.

The averages for the moderate rulemakings are similar for both NMSS and NRR. NRR on average expends more resources on simple rulemakings than NMSS. However, there is a huge difference in the average number of hours expended for a complex rulemaking, NMSS has expended more resources than NRR at each phase of a complex rulemaking. It is not clear why. It may be in part because of the artifact of the data the Task Force could obtain on expenditures; if more data had been available the differences might not have been as large. Of course additional data could also make the differences more pronounced. The Part 35 effort is not included because the expenditure data were not available (unknown TAC number before 1999). These values may also change significantly with the completion of a couple of

rulemakings. For example, the NRR Option 2 rulemaking has already expended nearly 23,000 hours on the proposed rule. When this rule is completed, the average for the proposed rule will significantly increase.

Both NMSS and NRR should closely monitor the charges to rulemaking TACs. Resource expenditures significantly different than estimated at the outset of rulemaking should be a red flag to management. Either not enough resources are being applied to the effort and it may be in danger of missing future milestones or the rulemaking has encountered challenges or issues that should be surfaced for management action. Both offices should also continue to collect the data so that a better database will be available for future use. The data (in Appendix C) also show that both NMSS and NRR do a poor job of estimating necessary effort to conduct a rulemaking. The rulemaking budget has been either over or under estimated by ± 20 percent for the majority of rulemakings; 69 percent for NMSS and 75 percent for NRR. NRR underestimates 63 percent of the time and NMSS 54 percent of the time. There are several ongoing rulemakings where the budget estimate has been exceeded at the proposed rule stage. For example, the budget estimate for the 10 CFR Part 71 rulemaking was 4.81 FTE. The staff had already charged 9.3 FTEs when the proposed rule was published. It might be useful for management to evaluate these expenditures to better understand why so much effort has been expended on the significantly underbudgeted rulemaking activities. Both NMSS and NRR should use the existing expenditure data to better estimate the effort necessary to conduct a rulemaking.

Benchmarking NRC's Rulemaking Performance

Using the rulemaking data collected internally, the task force was able to create a statistical profile of NRC's rulemaking performance. To provide an interpretative context for this data, the task force asked several other Federal regulatory agencies to supply key information about their own rulemaking procedures and performance. The 10 agencies targeted by the task force were chosen because they were similar to NRC in either administrative structure or public service mission.

The task force sent each counterpart agency a survey instrument consisting of three parts:

- A general request for information about the counterpart agency's current rulemaking procedures.

- A request for specific data about proposed and final rules that the counterpart agency had published in the last 5 years.

- A series of questions about specific elements of the counterpart agency's current rulemaking practices.

A cover letter explained the mission of the task force, and noted that the rulemaking improvement report under development by NRC task force was intended for internal NRC use only. Cooperating agencies were assured that, if NRC subsequently made all or part of the report publicly available, benchmarking information used in the report would be summarized, and would not be identifiable by agency. The task force also offered to share the results of NRC's benchmarking effort with the responding agencies. A comparison of rulemaking efficiency among the agencies is discussed below. The rest of the benchmarking effort is discussed in Appendix E. The letter sent to other Federal agencies is also provided in Appendix E.

Four of the 10 agencies targeted responded to the request. All the responding agencies are health and safety regulators; none is an independent agency. As sub-agencies of Executive Branch departments, their regulations are subject to regulatory review under Executive Order 12866, a process from which NRC is exempt. However, the responding agencies described notice-and-comment rulemaking procedures broadly similar to those in place at NRC, and all reported using measures of rulemaking efficiency comparable to those identified in the survey.

Of the four responding agencies, three use a central rulemaking office to draft rules, manage rulemaking projects, and maintain official rulemaking files and tracking systems. In two of the three agencies, a project manager from the rulemaking office leads a rulemaking team that includes one or more technical experts, a lawyer, and, typically, an economist. In the remaining agency, a similarly constituted Working Group is headed by a team leader drawn from the technical staff. The staff of the rulemaking office secures all the necessary legal and policy clearances; coordinates the efforts of all offices contributing to the rulemaking package; ensures that rulemaking documents and packages conform to all administrative and statutory requirements; and guides the package through the required internal and external reviews.

In the fourth agency, a regulator that generates only a handful of new rules in an average year, rules are written by the technical staff, but the rulemaking office manages the project, coordinating staff effort across offices and ensuring that the package conforms to all relevant administrative and publication standards.

Rulemaking Efficiency: Comparing NRC to Counterpart Agencies

The second part of the survey asked the counterpart agencies to supply data on a set of quantitative measures of rulemaking efficiency. The period spanning the last 5 years was specified as the range for data collection. Agencies were also asked to indicate whether the figure provided for each performance measure represented hard data or an estimate. Agencies were asked to provide annual averages for:

- The number of FTEs budgeted for rulemaking;
- The number of final rules published;
- The number of proposed rules published;
- The number of published rules that aim to:
 - Enhance public safety,
 - Reduce regulatory burden, and
 - Achieve other ends;
- The number of APA-exempt rules published;
- The number of DFRs published;
- The number of days from the initiation of rulemaking to publication of a proposed rule;
- The number of days elapsed from publication of a proposed rule to promulgation of a final rule; and
- The number of days required to obtain OMB clearance for rulemaking-related Information Collection Requests.

Note: One of the four responding agencies, Agency C, differed from the rest of the comparison class in that its recent regulatory strategy and practice have not emphasized rulemaking. Although Agency C's rulemaking process is formally similar to that of NRC and the other responding agencies, its record of past performance is not really comparable. Agency C issues an average of only three rules per year, far fewer than NRC or any of the other counterpart agencies. This low-volume rulemaker also reported spending an average of 7 years developing

a rule, far longer than the average time for any of the three other agencies and far longer than the NRC average. However, because Agency C anticipates giving rulemaking a higher priority soon, it chose to participate in NRC's benchmarking exercise and exchange performance information with more active Federal rulemakers.

Dedicated Staffing Levels

Cross-comparison of staffing levels at the various agencies is complicated by the fact that most of the responding agencies consolidate the rulemaking function in a single unit, whereas only one, Agency C, uses a decentralized rulemaking process more directly comparable to NRC's. In reporting rulemaking FTEs, the responding agencies tended to report only FTEs fully dedicated to rulemaking; the effort of legal, Program Office, and related staff were often not figured into the total. The NRC figure was calculated by estimating yearly FTEs expended on rulemaking in all offices with any level of rulemaking responsibility. The figure had to be estimated because hard numbers could not be obtained from budget and planning records.

Table 2 below compares NRC staff resources devoted to rulemaking to the staffing levels reported by our counterpart agencies.

Table 2 Staffing Levels.

Rulemaking FTE	NRC	Agency A	Agency B	Agency C	Agency D
	50	18	50	30	44

Volume of Rulemaking

Over the period spanning 1997-2001, NRC published an average of 23 final rules and 19 proposed rules each year. Agencies B and D promulgated a similar number of final rules in the same period, whereas Agency A published an average of 63 final rules a year, and Agency C published only 3.2 final rules per year. Agency A reported that a significant number of its rules are straightforward, routine, and non-controversial, similar in nature to NRC cask rule amendments.

The chart in Figure 12 shows how NRC rule volume compares to that of the counterpart agencies.

Average Annual Number of Final & Proposed Rules 1997-2001

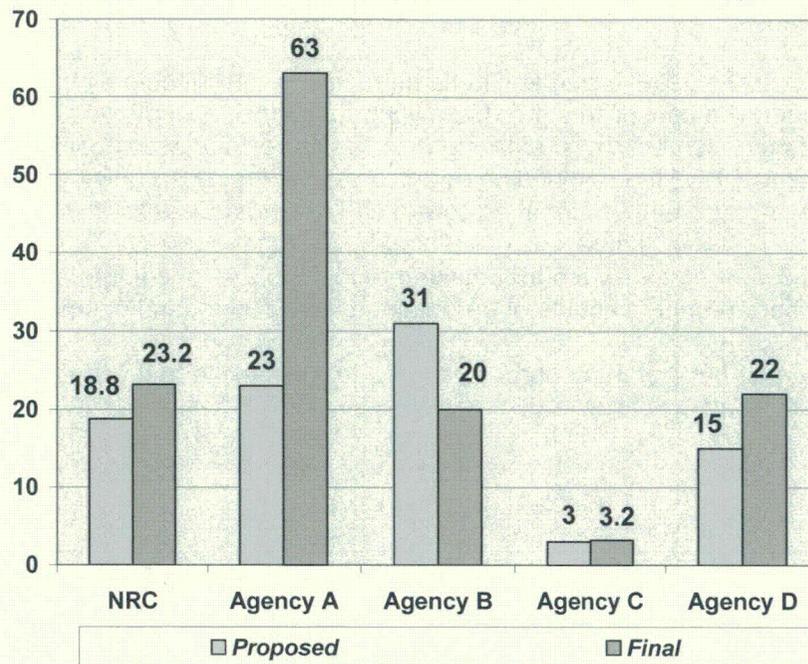


Figure 12. Average Annual Number of Final and Proposed Rules 1997-2001.

Types of Rules Promulgated

Three of the four counterpart agencies reported that between 85 and 95 percent of their annual rulemaking workload consisted of public safety enhancement rules. The exception was Agency A, which reported both a steady number of rulemakings devoted to health and safety (approximately 29 percent of yearly output) and a high volume of routine, non-controversial amendments to rules governing the import and export of regulated substances (64 per cent of yearly output).

NRC typically lists 21 percent of its ongoing rulemakings in the burden reduction category. None of the counterpart agencies placed more than 15 percent of its rulemaking workload in that category. The chart below summarizes agency rulemakings by type.

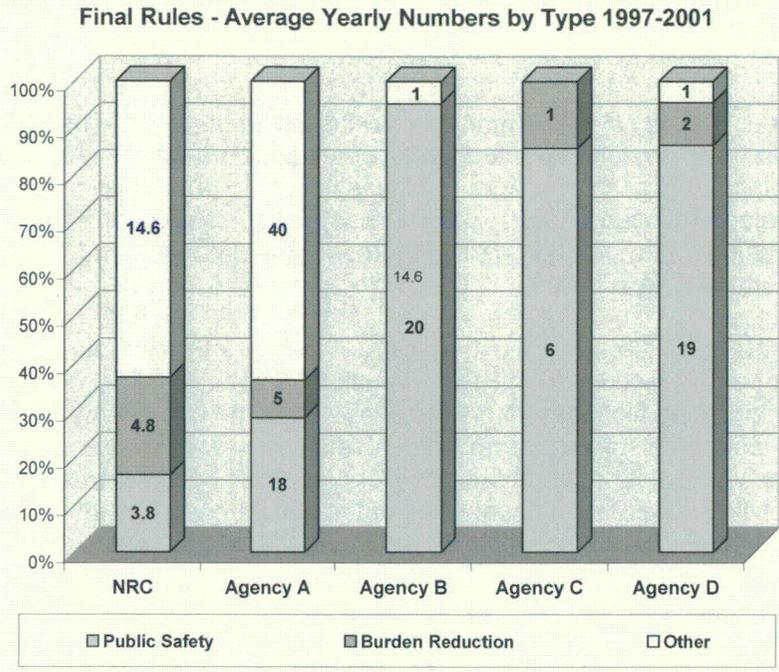


Figure 13. Final Rules - Average Yearly Numbers by Type, 1997-2001.

Time Required to Complete a Rulemaking

With respect to the timeliness of the rulemaking process, comparing NRC’s performance to that of its counterpart agencies is complicated by the difficulty of pinning down how and when a rulemaking is initiated. In the case of NRC, though rulemaking is officially initiated when the Commission approves a rulemaking plan, the time and effort expended in developing a plan should be included when assessing the overall cost of the rulemaking project. Internal rulemaking data gathered by the Task Force reveal that, on average, RMPs take longer to develop than either proposed or final rules. Figure 14 shows how the different stages of the NRC rulemaking process break down in terms of time elapsed to completion.

The responses from our counterpart agencies indicate that the rulemaking clock “starts” at different points in different agencies. Two of the agencies, Agency A and Agency D, start the clock early and begin collecting

Breakdown of Time to Promulgate NRC Rules 1997-2001

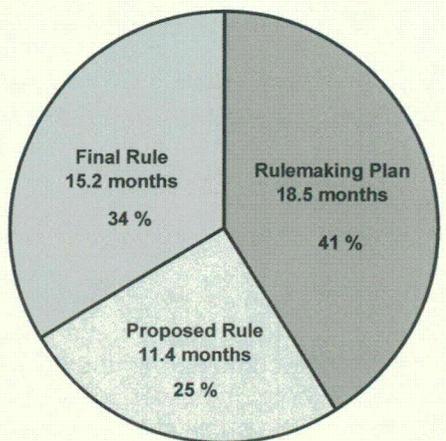


Figure 14. Breakdown of Time to Promulgate NRC Rules

data and tracking progress on a rulemaking project as soon as a draft proposal is formulated. Both these agencies have central, automated tracking systems designed to follow agency rules from inception to promulgation, and to collect data and generate statistics on agency rulemaking overall.

The other two agencies and NRC use manual tracking systems—office-specific correspondence or work logs and updated tables of action items—from which it is difficult to retrieve data for diachronic analysis. Agency C was unable to provide even an estimate of the time taken to develop proposed rules. Agency B was able to estimate the total time taken to complete a rulemaking, but generated partial figures for the proposed and final rule stages by simply dividing the total time in half.

To develop statistics on NRC's rulemaking efficiency, the Task Force first had to comb through multiple sources of data—discontinued RES rulemaking databases, TAC number reports, Program Office rulemaking files, regulatory histories—since no one source had comprehensive information. The task force steadily compiled this data in a new database created in MS Access. When fairly complete data on the last 5 or 6 years of NRC rulemakings had been collected, the analytic and reporting capabilities of the software were used to generate the numbers used in this section.

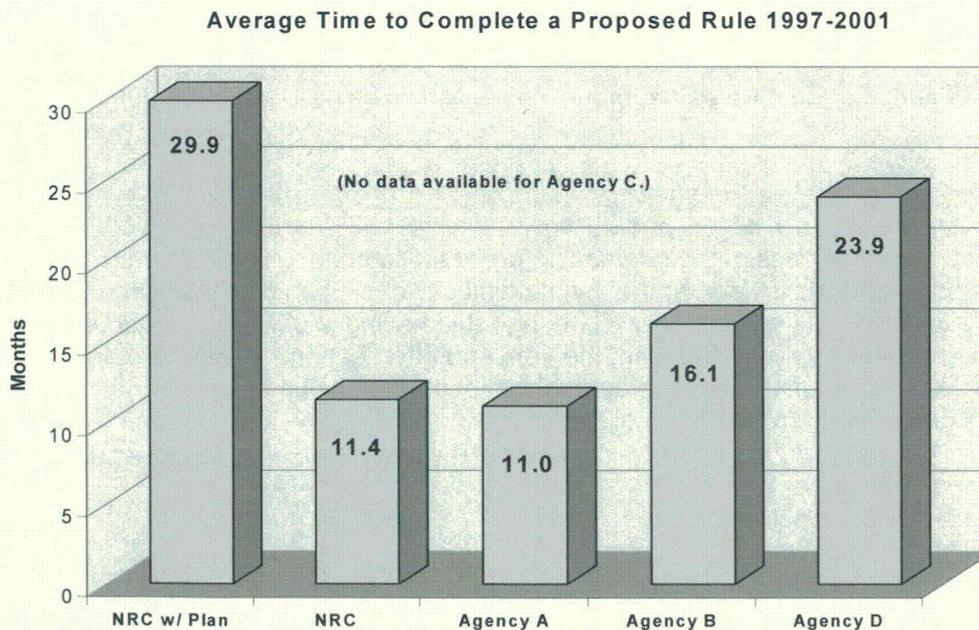


Figure 15. Average Time to Complete a Proposed Rule, 1997-2001.

Figure 15 shows how the time typically taken by the NRC to develop a proposed rule compares to the performance reported by our counterpart agencies. Two figures are given for the NRC: one reflects the average combined time expended on both rulemaking plans and the proposed rules that arise out of them; the other counts only the average time elapsed from the approval of a rulemaking plan to the publication of a proposed rule.

At the final rule stage, official rulemaking milestones become part of the public record, making data collection and analysis much easier. Counterpart agencies determine the time taken to develop a final rule by measuring from the publication date of the proposed rule—or, in some cases, the closing date of the comment period—to the publication date of the final rule. The task force calculated the final rule average completion time for NRC by counting from the publication date of the proposed rule; at least one of the responding agencies, Agency D, calculated its figure from the comment closing date. Figure 16 shows the NRC's performance to be very much in line with that of Agencies B and D, regulators which devote a similar number of FTEs to an average yearly rulemaking workload of roughly the same size.

Average Time to Complete a Final Rule 1997-2001

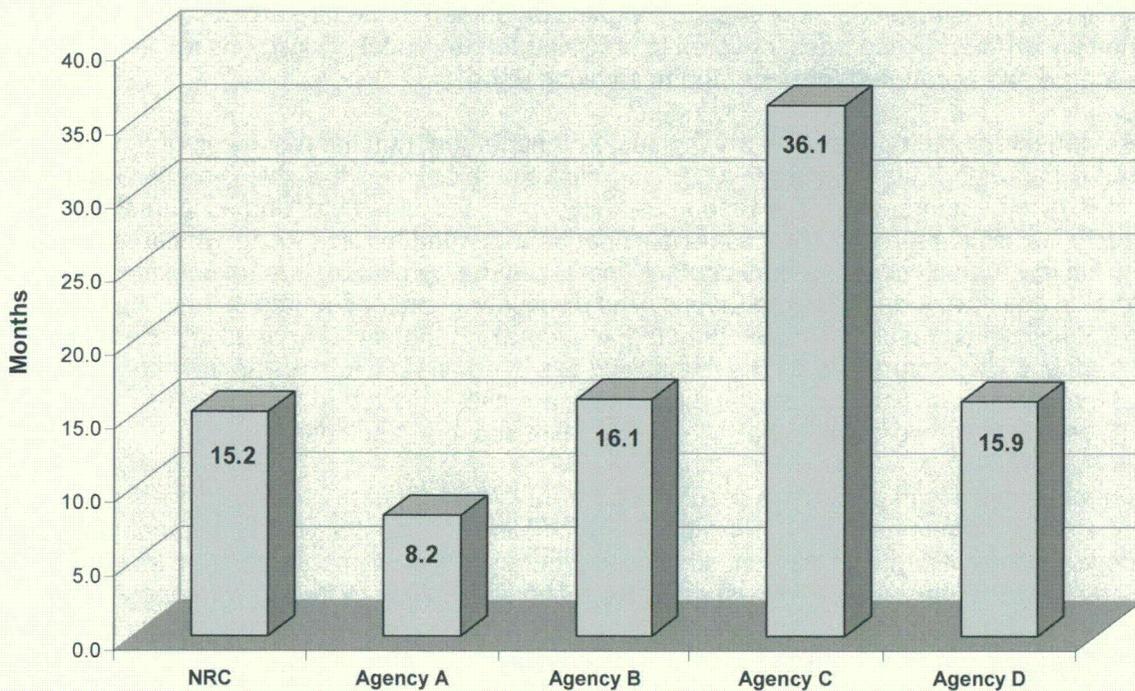


Figure 16. Average Time to Complete a Final Rule, 1997-2001.

Process Improvements

Based on the stakeholder input and collected data, the Task Force targeted several areas for further review and has made recommendations that, if implemented, should improve the efficiency and effectiveness of the overall rulemaking process.

Rulemaking Initiation Screening

The foundation of most effective regulations rests on well defined technical bases. The NRC Regulations Handbook states (NUREG-0053) that rulemakings should not proceed without adequate technical bases. Yet, entry into rulemaking when there are unresolved technical or major policy issues associated with the contemplated rulemaking continues to remain an agency concern.

Many of the most difficult rulemakings (in terms of time and effort) are started without sufficient technical basis. Some of the delays and resources expended on these protracted rulemakings have nothing to do with the rulemaking process but instead can be attributed to developing a sufficient technical basis to support the rulemaking or reacting to policy direction provided after the rulemaking process has begun. Beginning a rulemaking prematurely, before the technical basis had been established, may explain a significant portion of the large expenditures noted for complex RMPs. Resources devoted to resolving the technical or policy issues are considered and accounted for under the rulemaking effort.

There appears to be a perception among some management that the resolution of technical issues is part of the rulemaking process. The Task Force believes that this is a misconception that needs to be addressed. The resources, milestones, management, and accountability of the technical issue resolution process should not be attributed to rulemaking. Accounting for technical issue resolution in rulemaking only increases the perception that rulemaking is inefficient and costly. In the same manner, the discovery of an inadequate technical basis after an RMP is initiated results in costs attributed to rulemaking that should not be included under that banner. This occurs even if the rulemaking is placed on hold to develop the necessary policy or technical basis. The time and resources are still attributed to rulemaking. These practices add to the perception that rulemaking takes too long and costs too much.

Some mechanism is necessary to assure that the development of the technical basis does not count against the rulemaking effort from either a timeliness or cost accounting standpoint. If an approved technical basis for a rulemaking concept does not exist, management should implement some other process to establish the technical sufficiency before commencing a rulemaking. For example, a Task Action Plan or a Research Users Need request should be considered. Similarly, if a known major policy issue exists, it should be adjudicated by the Commission through a policy paper before preceding with a rulemaking plan. Some policy issues can be decided through rulemaking; management should exercise judgement when determining if a policy issue should be resolved in advance of the rulemaking.

Premature entry into rulemaking space can easily lead stakeholders to believe that the agency has already made up its mind on the appropriate course of action to address an issue (i.e., rulemaking), before having all of the facts on which to base a decision. This leads to a reduction in public confidence. The agency's actions on the control of solid material serves as a prime example. Many stakeholders accused the NRC of having made up its mind to conduct a rulemaking, while in fact the agency had not decided that rulemaking was the correct course of action.

Development of the technical basis along with the rule language and Statement of Considerations is also an inefficient and ineffective use of limited staff resources. The staff ends up doing extensive revisiting of issues and rewriting prepared text because the technical basis did not support the staff's anticipated outcomes at the beginning or at the middle of the development effort.

To avoid these pitfalls, better screening before rulemaking is initiated should be conducted. Additionally, potential rulemakings for which the technical basis is under development should not appear as an entry in the RAP or in any of the rulemaking tracking systems. These precautions should reduce the likelihood of individuals associating technical basis development with the rulemaking proceeding. After the development of the technical basis, rulemaking action may be initiated and the clock can start. The Task Force recommends that rulemaking not begin until after development of the technical basis.

We recommend that each office have a system in place to screen out premature rulemakings. This process should ensure that only those rules for which the necessary technical basis is in place and major policy direction has been given are actually counted as a rulemaking action. The process used by the offices for screening should be described in their office procedures. Actions for which the technical basis is not complete or for which required policy decisions have not been made should not be considered ripe for rulemaking and should not be accounted for under the rulemaking process.

NMSS should be more stringent in following the current initiation process, i.e. the user need memo. Requesting divisions are currently supposed to prepare a user need memo to initiate a rulemaking action. The user need memo contains information on the technical basis and provides a sense of the priority that the requesting division places on the issue. We note that, in actual practice, this process is not always used. When this initiating mechanism is not used, rulemaking management must question whether the technical basis and necessary policy decisions are in place to support the rulemaking. If not, management must explain to the requesting division that the technical basis or major policies must be in place to initiate a rulemaking.

NRR does not currently have a system in place to screen rulemakings, any division can initiate a rulemaking action on its own. NRR should develop some type of screening system.

These actions, if adhered to, should improve the negative perception on rulemaking timeliness.

Earlier Stakeholder Involvement

Most RMPs are developed with no public involvement. Decisions on the merits of an initial rulemaking concept, including decisions on whether rulemaking is the preferred means of addressing an issue, are made without the benefit of public stakeholder input. However, one of the most important assessments contained in a rulemaking plan is the impact of the rule on licensees. An RMP generally provides a rudimentary qualitative analysis of the expected costs of the rulemaking under consideration versus its expected benefits. While the NRC staff can make educated judgements on the costs and benefits, licensees are certainly the best source of this information.

There are several examples of recent rulemaking activities where the staff misjudged the impacts of a rulemaking on licensees (e.g., shutdown and low power operations, the first fitness for duty rulemaking, and the training and education requirements in Part 35). Interaction with public stakeholders on a new rulemaking concept during the development of an RMP will likely improve the agency's opportunity to understand the potential impact of a rulemaking on licensees. Soliciting comments and suggestions from the public at a preliminary stage (similar to a scoping meeting) would allow the staff to consider public input before committing significant resources to a given rulemaking concept to make decisions and recommendations based on

more complete information. The Commissioner Assistants indicated that they preferred knowing the views of stakeholders when reviewing an RMP or proposed rule.

Early stakeholder communications on a rulemaking concept comports with increased public confidence. The Task Force conducted a public survey on rulemaking communications as part of the study in this report. Public comments from the survey (which are summarized in another section of this report) endorse the idea of sharing the staff's rulemaking intentions with the public as soon as possible. However, they also caution against burdening the process with unnecessary communication efforts. Agreement States also indicated they wanted to be involved at an early stage. Increasing public confidence by early and aggressive staff interaction with the public supports one of the agency's strategic performance goals. Furthermore, nearly all SRMs approving RMPs advocate aggressive and early staff interaction with stakeholders. There is little risk in sharing a pre-decisional rulemaking or concept with the public provided it is indicated that the concept does not represent the Commission's position.

The Task Force recommends that rulemaking concepts be communicated with Agreement States and public stakeholders as soon as possible. Information to be conveyed primarily involves the issue that would be potentially addressed by rulemaking. Methods of obtaining early stakeholder feedback include but are not limited to posting on the website and/or the TCF, public meetings, and publication in the *Federal Register*. We do not intend for this to be a complicated process or a formal process like an ANPR; senior management approval should not be necessary to solicit the public input. Because some rulemakings are straightforward or simple enough so that early stakeholder involvement may not be necessary, we recommend that judgement be exercised in determining when to engage stakeholders at an early stage.

Currently, an RMP is not available for public scrutiny until it is formally approved and made publicly available in ADAMS and placed on the RuleForum webpage. Despite these actions and the inclusion of the rulemaking in the Regulatory Agenda, most public stakeholders remain unaware of the rulemaking action until the proposed rule is published in the *Federal Register* (with the exception of some high visibility rulemakings where draft rule language is shared with the public before the proposed rule is issued). Given the resources and effort invested in developing a proposed rule, and the importance of public comments to the rulemaking decision-making process, the proposed rule stage seems too late for effectively communicating the staff's intentions to the public. This opinion is corroborated by the responses to the communications survey conducted as part of this study.

The APA does not prohibit communicating rulemaking concepts to the public before the proposed rule stage. In fact, a primary intent of the various Executive Orders issued on rulemaking since the Carter administration was to stimulate earlier public involvement in rulemaking actions. While Commission policy prohibits sharing pre-decisional information with the public, rulemaking information is not specifically mentioned in the Management Directive. The staff has sought and received Commission permission to release draft rule language on a case-by-case basis. The draft language is typically published in the *Federal Register* and/or posted on the webpage for public comment. The information is marked as draft, pre-decisional so that it is obvious that the information has not yet been endorsed by the Commission. Therefore, the RCC or individual offices should seek generic approval to make predecisional rule language, draft rulemaking plans, and concepts publicly available.

The advantages of this early communication are:

- Significant flaws or oversights in the rulemaking concept are likely to be uncovered;

- Public stakeholder confidence is enhanced;
- *Commission and management confidence in the staff's rulemaking plan* recommendations would be bolstered by knowing that the public had already been given early opportunity to weigh in on the concept; and
- Stakeholder interest and support could be gauged in advance. The level of interest could provide input for the priority of the rule and the level of stakeholder engagement.

The disadvantages early communication are:

- Expenditure of additional resources;
- Increase in the schedule for some actions; and
- Stakeholders may also decide to lobby the Commission on a concept they oppose before the Commission is fully aware of potential rulemakings.

The staff would not be expected to respond to comments in the rulemaking plan in detail. Rather, the staff could use the comment information to either validate its approach or make appropriate adjustments when preparing the rulemaking plan and proposed rule or, in some circumstances, terminate the rulemaking effort. The rulemaking plan should provide an indication of the level of stakeholder support and interest.

Implementation of this recommendation will require Commission approval.

Rulemaking Plans

RMP development is one component of the NRC rulemaking process that exceeds APA requirements. The data appear to support the view that RMPs have become too elaborate and complex - too much time and too many resources are used to prepare a RMP. Additionally, many stakeholders no longer consider approval of the RMP to be the point in time for which rulemaking is initiated. In theory, the RMP is an overview document that focuses on critical planning at the earliest stages of rulemaking, with the objective of saving time and resources in later rulemaking stages. Data do not support either a savings of time or resources. Because the RMP is not an element of the APA, the staff, with Commission approval, has total flexibility in changing this stage of the rulemaking process.

The staff appears to be constructing the RMPs to showcase draft rule language, and developing justification to support the rule. With the amount of time and effort being invested in RMPs, it could be concluded that the RMP has become a preliminary proposed rule. In addition, the problem of determining when a rulemaking starts may have been solved by starting the clock when the RMP is approved. However, there is now a problem in determining when a RMP starts.

The process elements of the RMP as currently described in the Regulations Handbook and MD 6.3 are, for the most part, still very good ideas. However, the current direction of the RMP needs to be changed back towards its original intent and objectives. RMPs have often been developed and approved without sufficient foundation to begin a rulemaking (e.g., significant technical issues are known to exist and remain unresolved). This is contrary to the purpose of the RMP.

Management should consider reducing the scope and complexity of the RMP within the bounds of the current RMP procedures and processes.

The RMP should be refocused on the higher level management concerns that formed the original justification for the RMP. Specifically:

- What is the problem that the rulemaking is designed to correct and how will the rulemaking fix the problem?
- Why is NRC rulemaking action necessary, as opposed to other potential solutions?
- Does there appear to be a qualitative cost-benefit justification for the rulemaking?
- Will the rulemaking meet the backfit test or other legal considerations?
- Has a technical basis supporting the rulemaking been established and sanctioned by the Agency?
- Have all policy issues associated with the rulemaking been identified as appropriate for resolution in the rulemaking? (Rulemakings are a vehicle for resolving policy issues; therefore, it is not necessary that all policy issues be resolved prior to the rulemaking.)
- How will NRC establish licensee compliance with the rulemaking and what additional documents and efforts will need to be prepared to support the rulemaking (e.g., regulatory guides, standard review plans, inspection modules, staff and inspector training, etc.)?

The alternatives should be presented in a general-concept manner-- rule language should never be included in the RMP. The alternatives should be fairly presented, without emphasis on the staff's preferred action. The rulemaking plan should state the public participation/information opportunities that will be provided. As discussed earlier, the staff does a poor job of estimating the time and effort necessary to conduct a rulemaking. When preparing a resource estimate, the staff should look at past efforts to help make an estimate. A full milestone schedule should be developed in determining the schedule, so that a better estimate of time can be provided in the RMP. Any assumptions or limitations to the schedule should be mentioned. Adhering to the original concept of RMPs should result in timelier and less burdensome RMPs.

If simplification of the RMPs occurs within the bounds of the current procedures, Commission or EDO approval should not be necessary.

The Commission has recently approved the initiation and development of short-term, limited-scope, rulemakings without formal RMPs. We should consider whether to eliminate RMPs for other simplified, routine, or standardized rulemaking processes (such as recently granted by the Commission in its SRM on SECY-02-0081 and as done for CoC rulemakings).

Concurrence Process

The concurrence process was probably the area of greatest NRC stakeholder complaint. Concerns such as the process takes too long, issues are being raised at the last minute, and the same issues are being readdressed were common themes. Most, but not all, the problems seem to occur in obtaining division-level concurrence within the Program Office. The Task Force considered the concurrence process and how some of the problems could be alleviated and recommends several changes.

First, there should always be a management briefing to the Working Group at the beginning of the process. This provides an opportunity for management to express its expectations for the rulemaking action and the Working Group to make sure it understands the specific issues associated with the rulemaking. A lot of time and effort can be wasted if the Working Group did

not completely understand the direction that management expected the rulemaking effort to take.

Second, there should be more informal division-level briefings by the Task Leader/Working Group. Once the Working Group has determined the specific course of action, but before completion of the rule language, regulatory analysis, etc., the appropriate division-level managers should be briefed on the planned approach. This provides an opportunity early in the process to make sure everyone agrees with the approach to be used. If, in the course of Working Group deliberations, it is determined that a different approach should be used, the Task Leader should hold another briefing to explain why the new approach is necessary. When the package is ready for division concurrence, the Task Leader/Working Group should conduct a division-level briefing on the rule package. This provides an opportunity for division management to ask questions. These additional interactions should speed up the review and concurrence process, and should not add significantly to the resource expenditures.

Third, concurrence should be delegated down to the lowest level possible. Obtaining a division level concurrence typically involves a review by four to six people - a staff level person, a section chief, a branch chief, and the division director. It may also include a technical assistant and a deputy division director. If the division has a representative on the Working Group, the Working Group member or his/her first-line supervisor should be authorized to concur for the division. This would also help ensure that the Working Group member is bringing his/her management's view to the table. If the Working Group member is to concur, there would likely be more communication between the Working Group member and his/her management. Fewer touches on a package should speed up the concurrence process. Additionally, a maximum time for divisions to review and concur should be established for each package. Typically this would be no more than 2 weeks, but could be much less for simple-to-moderately complex rules. If at the end of this time, the division has not responded, it should be assumed that the division has no concern with the package, and it should be issued for office concurrence. Too often packages sit on manager's desks not because they have problems with the package, but because they are too busy with other actions. Establishing a time limit would work as a forcing function and could speed up the concurrence process. Division-level concurrence should always be in parallel. An alternative method would be to hold a meeting near the end of the concurrence period for all concurring divisions. This meeting would be intended to discuss and resolve any outstanding issues. The goal would be to have concurrence at the end of the meeting. Consideration should also be given to having the branch chief sign the package out for office concurrence, instead of a division director. There is no apparent benefit gained by having the division director sign out the rule packages for office concurrence.

Fourth, office concurrence should always be in parallel. MD 6.3 provides 20 days for the process. This should provide adequate time for office review and comment. There are instances where it takes longer; sometimes, this is because the package gets misplaced. The office concurrence memos should be revised to request the receiving office to provide the reviewer's name on receipt, to the rule contact. This would eliminate the problem of the package "getting lost in the mail". The requesting office would know within a day or two whether the package was received. Offices should also consider delegating the concurrence to a lower level; CFO and ADM already do this. Again, a meeting could be held near the end of the concurrence period to resolve any outstanding issues. Management Directive 6.3 currently provides a mechanism for resolving issues preventing office concurrence - bringing the issue to the EDO. However, managers are reluctant to elevate such issues to the EDO. There are instances when this is the appropriate action and managers should be encouraged to use all of the tools at their disposal.

Once inter-office concurrence has been received, the package should not go back to divisions, unless there were significant changes. An office-level brief should be conducted for the office director and/or his/her deputy to facilitate concurrence at this level.

Fifth, managers and technical assistants, etc., who are reviewing a package should consider the value of their comments, before making them. Comments that are strictly style or edits probably should not be made as long as the text is clear and understandable. Edits can actually change the meaning; often, this is not realized by the person suggesting the change. A lot of effort can be expended on the final steps to make the package 'perfect.' These changes decrease the efficiency and effectiveness of the organization and can significantly increase the time. If the comments are not adding value to the package, they should not be made.

The offices should consider these suggestions and implement those that work for their organizations. Although not addressing all the problems with concurrence, if implemented, these suggestions should improve the efficiency and effectiveness of the concurrence process, as well as the timeliness of the process.

Working Group Function

Overall, the Working Group concept works fairly well. However, a few concerns were raised, mostly involving communication and time commitment. Too many Working Group members come to meetings unprepared and are, therefore, unable to discuss the various issues associated with the rulemaking, or, for various reasons, are unable to provide input, in a timely manner, to support the milestones. Rulemaking is often near the bottom of the priority list for the non-rulemaking staff. The members do not always bring management views to the Working Group. Task Leaders and other Working Group members do not always keep management informed as to the status of activities, or of potential problems. The Task Leader does not always keep other Working Group members adequately informed. Some Working Group members felt that the Task Leader did not explain his/her roles and responsibilities, and in some cases did not even understand what those roles and responsibilities were. The Task Force considered several ways to improve Working Group function. First, expectations for Task Leaders and other Working Group members need to be spelled out. Working Group members' management need to understand the expectations and commitment of its staff. Both of these could be accomplished with a list of responsibilities and expectations that would be provided to each Working Group member and to the first-line supervisor. Each individual could sign the document to signify their understanding of the expectations and time commitment. The responsibilities and expectations would be discussed at the first Working Group meeting. A separate listing could be prepared for the Task Leader. The Task Force recommends that Working Group and Task Leader responsibilities and expectations be developed and used. The responsibilities and expectations could be placed in the office procedures. Table 3 is a list that could be used as a starting point in the development of these products. Another option for consideration would be to use the work request concept that NRR uses for the technical reviews to support licensing. There is no reason why NRR could not adopt this approach to support rulemaking, particularly since NRR staff is already familiar with the concept. The Task Force also recommends that the Task Leaders and Working Group members devote additional effort on communication issues. For example, efforts should include better communication within the group on expectations, schedules, and potential time conflicts and between the group and management to communicate management expectations and perspectives and providing status reports. Better communication should improve the efficiency and effectiveness of the Working Group.

Table 3. Responsibilities of Working Group Members

Responsibilities of Working Group members from other divisions or offices are as follows:

Provide technical input to rule

- Statement of Considerations
- Rule language
- Estimate of information collection burden
- Response to comments
- Monitor/review contractor effort

Keep management apprised of rulemaking

- Notify management of potential problems or policy issues
- Obtain management comments on rule package
- Obtain management input on policy decisions at early stage
- Obtain management concurrence on rulemaking

Support management briefings and any public meetings

Prepare associated guidance

- Make sure final guidance available at the time the rule is implemented (licensing, inspection, enforcement)

General Operating Standards

- Attend Working Group meetings
- Come prepared to discuss issues
- Provide input on time
- Stay focused to task
- Clearly state positions/concerns

(Source Attachment 1 of the NMSS Policy and Procedure on Rulemaking)

As a separate issue the Task Force recommends that the rulemaking Working Groups include a representative from ADM and CIO. These members would facilitate interactions with their respective offices. ADM has indicated that they would like to see an early draft of the Federal Register notice, so that some of the format concerns can be addressed earlier. Because of the staff concern with the development and approval of the OMB supporting statement, the Task Force believes that it would be beneficial to have a CIO member on the group to assist with the preparation of the statement. These members would not be expected to participate in all of the Working Group meetings or review all of the drafts. The timing of their participation would be established by the Task Leader in coordination with the particular member.

OGC and Agreement State Pilot Programs

In many agencies, the Office of General Counsel (or equivalent) has the lead responsibility for conducting rulemakings. Several staff, including OGC staff, suggested that NRC consider this

approach. The Assistant General Counsel for Rulemaking and Fuel Cycle has agreed to participate in a pilot program to test the concept. In the pilot, OGC would have the lead for a specific rulemaking and the Program Office would provide technical support. OGC has agreed to take the lead for two to three rulemakings in both NRR and NMSS. The Task Force recommends that this pilot approach be tested using two to three rulemakings from each office. Careful data (time and charges) should be collected on these rulemakings, to compare with data from similar rulemakings for which the Program Office had the lead.

Another pilot program that NMSS should consider was recommend by the National Material Program review and is supported by the Agreement States. Under the pilot, an Agreement State, with particular expertise in an area, would have the lead for the rulemaking. NRC staff would participate on the Working Group. Both the States and NRC have budget constraints that would have to be considered. However, the concept is worth testing. NMSS should explore this option with the Agreement States to find a potential rulemaking to run as a pilot. NMSS and STP should establish a protocol on how this process would work. Neither M.D. 5.3 or the NMSS office procedure adequately address Agreement State participation and/or lead for rulemaking actions. The Task Force recommends that a rulemaking be conducted as a test for the Alliance option under the National Material Program.

Implementation of these two pilot programs might require Commission or EDO approval.

Miscellaneous

The Task Force considered several suggestions that would help improve stakeholder confidence. One recommendation was to have earlier stakeholder involvement as discussed in the Rulemaking Initiation section. Another recommendation was to hold a meeting or meetings on rulemaking. The meeting could be part of a bigger annual meeting such as the Regulatory Information Conference, or be a separate meeting. Topics for consideration at the meeting include a general rulemaking process overview; how stakeholders can participate in the process effectively; the top ten rules being actively worked; rule status; upcoming public participation opportunities; rule prioritization basis; and rule concepts currently under consideration for rulemaking. This would allow stakeholders to provide their views on prioritization, interest level, etc, and serve as an educational tool to educate the public on the rulemaking process. These interactions could help dispel the notion that rulemaking occurs in a black box and takes too long and could increase public confidence. Educating the public on the process could also increase the efficiency because they would have a better understanding of how to participate. However, holding such a meeting or meetings would require some staff resources to prepare. It should be noted that rulemaking is already discussed at the annual meetings for the Organization of Agreement States and the CRCPD. It is unknown whether there will be adequate stakeholder interest to justify routine meetings, therefore, the Task Force recommends, on a pilot basis, that one meeting on rulemaking be held. Stakeholder interest would determine whether future meetings of this nature were to be held and the frequency for holding the meeting such as annual, biennial or more or less frequent. Note that Commission approval to discuss preliminary rulemaking concepts at the meeting would be necessary.

Stakeholders have suggested (in response to the questionnaire and at a public meeting on Part 71) that NRC allow submittal of comments by fax and by e-mail with attachments. Several stakeholders indicated that the RuleForum website and the Technical Conference website were not easy to use for the submittal of comments. It is possible that if e-mail comments were allowed, the Agency might receive incomplete, less thought-out comments, however making it easier to comment is probably worth the risk. The Task Force recommends that ADM explore

the possibility of allowing comments by fax and e-mail. Both the fax number and e-mail address would be provided in the Federal Register notice.

Conclusions

The changes made in the past to revise the rulemaking process (i.e., initiation of rulemaking plans and various reorganizations) do not appear to have improved the timeliness of rulemaking. There have been many changes in the regulatory environment that make it difficult to judge the effectiveness of these changes (i.e., maturing industry, more stakeholder involvement, etc.). The Program Offices are now in a better position to focus on those rules that are important to their organization. The rulemaking process is not broken. However, that does not mean that improvements cannot be made. The Agency continues to issue good-quality rules at a rate only slightly lower than 10 years ago. There is no true basis for making a comparison on efficiency, because resource data on individual rules were not maintained before 1998. One positive outcome of this report is the collection of basic information that can be used for future review efforts. Although we have concluded that the rulemaking process is working, we have identified several areas that could improve timeliness, accountability, staff empowerment, training, reporting, and public confidence. However, it must be noted that as the agency seeks more stakeholder involvement, this will likely increase the time and effort needed to complete rules.

Summary of Recommendations

The Task Force has made recommendations throughout the report that would improve various aspects of rulemaking. Some of these are in the support area and would not directly affect either the quality or timeliness of rulemaking. Several recommendations have been made that, if implemented, should improve either the quality or timeliness of rulemaking activities. The recommendations presented below are grouped into general categories for ease of consideration and use.

Process

Simplify rulemaking plans and focus on the basics. (Process Improvements, Rulemaking Plan; pages 82-83)

Revise the concurrence process for rulemaking actions to encourage empowerment of staff and other measures to reduce concurrence time. (Process Improvements, Concurrence Process; pages 83-85)

Create and/or use a rulemaking initial screening process. (Process Improvements, Rulemaking Initiation Screening; pages 79-80)

Do not initiate rulemaking related activities until after completion of the technical basis. (Process Improvements, Rulemaking Initiation Screening; page 80)

Consider centralizing NRR rulemaking management within the policy and rulemaking program of NRR to ensure the most efficient use of rulemaking resources. (Organization of NRC rulemaking; pages 14-15)

Conduct a pilot where OGC would have the lead for developing the rule package. (Process Improvement, Pilot Program; pages 86-87)

Conduct a pilot where an Agreement State or CRCPD/OAS would have the lead for developing the rule. (Process Improvement, Pilot Program; page 87)

Consider use of a shorter comment period for some proposed rules, if legally permissible. (External Stakeholders; page 65)

Public Participation

Engage external stakeholders at an earlier stage of the process. (Process Improvements, Earlier Stakeholder Involvement; pages 80-82)

Hold a pilot public meeting on rulemaking. (Process Improvement, Miscellaneous; page 87)

Develop criteria on enhanced public participation that would include criteria on what tool to use in various situations. (External Stakeholder Survey; page 65)

Develop a mechanism to allow stakeholders to provide comments by e-mail with an attachment. Also consider providing a fax number for providing comments. (Process Improvements, Miscellaneous; pages 87-88)

Tracking

Develop a centralized rulemaking status web page (for internal NRC use only) that provides all essential rulemaking information and that could be used as a common feeder for reports. (Improvement of Internal Tracking and Reporting; pages 32-33)

Remove all rulemakings from the CTM except those that are recognized as Agency-level high-priority, and are in direct support of the strategic plan. (Improvement of Internal Tracking and Reporting; page 33)

Reassess the purpose and function of the RAP to streamline and improve its usefulness as an information and management tool. (Improvement of Internal Tracking and Reporting; page 33)

Training

Develop training material that could be used to help explain the rulemaking process for both internal and external stakeholders. (Internal Stakeholder Survey, Miscellaneous; page 54)

Develop regulatory analysis training (either internal or external) as required training for all rulemaking staff. (Internal Stakeholder Survey, Miscellaneous; page 55)

Develop training sessions for rulemaking staff on the clearance process and how to prepare an OMB supporting statement. (Internal Stakeholder Survey, Rule Package Content; page 52)

PBPM

Compile and maintain an accurate database on rulemaking resource expenditures and timeliness for all rulemaking activities. The database should be used in estimating schedules and budgets in rulemaking plans. (Budgeting for Rulemaking, Budget Details; page 40)

Develop performance measures that more accurately reflect rulemaking performance. (Performance Measures for Rulemaking; page 43 and Appendix C)

Develop a better TAC management process that includes TAC discipline. (Technical Assignment Control Numbers; pages 45-46)

Use PA codes that are dedicated to rulemaking. (Budgeting for Rulemaking, Budget Details; page 41)

Analyze the items that comprise the expended rulemaking budget to ensure that only rulemaking activities are included. (Budgeting for Rulemaking, Budget Details; page 41)

Develop standardized criteria for prioritizing individual rules. (Prioritization of Rules; page 42 and Appendix C)

Guidance and Support

Develop ADM and OGC rule checklists. (Internal Stakeholder Survey, Rule Package Content; page 52)

Develop a rulemaking package checklist. (Internal Stakeholder Survey, Rule Package Content, page 52)

Create a rulemakers' webpage. (Internal Stakeholder Survey, Miscellaneous; page 54)

Issue guidance documents for public comment as companions to the proposed rule. (Internal Stakeholder Survey, Rule Package Content; pages 51-52)

Complete MD 3.54, "Collection of Information and Reports Management." (Rulemaking Process, Rulemakings with Collections of Information; page 25)

Clarify the practice or guidance on including the OMB supporting statement as an appendix to the regulatory analysis. (Rulemaking Process, Rulemakings with Collections of Information; page 25)

At the next revision of the office procedures include additional detail of a how-to-nature. (Internal Stakeholder Survey, Miscellaneous; pages 53-54)

At the next revision of the Regulations Handbook include more examples and explanations. (Internal Stakeholder Survey, Miscellaneous; pages 53-54)

Consider eliminating the publication of a separate notice for information collection requirements and revise the Statement of Considerations for the proposed rule to cover the essential elements. (Rulemakings with Collections of Information; page 26)

Working Group

Assign an RMB and ADM member to the rulemaking Working Group. (Process Improvements, Working Group Function; page 86)

Develop Working Group Member and Task Leader expectations and responsibilities. (Process Improvements, Working Group Function; pages 85-86)

Improve Working Group communications among members and management. (Process Improvements, Working Group Function; page 85)

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- NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," January 1997.
- Paperwork Reduction Act (44 U.S.C. 3501 et seq.).
- Regulatory Flexibility Act (5 U.S.C. 601 et seq.).
- SECY-94-141, "Improvement of the Rulemaking Process," May 23, 1994.

SECY-97-220, "Implementation of DSI 22 Research," September 30, 1997.

Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121).

Appendices

Appendix A: Task Force Charter

CHARTER RULEMAKING PROCESS IMPROVEMENTS

PURPOSE:

This task group is established to review the current NRC rulemaking process and identify areas with potential for improvements and/or enhancements. A sub-task is to evaluate the regulatory analysis guidelines. In fulfilling its purpose, the task group should use as a guiding principle the NRC's four performance goals: maintaining safety; reducing unnecessary regulatory burden; enhancing public confidence; and improving the efficiency, effectiveness, and realism of NRC decisions.

MEMBERSHIP:

NRR and NMSS will jointly manage the task force for this initiative and ensure coordination between the efforts of this task force and those of the sub-task force chartered to review the regulatory analysis guidelines per the commitment in SECY-01-0162. The members will report directly to the Branch Chiefs of NRR/RGEB and NMSS/RGB on a routine basis. The project managers of the initiative are:

Bill Huffman, NRR
Merri Horn, NMSS

The task force will be comprised of representatives from NRR, NMSS, OGC, and ADM. However, the task force will solicit input from internal stakeholders, both at the staff and management levels.

Task Force Members

Mike Ripley, Brian Richter, Dennis Allison, NRR
Mark Haisfield, Gary Comfort, NMSS
Neil Jensen, OGC
Victoria Voytko, Mike Lesar, ADM

Regulatory Analysis Sub-Task Force Members

Dennis Allison, NRR
Clark Prichard, NMSS

PROCESS:

The task force will evaluate current legal requirements and both agency and office policies for the NRC rulemaking process. The task force will consider all stages of the rulemaking process (e.g., rulemaking plan, ANPR, Issues paper, proposed rule, final rule) and internal steps for each stage to understand what is currently done and why. The underlying existing and future need for each phase of the rulemaking process should be examined. As part of the effort, the role of internal and external stakeholders (to include Agreement States) should be considered. The task force will meet with rulemaking staff and other internal organizations involved with rulemaking. This may include the need to solicit input from external stakeholders. In addition, the task group should examine the information systems that are required to be "fed" as part of the ongoing rulemaking

process. The regulatory analysis sub-task group will use SECY-01-0162 and the Staff Requirements Memorandum of January 19, 2001 on SECY-00-0198 as the guidance documents for this sub-task. The sub-task will seek external stakeholder input before reporting on its recommendations.

LEVEL OF EFFORT:

Due to budget constraints, this will not be a full time task group. It is anticipated that each task group member will expend up to 5 days/month on this effort. Total FTE contributions from the participating organizations during FY 2002 are expected to be as follows:

NRR	1.0 FTE
NMSS	0.8 FTE
OGC	0.25 FTE
ADM	0.25 FTE

PRODUCTS:

- 1) The RCC will be provided status updates (verbal) at the RCC meetings.
- (2) A report that summarizes the scope of the review and provides recommendations for improvement.
- 3) Regulatory analysis guideline recommendations.

REPORT TIMEFRAME:

The report on the regulatory analysis sub-task is due to the Commission on April 30, 2002.

The Task Group should complete and submit the report to the RCC within approximately 1 year.

SOURCE DOCUMENTS:

Administrative Procedure Act
E.O. 12866, Regulatory Planning and Review
NUREG/BR-0053, "Regulations Handbook"
Management Directives 6.3, 5.3, 3.54
NMSS and NRR Office letters/instructions
Rulemaking Activity Plan
Regulatory Agenda
Strategic Plan
Operating Plans for Nuclear Reactor, Nuclear Materials, and Nuclear Waste Safety Arenas
Risk-Informed Regulation Implementation Plan
High Level Guidelines for Performance-Based Regulation
Empowerment initiatives
MOUs between EDO and ACRS and ACNW
CRGR Charter
ACMUI Charter
NUREG/BR-0058, Revision 3, Regulatory Analysis Guidelines
Federal Register Act

Paperwork Reduction Act
National Environmental Policy Act
Regulatory Flexibility Act
Small Business Regulatory Enforcement Fairness Act (Congressional Review Act & amendments to Reg. Flex. Act)
National Technology Transfer and Advancement Act of 1995 (Voluntary consensus standards)
Treasury and General Government Appropriations Act, 1999 (family well-being)
E.O. 12889 - implements the North American Free Trade Agreement (75 day comment period)
NUREG/BR-0184, Regulatory Analysis Technical Evaluation Handbook"

OTHER RESOURCES:

DSI-22
SECY-94-141
Work Planning Center
GAO Report GAO-01-821

Appendix B: Rulemaking Resource Expenditure Data

Some rules have no hours listed because either no specific TAC number was established or individuals did not charge time to the TAC. In some cases, the TAC may have been opened during development of the rule activity and does not reflect all effort expended. Note that not all Working Group members and offices charge time to the TAC. The FTE value is based on 1350 hours per FTE for NMSS and 1460 hours per FTE for NRR. Budget numbers are from either the rulemaking plan or the Rulemaking Activity Plan, in some cases budget estimates could not be located. Tables B.1 - B.3 provide the expenditure information for completed rulemakings. Expenditure data for ongoing rulemakings is captured in Tables B.4 and B.5. Tables B.6 and B.7 provide the average and range for simple, moderate, and complex rulemakings in NMSS and NRR. Table B.8 provides the average and ranges for Certificate of Compliance rulemakings.

RULEMAKING RESOURCE EXPENDITURE

Table B.1. NMSS Completed Rulemakings Expenditures.

Rulemaking Number	TAC Number	Rule Title	RMP	Proposed Rule	Final Rule	Post	Total Hours	Total FTEs	Contract Cost; \$K	Over/Under Budget
531	L21280	Dosimetry	0	0	1147.2	0	1147.2	0.850	0	0.35
520	L20327	GL - Registration	0	1645.5	1407.6	64	3117.1	2.309		0.81
519	L20326	GL	0	186	206.5	3	395.5	0.293		-0.26
No number assigned	L20695	Changes, Tests, Experiments-Minor Corrections (P72)	0	0	51	0	51	0.038	0	
436	L21157	GTCC	281	1106	1991.8	0	3378.8	2.503	\$32.3	0.7
499	L30141	P76 Amendments Certification	58	258	251	1	568	0.421	0	-0.38

Rulemaking Number	TAC Number	Rule Title	RMP	Proposed Rule	Final Rule	Post	Total Hours	Total FTEs	Contract Cost; \$K	Over/Under Budget
438	L21159	P72 - Clarification and Addition	202	1182	837.5	0	2221.5	1.646		-0.05
506	L21174	50.59 PRN 72-3 NRR lead	0	349	360	77	786	0.582		NA
433	L21143	Elimination of 30 day P72	97	403.5	356.5	0	857	0.635		0.24
439	L21144	Expand Applicability P72	0	742	1271.5	37	2050.5	1.519		0.67
437	L21146	P20 Dosimetry	3	14	175	0	192	0.142		-0.06
446	L21158	Miscellaneous Changes P72	0	97	928	0	1025	0.759		-0.09
567	none	Terminate 274i Agreement - LA (no TAC established)	0	0	0	0		0.000	0	
582	none	AEOD (no TAC established)	0	0	0			0.000	0	
440	L21165	Energy Compensation Source	0	536.5	293	11	840.5	0.623	\$47.2	-0.38
351	L30113	Part 70	5334	8279.5	2318.5	25.5	15957.5	11.820		9.28
351	L30138	Part 70 Reg Analysis	0	938.3	23	0	961.3	0.712		Included above
513	L50105	Yucca Mnt (specific TAC not used by IMNS)	0	2017.5	6831.6	0	8849.1	6.555		1.03
513	A10203	EPA Standard - Yucca (7/31/99 - 4/15/00)	0	2631			2631	1.949		Included above

Table B.2. NRR Completed Rulemakings Expenditures.

Rulemaking Number	TAC Number	Rule Title	RMP	Proposed Rule	Final Rule	Post	Total Hours	Total FTEs	Over/Under Budget
164	MA1425	Skin Dose Limit-Hot Particles	428	2214	730		3372	2.310	0.61
318	MA1532 M80330	Codes and Standards ASME		905	3766		4671	3.199	1.15
366 ABWR	M84972	Standard Design Cert		739	2259		2998	2.053	
366 CE80+	M89992	Standard Design Cert		559	2231		2790	1.911	
405	M96503 M82216	Reduce Physical Protection Req.	350	1659	675		2684	1.838	1.34
413	M94610	Frequency of Audits for EP	266	438	1134	7	1845	1.264	0.39
424	M92806	NPP Decommissioning Financial Assurance	853	693	1530		3076	2.107	1.58
484	M96056	Initial Operator License Exam Req.		340	1459		1799	1.232	0.38
504	MA2215	Design Cert for AP600	136	1392	470	99	1998	1.368	0.22
506	M94269 MA1378 MA4584 MA5440 MA8907	Changes to Conform w/50.59	248	1637	2273	447	4605	3.154	-.25
507	MA2149	Revised Source Term for P50 & 100	54	1004	1520	106	2578	1.766	.07
508	MA0609	Env Impacts of HLW Transportation		701	1740	229	2670	1.829	-0.66

Rulemaking Number	TAC Number	Rule Title	RMP	Proposed Rule	Final Rule	Post	Total Hours	Total FTEs	Over/Under Budget
509	M94188 MA0158	Monitoring the Effectiveness of Maintenance		2905	3177	802	6884	4.715	2.47
512	D26040 MA0994 MA4284 MA6903	Event Reporting Req		1108	2226	195	3529	2.417	-1.58
524	MA2147	KI		2068	2830	847	5745	3.935	2.61
532	MA3580	Amend to Fire Protection App R		571	469		1040	0.712	0.43
533	MA1917	Changes to ECCS Evaluation Models App K	354	594	679	13	1640	1.123	-0.28
535	MA3744	Use of Simulators in Operator Licensing	1164	692	2304	8	4168	2.855	1.31

Table B.3. NMSS Completed CoC Rulemakings Expenditures.

Rulemaking Number	TAC Number	Rule Title	RMP	Proposed Rule	Final Rule	Post	Total Hours	Total FTEs	Contract Cost; \$K	Over/Under Budget
561	L21244	CoC - Fuel Solutions	0	31.5	259.5	0	291	0.216	0	-0.48
536	L21216	CoC - TN68	0	111	735	1	847	0.627	0	-0.07
390	L21161	CoC - VSC-24, A1	0	243	408	36	687	0.509	0	-0.19
530	L21215	CoC - TN32	0	148.5	533	0	681.5	0.505	0	-0.20
529	L21213	CoC - HISTAR 100	0	0	1122	93	1215	0.900	0	0.20
546	L21214	CoC - NAC-MPC	0	177	461.5	92	730.5	0.541	0	-0.16
537	L21218	CoC - HISTORM 100	0	17.5	112.5	0	130	0.096	0	-0.60
587	L20728	CoC - NAC-UMS, A2	0	0	37	0	37	0.027	0	-0.42
584	L20718	CoC - Westinghouse MC-10	0	0	114.5	0	114.5	0.085	0	-0.37
586	L20725	CoC - NAC-MPC, A1	0	0	82.5	0	82.5	0.061	0	-0.39
578	L20706	CoC - Nuhoms, A3	0	0	374	0	374	0.277	0	-0.17
572	L20657	CoC - VSC-24, A3	0	0	313	0	313	0.232	0	-0.22
570	L20682	CoC - Fuel Solutions, A1	0	0	275	24.5	299.5	0.222	0	-0.23
566	L20650	CoC - TN32, A1	0	0	189.8	57	246.8	0.183	0	-0.27
565	L20649	CoC HISTAR, A1	0	0	155	0	155	0.115	0	-0.34
563	L20643	CoC - NAC-UMS, A1	0	0	262	66	328	0.243	0	-0.21
544	L21243	CoC - Nuhoms, A2	0	0	200	0	200	0.148	0	-0.30

Rulemaking Number	TAC Number	Rule Title	RMP	Proposed Rule	Final Rule	Post	Total Hours	Total FTEs	Contract Cost; \$K	Over/Under Budget
539	L21242	VSC-24, A2	0	0	598	2	600	0.444	0	-0.01
538	L21219	CoC - NAC-UMS	0	150	654	0	804	0.596	0	-0.10
518	L21145	CoC - Nuhoms, A1	0	974	186	16	1176	0.871	0	0.42
589	L20745	CoC - Nuhoms, A4	0	0	14.5	0	14.5	0.011	0	-0.44
575	L20704	CoC - HISTAR, A2	0	0	159	0	159	0.118	0	-0.33
585	L20741	CoC - Fuel Solutions, A2	0	0	74.9	0	74.9	0.055	0	-0.40
591	L20749	CoC - NAC-MPC, A2	0	0	96.7		96.7	0.072	0	-0.38
592	L20752	CoC - Historm, A1			176.2		176.2	0.131	0	-0.32

Table B.4. NMSS Ongoing Rulemakings Expenditures.

Rulemaking Number	TAC Number	Rule Title	RMP	Proposed Rule	Final Rule	Post	Total Hours	Total FTEs	Contract Cost; \$K	Budget/ Contract
590	A10203	Unlikely Natural Processes and Events P63 (1/19/02) (no specific TAC established) (4/22/00 - 8/10/02)	0	1776	178		1954	1.447		
309	L30116	MC&A (8/10/02)	737.5	377.5	255.2		1370.2	1.015	0	1.2/\$0
480	L50107	Financial Assurance (8/10/02)	913.5	859.8			1773.3	1.314	\$49.3 \$113.8	2.4/\$145
501	L30142	Tribal Notification (8/10/02)	1675.3	695.1			2370.4	1.756		2.1/\$0
447	L20648	Transfer Part 40 (8/10/02)	0	1023.7			1023.7	0.758	\$40.6	5.0/\$0
573	L20674	Modify Event Reporting (8/10/02)	1305.6	1304.8			2610.4	1.934	\$50	1.0/\$94
496	L21156	Part 71 (8/10/02)	3351.9	9182.6	658.7		13193.2	9.773	\$66.9 \$408.2	4.81
496	L21142	Part 71 Fissile Exempt (closed)	2271	12			2283	1.691	\$47	0.7/\$0
588	L20726	CoC - Standardized Advanced Nuhoms (8/10/02)	0	156.5	524.5		681	0.504	0	0.7/\$0
576	L20708	Notification of Dose P35 (2/16/02)	0	287.9			287.9	0.213	0	1.2/\$0
592	L20752	CoC - HISTORM, A1	0	0	176.2		176.2	0.131	0	0.45/\$0

Rulemaking Number	TAC Number	Rule Title	RMP	Proposed Rule	Final Rule	Post	Total Hours	Total FTEs	Contract Cost; \$K	Budget/ Contract
497	A10170	Part 35 (7/24/99 - 4/20/02)	0		2207.6		2207.6	1.635	\$249.1 \$64.4	10/\$299
441	L21160	Geological and Seismological P72 (8/10/02)	20843.9	1847.1			22691	16.808	\$344.4 \$200.3	3.8/\$200
441	L21147	Revise Geol & Seis P72 (closed)	596.5	20			616.5	0.457		
571	L20668	Entombment (8/10/02)	2734.2				2734.2	2.025		3-5/0
564	L20665	Distribution of Source Material to Exempt Persons P40, (PRM-40-27, PRM-40-28) (8/10/02)	1543				1543	1.143		2.05
543	L21238 (no longer valid)	Implement US/IAEA Safeguards (2/23/02)	777				777	0.576		2.45
474	L21183	Requirements for Panoramic Irradiators (PRM-36-01) (8/10/02)	692.4				692.4	0.513		
400	L20729	Exemptions from Licensing and Distribution of Byproduct Material P30, 31, 32 (8/10/02)	1549.3				1549.3	1.148	\$122	
400	L21181	Revise 30.18 Multiple Exemptions	0				0	0.000		

Table B.5. NRR Ongoing Rulemakings Expenditures.

Rulemaking Number	TAC Number	Rule Title	RMP	Proposed Rule	Final Rule	Post	Total Hours	Total FTEs	Budget/ Contract
116	MA1423	Table S-3 and S-4	962				962	0.659	
505	MA3567	Update P52 with Lessons from Design Certification	70	2255			2325	1.592	1.0
547	MA7146	Integrated, Risk-Informed Rule for NPR	2015	461			2476	1.696	6.0/\$250K
548	MA6844	Reduction in the Scope of Random Fitness for Duty Testing	103	972			1075	0.736	0.9
549	MA6670 MA7144	Security Req for Power Reactor Licensees	2293	6786	399			0.000	7.5
550	MA6383	Decommissioning Trust Provisions	180	1382	791		2353	1.612	0.5/\$100K
551	MA6058 MA6057 MA8337 MA8899 MA8612 MA8584 MA8319 MA5952 MA5951 MA5362	Risk Informing Special Treatment Regulations	11351	22747			34098	23.355	47/\$3.0Mil
554	MA6458 M85142	Reactor Fire Protection	229	1441			1670	1.144	2.0/\$150K

Rulemaking Number	TAC Number	Rule Title	RMP	Proposed Rule	Final Rule	Post	Total Hours	Total FTEs	Budget/ Contract
555	MA7169 MA8112	Standardized Process for Allowing Licensees to Release	338	1936	629		2903	1.988	3.0/\$250K
556	MA7035	Update 50.55a to incorporate ASME code (96-00)	231	3178	1709		5118	3.505	3.5/\$150K
557	MB1640 MA8167	Change in Frequency in Offsite EP Exercises	526	409			935	0.640	2.0
558	MA8073	Specification of Acceptable ASME BPV Code Cases	1055	643	31		1729	1.184	1.0
559	MA6384	EAL Approval Clarification	980	49			1029	0.705	2.0
569	MA8667	Submission of Financial Info	929	1348			2277	1.560	1.0/\$50K
579	MA8071 MB1080	Risk Informing Gas Combustible Control Req	2010	1340			4006	2.744	3.6/\$297K
580	MA8071 MB2762	Worker Fatigue	2471	461			2932	2.008	2.6/\$300K

Table B.6. NMSS Rulemakings Average Expenditures.

Rule Stage	Simple Average	Simple Range	Moderate Average	Moderate Range	Complex Average	Complex Range
Rulemaking Plan	1016.9	202 - 1543	1108.3	737.5 - 1675.3	10,779.1	5334 - 21440.4
Proposed Rule	475.6	287.9- 1182	1000.4	277.5 - 1776	5314.7	1645.5 - 9217.8
Final Rule	524.3	175 - 1147.2	1631.6	1271.5 - 1991.8	3526.9	1407.6 - 6831.6
Total (Hours)	2016.8		3740.3		19620.7	

Table B.7. NRR Rulemakings Average Expenditures.

Rule Stage	Simple Average	Simple Range	Moderate Average	Moderate Range	Complex Average	Complex Range
Rulemaking Plan	733.6	350 -1055	665.5	54 - 2471	2425.7	103 - 11351
Proposed Rule	833.6	571 - 1659	1392.9	340 - 3178	2005.9	559 - 6786
Final Rule	890.8	469 - 1740	1663.7	730 - 2304	2323.3	470 -3766
Total (Hours)	2458		3722.1		6754.9	

Table B.8. NMSS CoC Rulemakings Average Expenditures.

Rule Type/Stage	Average	Range
New CoC (5) Proposed Rule	97.1	17.5 - 177
New CoC (7) Final Rule	553.9	112.5 - 1122
Amend CoC (2) Proposed Rule	608.5	243 - 974
Amend CoC (2) Final Rule	297	186 - 408
Amend CoC (15) Direct Final Rule	189.95	14.5 - 598

Appendix C Proposed Prioritization Rating Factors and Performance Measures

Proposed Prioritization Rating Factors

In developing the proposed prioritization rating factors, the Task Force considered the Agency performance goals, the current prioritization process, and other factors that can impact the prioritization of a rulemaking activity. Draft criteria were developed and tested against current rulemaking activities. Both individual Task Leaders and management were asked to evaluate various rulemaking activities. Feedback from this test group was used in the revision of the factors. It is recognized that other factors may influence the final priority of a rulemaking, such as Congressional or Commission direction or even stakeholder interest. However, we believe that a more informed decision can be made through the use of standard criteria. It is recommended that these or similar criteria be used on a pilot basis. At the end of the pilot, the effectiveness of the criteria can be determined and revision made as necessary.

The criteria address the performance goals of: maintain safety; reduce unnecessary regulatory burden; increase efficiency, effectiveness, and realism; and increase public confidence. A fifth factor on regulatory reform initiatives is included to address risk-informing the regulations. Each rulemaking would be scored individually using the factors with points allotted for each factor (the number to the left of the description). The total score for each rulemaking would be determined by adding the points allotted for each factor. The total scores would be compared to determine the relative priority of each rulemaking action. The criteria are described below.

Rulemaking Prioritization Rating Factors

Safety/Safeguards Contributors

Safety/Safeguards Significance

- 6 Adequate protection of safety/safeguards - A rulemaking action necessary to achieve, reestablish, or redefine the adequate protection of public health and safety or common defense and security, based on new information, risk insights, or other developments not previously considered. As an example, a rulemaking that addresses issues where there is evidence that the current level of safety may be insufficient or eroded. This would include new information having a significant impact on accident initiation, mitigation, or consequences. This would also include newly identified credible safeguards threats. Rulemakings in this category are not common.
- 2 Enhancement of safety/safeguards - A rulemaking action that will provide safety or security enhancements justifiable on a cost-benefit basis. Where applicable, the rulemaking action would be expected to meet backfit criteria.
- 0 No impact, or slight impact on safety/safeguards - A rulemaking action that has a primary purpose not related to safety (such as reducing burden or improving efficiency/effectiveness) and is, therefore, expected to have little to no impact on safety/safeguards. This is typically the rating that would be applied to rulemaking actions directed at improving other aspects of the regulatory framework while still maintaining

safety. In some instances, the rulemaking action may slightly reduce safety in some areas, as long as the overall safety level is essentially maintained.

Burden Reduction Contributors

Burden Reduction (Dollars \$) [Effect of rulemaking actions on tangible monetary costs to licensees not related to reporting or record keeping]

- 2 Significant cost \$ savings - A rulemaking action that significantly decreases costs to a given class of licensee.
- 1 Some cost \$ savings - A rulemaking action that results in some decrease in cost to a given class of licensee.
- 0 Minimal change in cost \$ - A rulemaking action that results in minimal or no cost to a given class of licensee.
- 1 Some cost \$ increase - A rulemaking action that results in some increase in cost to a given class of licensee.
- 2 Significant cost \$ increase - A rulemaking action that significantly increases cost to a given class of licensee.

Note: The cost to a given class of licensee refers to the sum total cost (or savings) on all the licensees that will be impacted by a rulemaking action, recognizing that there may be a wide variation in the costs or savings from one licensee to the next (i.e., cost per licensee times number of licensees impacted).

Burden Reduction - Information Collection [Rulemaking subject to OMB Clearance]

- 1 Significantly decreases information collection burden - A rulemaking action that results in a significant reduction in information collection costs.
- 0 Minor change or no change in information collection burden - A rulemaking action that results in minimal increase, decrease, or no change to the information collection costs or does not require OMB clearance.
- 1 Significantly increases information collection burden - A rulemaking action that results in significant increase in information collection costs.

Efficiency, Effectiveness, and Realism Contributors

Regulatory Efficiency and Effectiveness [This prioritization category refers to rulemaking impacts on NRC internal resources. See "Burden Reduction Contributors" for rulemaking impacts on licensees.]

- 1 Improves regulatory efficiency/effectiveness - Rulemaking actions that improve the consistency in implementation or predictability of NRC review, approval, inspections, or enforcement of a regulation. This factor primarily involves rulemaking actions that significantly reduce NRC resources directly related to a given regulation (e.g., a rulemaking action where a licensee would no longer need to obtain NRC approval of the licensee's implementation of the regulation). Another example might involve a clarification to a regulation, to the extent that issues pertaining to regional inspection or enforcement of the rule could be significantly reduced. Alternatively, changes to a rule that streamlines regulatory framework in terms of NRC internal processing or reviews could also be justified as efficiency, effectiveness-related. Although, in many cases, these types of rulemaking actions result in commensurate burden reductions on the licensees, this rating factor measures the rulemaking action's impact on NRC resources regardless of the impact on the licensee's regulatory burden.
- 0 No or slight impact on regulatory efficiency/effectiveness - A rulemaking that is expected to have little or no impact on regulatory effectiveness or efficiency.
- 1 Reduces regulatory effectiveness/efficiency - A rulemaking that is expected to reduce regulatory effectiveness and/or efficiency. (See note below)

Note: A rulemaking to improve safety or reduce licensee burden may actually result in reduced efficiency or effectiveness for NRC. For example:

- The rulemaking may necessitate additional NRC inspections.
- The rulemaking may require NRC review or approval of information where none was previously required.

Informed Decision-Making

- 1 Data and information to support a rulemaking action are complete - Sufficient data or information is available to support the technical basis of the rulemaking. In addition, sufficient data or information is available to prepare a quantitative regulatory analysis of a rulemaking action's cost benefit.
- 0 Data and information to support a rulemaking action are incomplete - Some data to support the rulemaking, but not enough to fully support the regulatory analysis.
- 1 Data and information to support a rulemaking action are inadequate - There is inadequate technical basis or cost-benefit information to make an informed decision on a given rulemaking action. However, management has directed the staff to proceed with rulemaking based on other considerations.

Scope of Licensees Impacted

- 1 Significant number of licensees actually impacted by a rulemaking action - Specifically, the net total number of licensees actually impacted (results in modification of facility, processes, procedures, record-keeping, reporting, or similar) by a rulemaking action (regardless of the costs or savings of the impact) would represent a significant number of the total of all licensees licensed under or subject to a specific part in Title 10 of the Code of Federal Regulations affected (e.g., Parts 20, 30, 31, 39, 40, 50, 71, 72, etc.).
- 0 Small number of licensees impacted by a rulemaking action - If the total number of impacted licensees is very small, consideration should be given to a different means for accomplishing regulatory change, such as using an exemption or an order.

Note: Not all rulemaking actions affecting a given part in 10 CFR actually impact all those licensed under the particular part. In addition, regulations may be optional or provide a choice that a licensee may not choose to implement, or the regulation may only impact the licensee if changes are made for some other reason not directly related to the amended regulation.

Public Confidence Contributors

Public Confidence

- 1 Enhances public confidence - A rulemaking action that is expected to increase public confidence.
- 0 Minimal change in public confidence - A rulemaking that is expected to have a minimal impact on public confidence.
- 1 Decrease public confidence - A rulemaking action that is expected to decrease public confidence.

Stakeholder Support

- 1 Significant stakeholder support - Extensive stakeholder support of a given rulemaking action is expected.
- 0 Mixed stakeholder support or minor interest- factional support and opposition is divided between industry stakeholders and nuclear watchdog organizations (does not mean that the comments have to be evenly divided but, in total, it is judged that there is not clear cut support for or opposition to the rulemaking effort). This rating factor would also apply to rulemaking actions where no significant interest in the rulemaking from any stakeholders is observed or anticipated.
- 1 Significant stakeholder opposition - Extensive stakeholder opposition of a given rulemaking action is expected.

Regulatory Reform Contributors

Is a Significant Outcome of the Rulemaking a Result of Risk-Management or Performance-Based Insights?

- 2 A rulemaking action that is both risk-informed and performance-based.
- 1 A rulemaking action that is risk informed.
- 1 A rulemaking action that is performance-based.
- 0 A rulemaking action that is neither risk-informed or performance-based.

Proposed Performance Measures

The primary considerations in developing the recommended performance measures and targets were: (a) consistency for all types of rules; (b) ease of measurement; (c) appreciation of the meaning of the measurement and target by management; and (d) that the measures encompass rulemaking attributes that have been found to be important. To generate an acceptable set of performance measures, it was concluded that the category of attributes to be measured for rulemaking should be established first. Based on review of performance measures for other NRC activities, the following categories were determined to be reasonably suitable for rulemaking, with flexibility to satisfy Office-specific variations. The general categories are:

- Outputs
- Timeliness
- Productivity
- Resources
- Quality

After much discussion, the Task Force developed some performance measures that could be used for assessing rulemaking activities. By adopting the recommended performance measures below, or similar alternatives, inefficiencies in the rulemaking process may be more easily identified in future assessments.

When setting performance targets, the targets should be presented in terms of percentages exceeding the target rather than percentages in compliance with the target limit. This is because the measure of items exceeding a limit does not imply any attributes to the remaining items in a group, whereas a measure of items within a limit might imply that all those items are under control—which may or may not be true.

Outputs

The number of final rules issued per year is a performance measure that can be established and easily assessed. Although issuance of final rules is the objective of any rulemaking program, the number of rulemakings completed in any given year is few and may not be indicative of the total effort or accomplishments (i.e., performance) of the rulemaking program. As an alternative, rulemaking output could include the intermediate actions leading to a final rule. There are three basic outputs from the rulemaking process that are typically associated with a

complete rulemaking, they are: rulemaking plans; proposed rules; and final rules (including abbreviated rulemakings). ANPRs and issue papers are also possible outputs. Each of these items is a distinct product output that must be completed and approved before the next step in the process can proceed.

The output performance measure for rulemaking should count the number of discrete rulemaking actions accomplished, during a given time period, rather than completed rules. A rulemaking action could be either an ANPR, a rulemaking plan; a proposed rule; or a final rule (including abbreviated rulemakings).

Timeliness

Timeliness as a performance measure is simply a measure of performance against a set time limit. For consistency, the timeliness measure should be assessed against the same product as used to measure output. As discussed above, the output product for rulemaking should be broken down into its constituent rulemaking action steps of: the rulemaking plan; the proposed rule; and the final rule (including abbreviated rulemakings).

One way to measure timeliness is to use a schedule milestone. For example, the current NRR operating plan sets a timeliness target against CTM milestones. The advantage of using schedule milestones as a timeliness indicator is that they account for the individual variations in rulemaking difficulty as well as management discretion in prioritizing and dispersing resources for rulemaking. On the other hand, it is difficult to discriminate between schedule slips of a day or a year when setting a target against a specific schedule date. There would also be difficulties in determining how to adjust the baseline schedule when circumstances outside the control of the rulemaking process (like Commission review and consideration time) result in unanticipated schedule variances. From a practicality standpoint, assessing this performance measure would likely require judgment and subjective assessment in some circumstances and could therefore be difficult to automate, using existing information technology.

Another approach to this measure would be to use an absolute time interval as a timeliness target. Current rulemaking data show that there is a substantial spread in the time it takes to accomplish a given step in the rulemaking process, depending on the complexity and priority of the rule. The current Agency goal is to complete a rulemaking 18 months after approval of the rulemaking plan. Based on this goal, it is reasonable to expect, on average, for rulemakings to be able to advance to the next step within 1 year, given sufficient management attention and application of resources.

A timeliness target that demands at least 75 percent of all rulemaking actions to advance to the next phase within 1 year is an example of a simplified time interval measure. By setting the percentage fairly low, margin for complex rulemaking is provided. To capture performance of those complex rulemaking actions that will probably exceed 1 year for any given step in the process, an additional timeliness target could be applied. An absolute time limit for issuance of any final rule is such a measure, with the target percentage rate being prescribed within a tighter band to provide assurance that no single rule will take too long. An example might be that 90 percent of all rules are finalized within 30 months of the starting date (date that the rulemaking plan was initiated).

In consideration of the frequency of the performance monitoring reports (monthly for NRR; quarterly for NMSS), there would be an advantage to reporting this measure conversely to the above examples. That is, instead of 75 percent of all rulemakings having advanced to the next

step within 1 year, the measure would be tracked as the percentage of rulemakings that have not advanced to the next step within 1 year, with the limit being less than 25 percent. The performance report would only indicate the percentage of rulemaking actions that have exceeded the one year limit with no implication on the status of those that have not.

A second area to measure performance is how promptly the office concurs on other office's rulemakings. The Management Directive indicates that offices should respond to a request for concurrence within 20 days. This may be actual concurrence, or a response with any questions or concerns regarding any technical analysis information or data that may invalidate or raise doubts about the proposal. This is not an unreasonable length of time. The goal should be to always respond within the 20 days. However, as a target, a response should be provided within the 20 days at least 90 percent of the time.

The timeliness performance measure for rulemaking should measure the absolute duration of each rulemaking action (rather than using a schedule milestone). The target should specify an acceptable percentage of the total number of rulemaking action outputs that can exceed the absolute time limit. A second target specifying a duration cap for an entire rule is also recommended. A reasonable archetype for these targets is presented below:

- No more than 25 percent of all rulemaking actions should take longer than 1 year.
- No more than 10 percent of all rulemakings should take longer than 30 months to complete starting from the initiation of the rulemaking plan.

The second timeliness performance measure should be that 90 percent of other office rulemakings are reviewed and a response provided within 20 days.

Resources

The resource performance measure is a straightforward accounting of all the staff-hour (or FTE) effort expended for all rulemaking TACs and is, therefore, easily measured. It is observed that this is a fairly standard performance measure for many PA codes and can be readily applied to rulemaking. The performance measure target of maintaining overall rulemaking resources within +/-20 percent of the budgeted resources is also reasonable and should remain the current standard.

Another method to measure resources would be to measure the effort expended on a per-rule basis. The staff estimates a budget for each rule in the rulemaking plan phase (or proposed rule if there is no rulemaking plan). The actual expenditures could be compared to the estimated expenditure. The performance measure would be that 80 percent of the rules should be within \pm 20 percent of its budget. This measure would be difficult to measure on a fiscal year basis because rules can be completed any time during the year and there are not a large number of final rules completed in any given year. Although this is harder to measure on a per-year basis, it would give a better view of the performance.

Productivity

Productivity as a performance measure is the amount of staff-hours (or FTEs) used per product output. To be consistent with outputs and timeliness performance measures, the productivity measure should also be applied against rulemaking action steps rather than completed rules. Data indicated that the amount of effort for a given rulemaking action (rulemaking plan, proposed rule, final rule) can vary considerably, depending on the complexity of the rule. In

addition, to meet timeliness goals, management may wish to apply additional resources to a given rulemaking process.

Identification of a "one size fits all" productivity target would be difficult, if not impossible, to define. It is difficult even within different complexity rankings- not all complex rulemakings have the same degree of complexity. The Task Force does not think that productivity is a good measure of rulemaking performance. There are too many variables, such as complexity, degree of stakeholder involvement, and level of management interest, to develop an average labor rate that could be used to measure performance in this area. However, if a productivity measure is desired, a separate average labor rate for simple, moderate, and complex rulemakings should be developed. The resource data presented in Appendix B could be used for this purpose.

Quality

The Task Force also considered a performance measure that is not typically included in the operating plan: quality. Overall the quality of NRC rulemakings is considered good. However, there is no current method to measure this. Two possible methods were considered. The first measure would be based on the number of final rules that are withdrawn because of problems with the rule. The performance measure would be zero final rules withdrawn. This would not include direct final rules that are withdrawn because of the receipt of adverse comments. This might be hard to measure because it may be difficult to tell when a rule is withdrawn due to problems and when it is withdrawn for other reasons (e.g., significant new information; intervening Congressional action). A second measure would be based on the number of corrections made to the final rule after publication. This measure would not include typesetting errors made by the Office of the Federal Register. The focus would be substantive changes, where the change affects the rights and responsibilities of licensees. The goal would be to have zero rules revised for this reason. However, since virtually no one expressed dissatisfaction with the quality of NRC rulemakings, the Task Force does not believe a performance measure for quality is needed. Final rules are subject to review in the courts. Thus there is an available external check on the legal soundness of NRC rules.

Appendix D: Compilation of Historic Data on NRC Rules

Appendix D provides information obtained from the ACCESS database. Table D.1 is a listing of the information contained in the database. Table D.2 is information from an example query for all the final rules published in 2002. Similar queries were run to obtain the input for the tables and figures in this appendix. Tables D.3 - D.8 provide the number of rulemaking actions (final rules, proposed rules, rulemaking plans, and advance notices of rulemaking) for the agency and specifically those initiated by NMSS and NRR. Figures D.1 - D.18 show the average and median times for various stages of rulemaking.

Table D.1. Rulemaking Database Content.

<p>Rulemaking Number RIN Number Type Priority Complexity Lead Office</p>	<p>Proposed Rule Date Proposed Rule FR Citation Proposed Rule SRM Date Proposed Rule SECY Proposed Rule SECY Date Proposed Rule Signed by EDO (Y/N) Proposed Rule EDO Signature Date</p>
<p>Final Rule Date Final Rule FR Citation Final Rule SRM Date Final Rule SECY Final Rule SECY Date Final Rule Signed by EDO (Y/N) Final Rule EDO Signature Date</p>	<p>ANPR or Issues Date ANPR FR Citation</p>
<p>RMP SECY RMP SECY Date RMP SRM Date</p>	
<p>Initiator Initiation Date Rule Title Affected CFR Parts Rulemaking Completed (Y/N) Terminated Before Finalized (Y/N) APA Exempt (Y/N) DFR (Y/N) Final Rule Withdrawn (Y/N) Comments Cask Certification (Y/N)</p>	

Table D.2. Example Query - 2002 Final Rules

Rulemaking Number	RIN Number	Lead Office	Final Rule Date	Time from PR Publication	Time from Initiation	Commission Review Time	Time from RMP Approval
164	3150-AG25	NRR	4/5/02	267	1490	49	1199
556	3150-AG61	NRR	9/26/02	419	896		856
497	3150-AF74	NMSS	4/24/02	1350	1861	145	1759
0	3150-AF74	NMSS	10/9/02				
0	3150-AG04	NMSS	4/29/02				
592	3150-AG97	NMSS	7/15/02	110	250		
591	3150-AG94	NMSS	3/15/02	0			
590	3150-AG91	NMSS	10/8/02	256	396	49	
582	3150-AG79	NMSS	1/25/02				
445	3150-AF61	CIO	9/6/02	0		49	1102
583	3150-AG95	CFO	6/24/02	89			
0	3150-AG96	CFO	9/11/02	140	2329		
0	3150-AG80	CFO	5/6/02	213			

Table D.3. Final Rules.

Calendar Year	Number of Final Rules - Total	Number of APA Exempt Final Rules - Total	Number of Direct Final Rules - Total
1990-1994	142 (28.4 average)	84	0
1995	26	5	0
1996	19	7	2
1997	24	10	4
1998	22	6	1
1999	24	1	2
2000	26	3	6
2001	20	4	9
2002	8	1	1

Table D.4. NMSS Final Rules.

Calendar Year	Number of Final Rules - NMSS	Number of APA Exempt Final Rules - NMSS	Number of Direct Final Rules - NMSS
1990-1994	NA	NA	NA
1995	2	2	0
1996	2	0	0
1997	0	0	0
1998	9	2	1
1999	7	0	0
2000	17	0	6
2001	13	1	9
2002	5	1	1

Table D.5. NRR Final Rules.

Calendar Year	Number of Final Rules - NRR	Number of APA Exempt Final Rules - NRR	Number of Direct Final Rules - NRR
1990-1994	NA	NA	NA
1995	2	0	0
1996	0	0	0
1997	0	0	0
1998	3	1	0
1999	11	0	1
2000	3	0	0
2001	2	0	0
2002	1	0	0

Table D.6. Proposed Rules.

Calendar Year	Number of Proposed Rules - Total	Number of Proposed Rules - NMSS	Number of Proposed Rules - NRR
1990-1994	95 (19 average)	NA	NA
1995	15	3	0
1996	10	1	1
1997	21	4	6
1998	16	8	4
1999	26	12	9
2000	13	9	1
2001	18	10	4
2002	13	6	2

Table D.7. Rulemaking Plans.

Calendar Year	Number of Rulemaking Plans - Total	Number of Rulemaking Plans - NMSS	Number of Rulemaking Plans - NRR
1995*	2	0	1
1996	11	2	3
1997	14	11	2
1998	10	4	6
1999	9	2	6
2000	9	2	6
2001	11	6	5
2002	0	0	0

* The use of rulemaking plans was initiated in 1995.

Table D.8. Advance Notice of Proposed Rulemaking/Issue Papers.

Calendar Year	Number of ANPR/Issues Papers - Total	Number of ANPR/Issue Papers - NMSS	Number of ANPR/Issue Papers - NRR
1990-1994	16 (3.2 average)	NA	NA
1995	0	0	0
1996	2	1	1
1997	1	1	0
1998	1	0	1
1999	1	1	0
2000	3	1	2
2001	1	1	0
2002	0	0	0

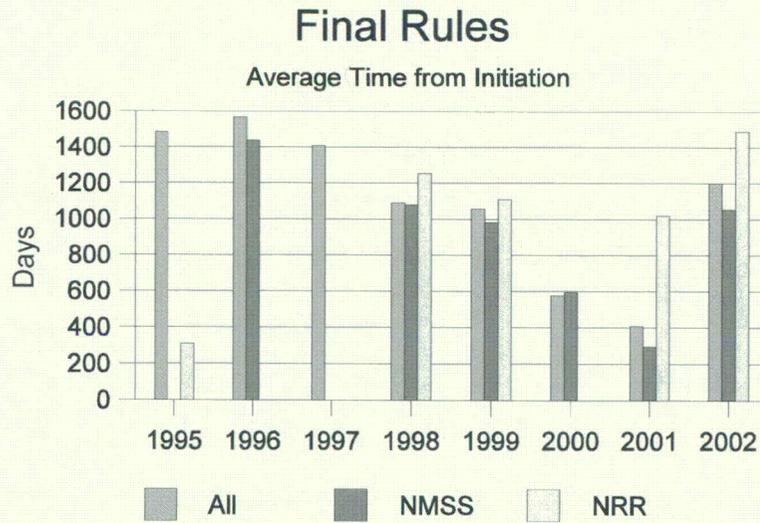


Figure D.1. Average Time from Initiation to Final Rule Publication.

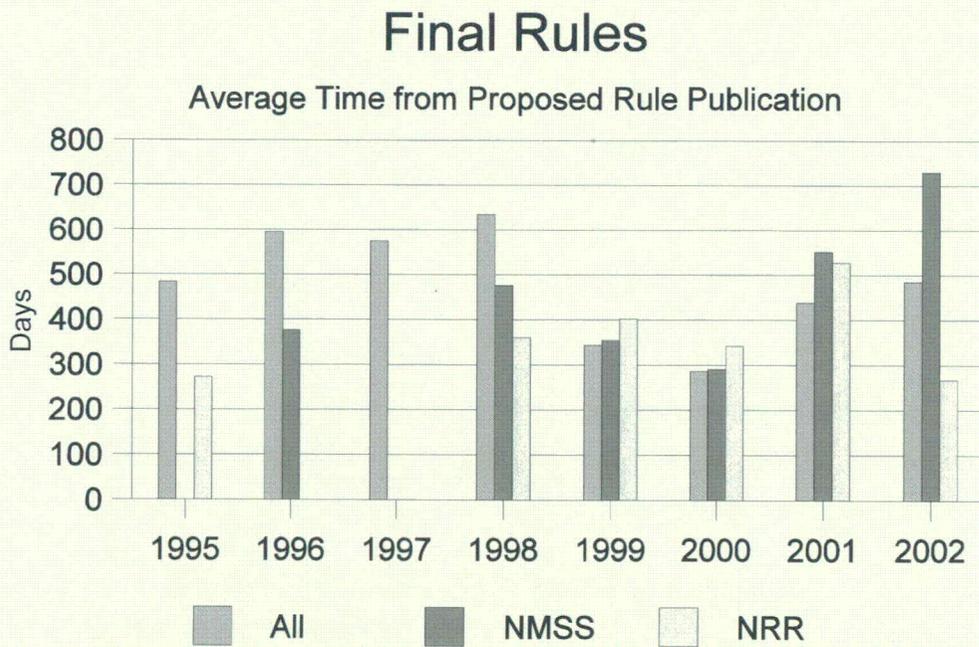


Figure D.2. Average Time from Proposed Rule Publication to Final Rule Publication.

Final Rules

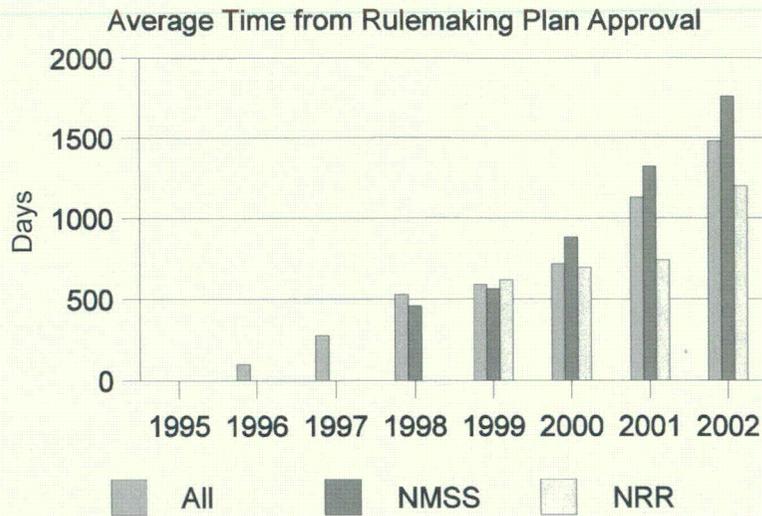


Figure D.3. Average Time from Rulemaking Plan Approval to Final Rule Publication.

Proposed Rules

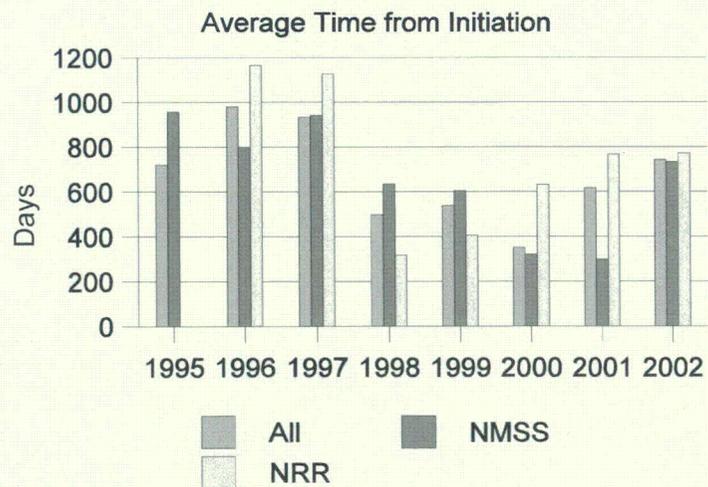


Figure D.4. Average Time from Initiation to Proposed Rule Publication.

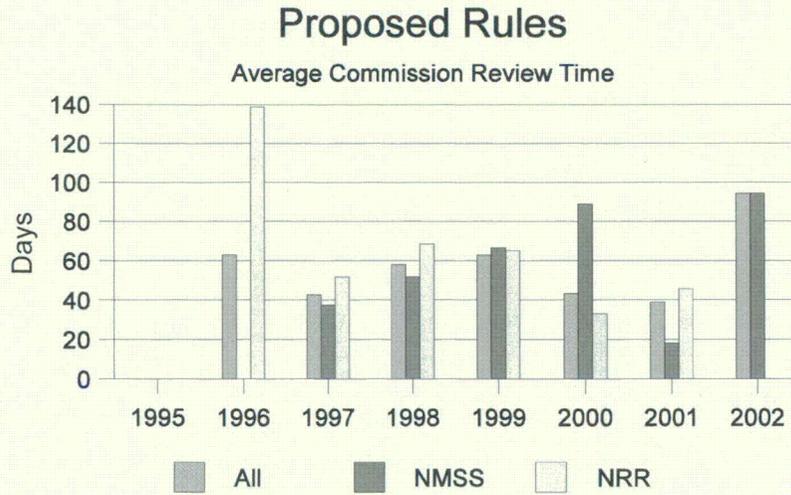


Figure D.5. Average Commission Review Time for Proposed Rules.

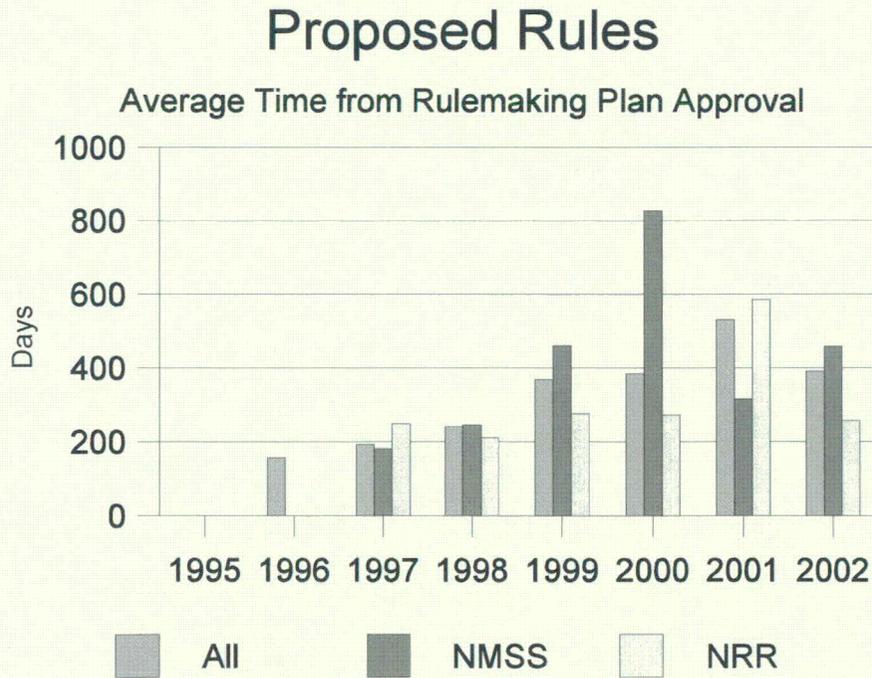


Figure D.6. Average Time from Rulemaking Plan Approval to Publication of Proposed Rule.

Rulemaking Plans

Average Time from Initiation

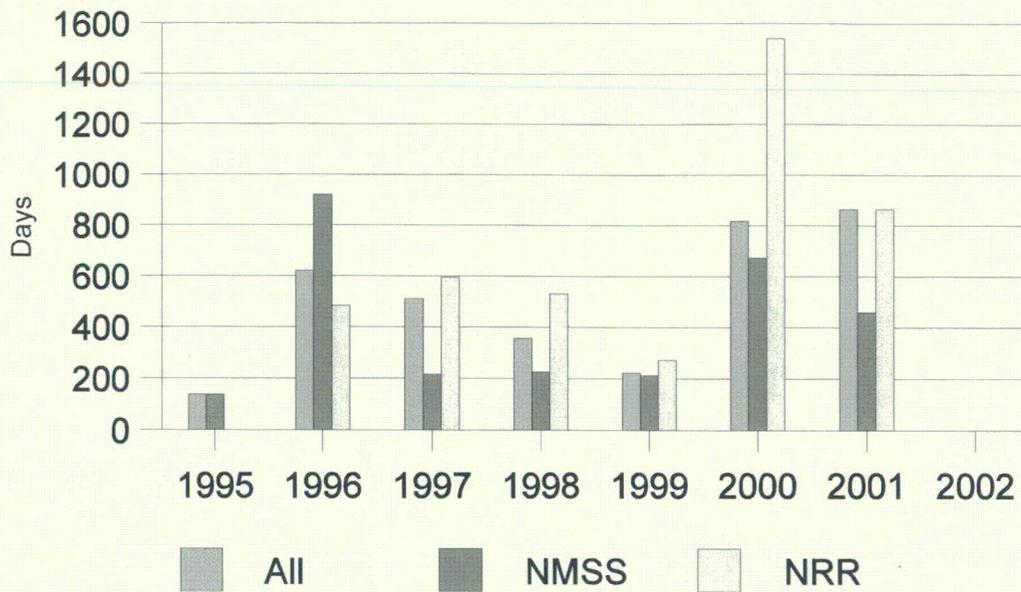


Figure D.7. Average Time from Initiation to Approval of Rulemaking Plan.

Final Rules

Average Commission Review Time

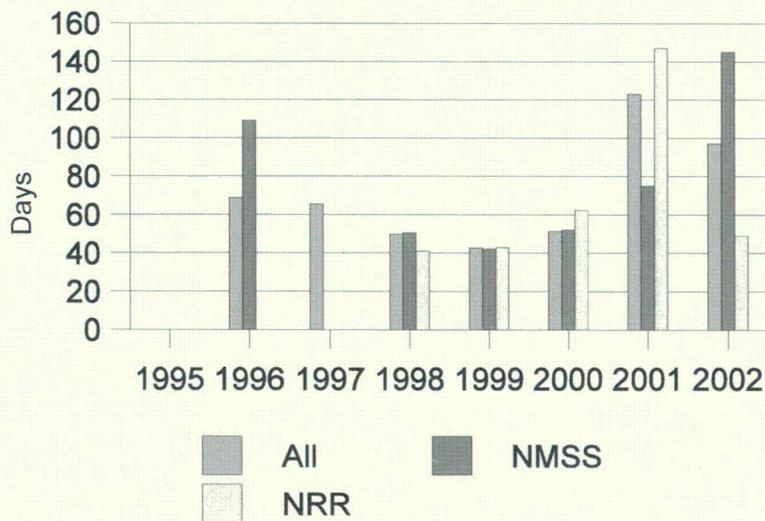


Figure D.8. Average Commission Review Time for Final Rules.

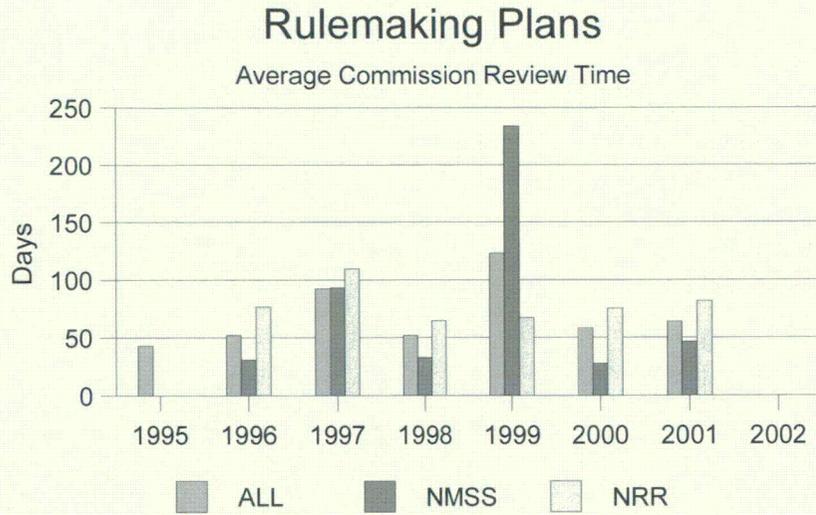


Figure D.9. Average Commission Review Time for Rulemaking Plans.

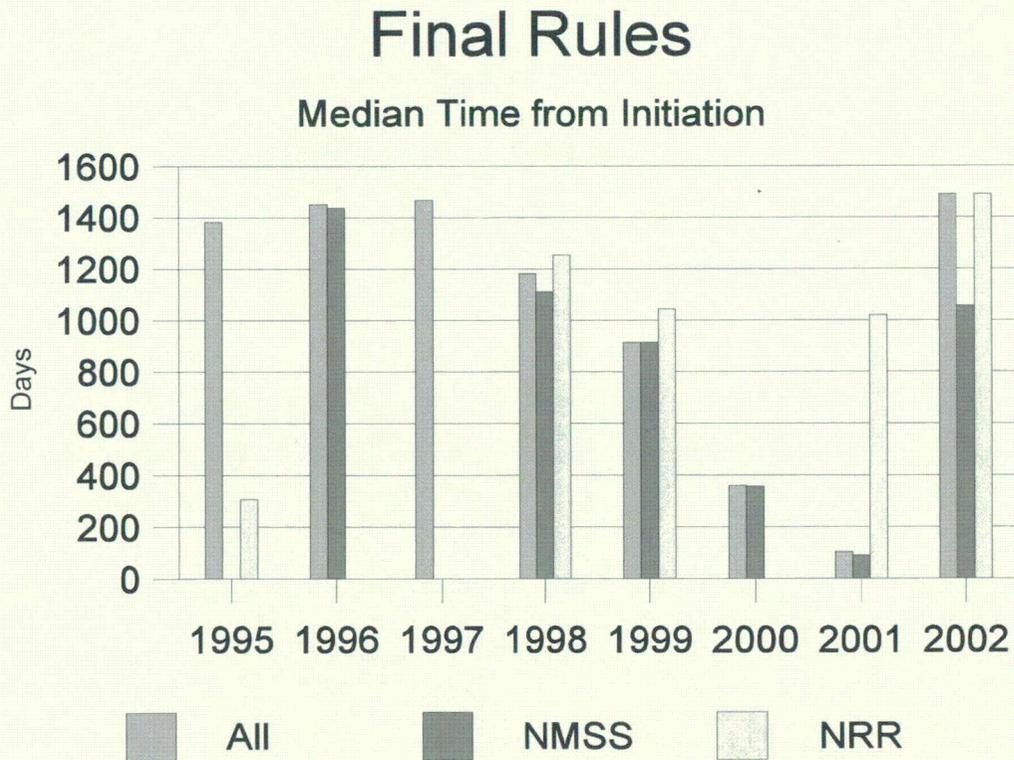


Figure D.10. Median Time From Initiation to Final Rule Publication.

Final Rules

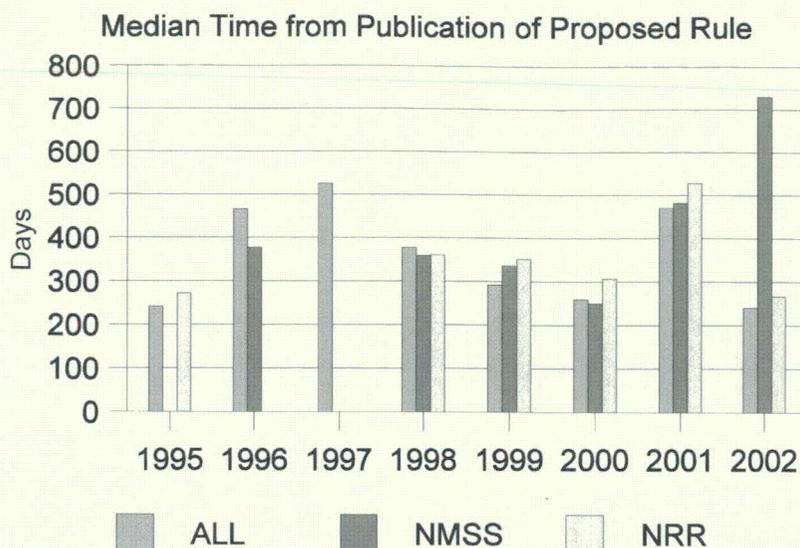


Figure D.11. Median Time from Proposed Rule Publication to Final Rule Publication.

Final Rules

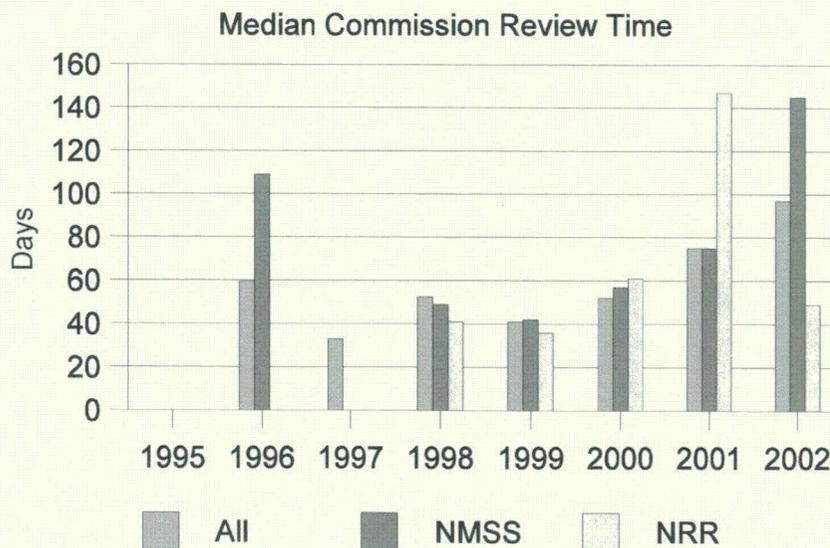


Figure D.12. Median Commission Review Time for Final Rules.

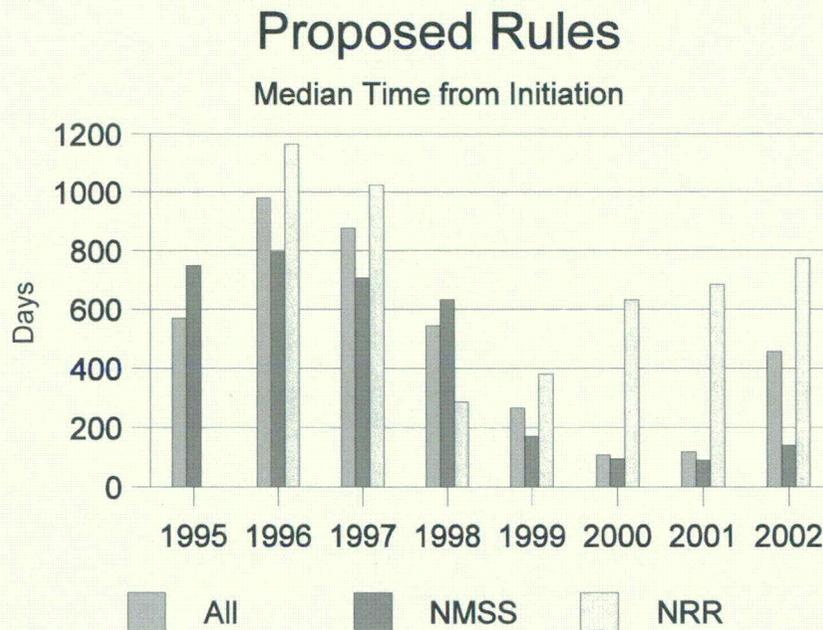


Figure D.13. Median Time from Initiation to Proposed Rule Publication.

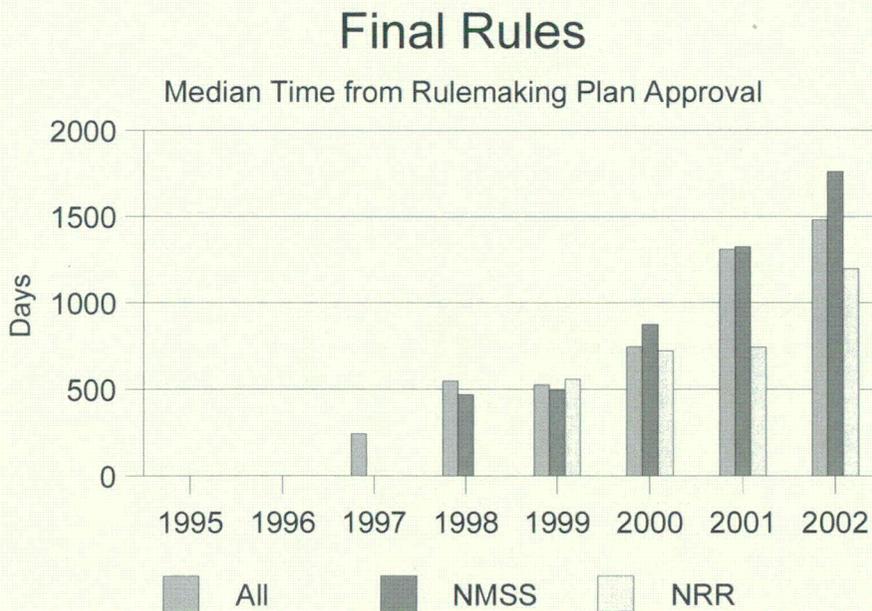


Figure D.14. Median Time from Rulemaking Plan Approval to Final Rule Publication.

Proposed Rules

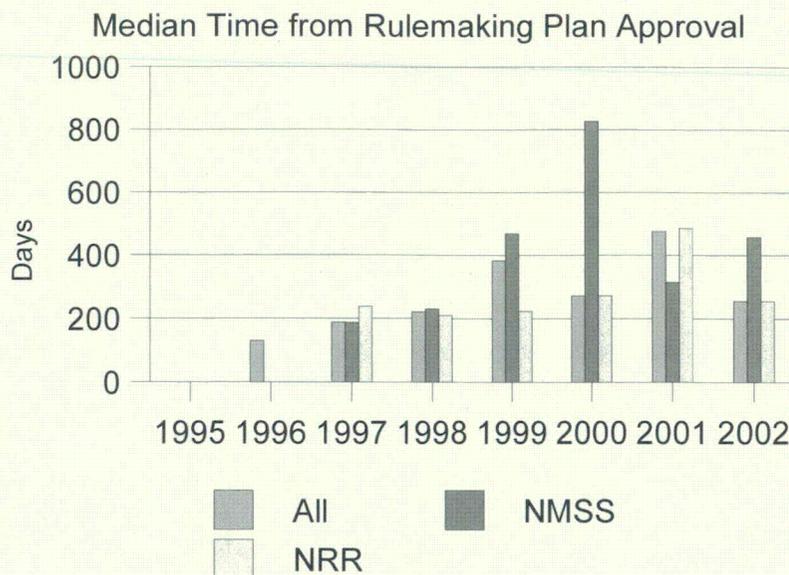


Figure D.15. Median Time from Rulemaking Plan Approval to Proposed Rule Publication.

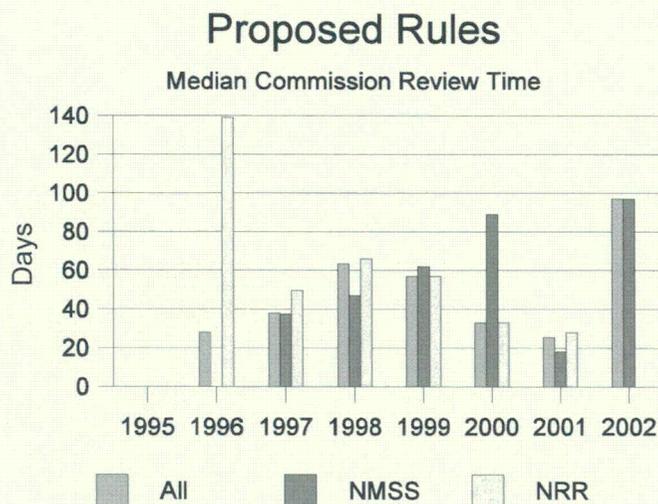


Figure D.16. Median Commission Review Time for Proposed Rules.

Rulemaking Plans

Median Time from Initiation

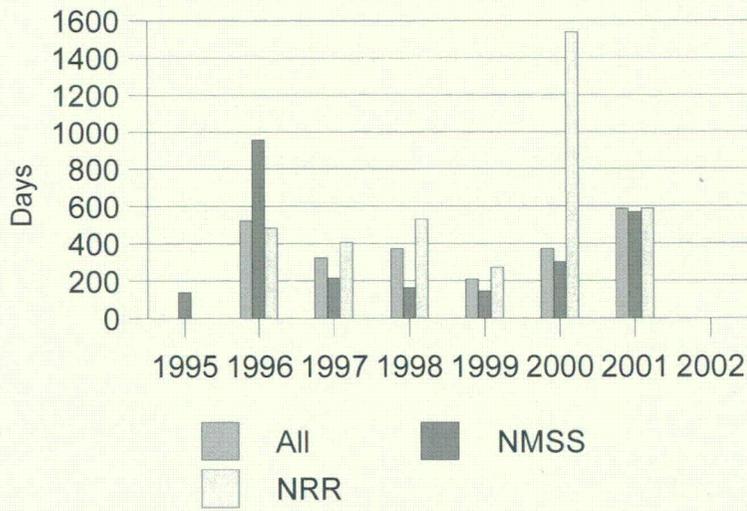


Figure D.17 Median Time from Initiation to Rulemaking Plan Approval.

Rulemaking Plans

Median Commission Review Time

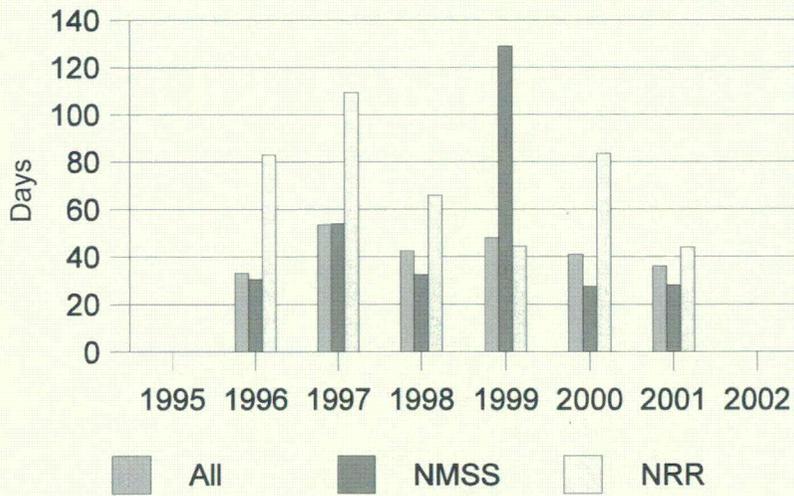


Figure D.18 Median Commission Review Time for Rulemaking Plans.

Appendix E: Benchmarking NRC's Rulemaking Performance

Benchmarking NRC's Rulemaking Performance

Using the rulemaking data collected internally, the task force was able to create a statistical profile of NRC's rulemaking performance. To provide an interpretative context for this data, the task force asked several other Federal regulatory agencies to supply key information about their own rulemaking procedures and performance. The 10 agencies targeted by the task force were chosen because they were similar to NRC in either administrative structure or public service mission.

The task force sent each counterpart agency a survey instrument consisting of three parts:

- A general request for information about the counterpart agency's current rulemaking procedures.

- A request for specific data about proposed and final rules that the counterpart agency had published in the last 5 years.

- A series of questions about specific elements of the counterpart agency's current rulemaking practices.

A cover letter explained the mission of the task force, and noted that the rulemaking improvement report under development by NRC task force was intended for internal NRC use only. Cooperating agencies were assured that, if NRC subsequently made all or part of the report publicly available, benchmarking information used in the report would be summarized, and would not be identifiable by agency. The task force also offered to share the results of NRC's benchmarking effort with the responding agencies. The letter sent to other Federal agencies is also provided at the end of this Appendix.

Comparing NRC's Rulemaking Procedures to Those of Counterpart Agencies

Four of the 10 agencies targeted responded to the request. All the responding agencies are health and safety regulators; none is an independent agency. As sub-agencies of Executive Branch departments, their regulations are subject to regulatory review under Executive Order 12866, a process from which NRC is exempt. However, the responding agencies described notice-and-comment rulemaking procedures broadly similar to those in place at NRC, and all reported using measures of rulemaking efficiency comparable to those identified in the survey.

Organizational Structure of Rulemaking

Of the four responding agencies, three use a central rulemaking office to draft rules, manage rulemaking projects, and maintain official rulemaking files and tracking systems. In two of the three agencies, a project manager from the rulemaking office leads a rulemaking team that includes one or more technical experts, a lawyer, and, typically, an economist. In the remaining agency, a similarly constituted Working Group is headed by a team leader drawn from the technical staff. The staff of the rulemaking office secures all the necessary legal and policy clearances; coordinates the efforts of all offices contributing to the rulemaking package; ensures that rulemaking documents and packages conform to all administrative and statutory requirements; and guides the package through the required internal and external reviews.

In the fourth agency, a regulator that generates only a handful of new rules in an average year, rules are written by the technical staff, but the rulemaking office manages the project, coordinating staff effort across offices and ensuring that the package conforms to all relevant administrative and publication standards.

Initiation of Rulemaking

All responders mentioned a similar set of rulemaking triggers, including legislation, petitions for rulemaking, accident or incident reports, technological change, staff identification of a health or safety hazard, and regularly scheduled regulatory reviews. One agency develops fully two-thirds of its rulemakings in response to petitions for rulemaking filed with the agency. Two of the four agencies initiate rulemaking by preparing a standard document that combines features of a user need memo and a rulemaking plan. Most of the responding agencies initiate rulemaking on the recommendation of program offices, but these initial judgments are conditional on subsequent review and endorsement of the project by upper management and agency leadership.

In one agency, rulemaking proposals written by technical experts (with the assistance of the rulemaking office) are formally reviewed by a rulemaking management council composed of division directors. This council is required to act on rulemaking proposals within 60 days of their submission, and has the power to approve rulemaking proposals, reject them outright, or return them to the staff for further development. Rulemakings approved by the council are assigned priorities, with some being fast-tracked and assigned a rulemaking team, whereas others are queued up for later initiation when agency resources become available. The rulemaking management council occasionally refers proposals to a standing rulemaking steering committee, composed of office directors and deputy directors with rulemaking responsibilities. The steering committee reviews potential rulemakings that raise important policy questions, would require significant interagency cooperation, or might conflict with the agency's current regulatory strategy.

Internal Review of Rulemakings

All the responding agencies use a concurrence process to vet rulemaking packages, and most reported that rules were typically reviewed and signed by the office of the agency Administrator. The responders are all agencies of Cabinet-level departments, and their rules often have to be approved by the office of the Department Secretary as well. All rules that OMB considers significant or major rules are subject to Department-level review, but routine, non-controversial, and purely administrative rules are generally approved at the agency or, in some cases, at the office level.

One agency noted that all its rules must be cleared all the way up to the Department Secretary's office at each stage of the rulemaking process.

One agency, in the interest of increasing efficiency and speeding up the rulemaking process, encourages offices and divisions to delegate concurrence authority to lower-level managers, or even to technical staff, whenever possible. This is the same agency that uses a rulemaking management council to vet rulemaking plans and to review rulemaking packages as they progress through subsequent stages of development. RMPs submitted to the council must detail delegations of concurrence authority in all participating offices; if concurrence is not delegated, this choice must be justified in the RMP. The rulemaking management council provides regular management oversight of all rulemakings, allowing individual offices involved in rulemaking to compress their concurrence chains with some confidence. Staff rulemaking teams regularly prepare and distribute executive summaries for all important rulemaking documents, allowing interested managers and agency leadership to easily keep abreast of rulemaking developments.

Improvement of the rulemaking process is the focus of a continuous improvement team established by one agency. Rulemaking staffers serve 1-year terms on the team, which is charged with reviewing project self-assessments submitted by rulemaking Working Groups after issuance of a rule. The improvement team studies completed rulemakings, then examines the

rulemaking process to determine if procedural changes could help the agency incorporate lessons learned. Another committee in the same agency focuses on ways of improving the agency's rulemaking documents, recommending changes to agency templates and style books as it deems appropriate.

External Review of Rulemakings

Executive and Congressional Regulatory Review

OMB review is a complicating factor in the rulemaking process of each responding agency. Because all the agencies are subject to regulatory review under Executive Order 12866, their concurrence procedures include reviews by offices responsible for managing agency compliance with OMB requirements. Rules must be reviewed for significance and regulatory analyses prepared and submitted to OMB. OMB is required to review and comment on all significant rules within 90 days of their submission, but the agency must then resolve OMB's comments before the rule can be promulgated. Though OMB review inevitably lengthens the time required to complete a rulemaking, agencies of Cabinet-level Departments can call upon staff economists and regulatory specialists at both the agency and the Department levels to help secure OMB approval.

Other forms of external review include review by other Federal agencies concerned in the rulemaking, by national or international standards-setting organizations, by international trade or law enforcement authorities, by Federal Advisory Committee Act committees, and by industry Working Groups. The nature and extent of external rulemaking review varies with the mission and regulatory authority of the agency. One agency regularly establishes rulemaking Working Groups composed of representatives from regulated communities; these external Working Groups are tasked with recommending solutions to specific problems connected with a given rulemaking. The agency is represented in the external group by one or more staff members, one of which is responsible for attending all meetings and reporting back to agency management and to the internal team working on the rulemaking.

Small businesses dominate the commercial community regulated by one agency. This agency has extensive interaction with the SBA, and puts significant staff effort into its regulatory flexibility analyses.

Public and Stakeholder Involvement

All the responding agencies reported scheduling public meetings during the comment period for the proposed rule; some hold hearings at the proposed rule stage on request. One agency routinely meets with stakeholders before making a decision to initiate rulemaking. This agency uses advance notices of proposed rulemaking to test out rulemaking proposals on the public and the industry and to solicit non-rulemaking solutions to the regulatory problem at hand. The agency employing the rulemaking management council mandates that each rulemaking plan submitted for review detail a public participation strategy for the rulemaking. The council can accept the staff plan for public participation or mandate a different approach.

Comparative Information on Rulemaking Topics of Special Interest

Finally, each agency was asked to provide brief answers to a series of questions about specific features of its rulemaking process.

How does your agency use information technology to track or facilitate rulemaking?

Two of the four responding agencies use fully automated database systems to track the progress of rulemakings through the development process. These databases are continually updated and contain current status, schedule, and summary information on all rulemakings in the system. One of these agencies also has a document tracking system, similar to ADAMS, in which rulemaking documents are made available to agency staff on a central server. This agency also tracks the final stages of high-priority rulemakings via a monthly watch list that shows all rules due for promulgation in the next 60 days. The list is used to coordinate and accelerate staff efforts on rulemakings that are approaching target completion dates set by Congress or the Executive.

One of the responding agencies has converted rulemaking logs created in MS Word into an MS Access database, but has not yet fully automated its tracking system. This agency is working on upgrading the database and adding sophisticated reporting capabilities. The remaining agency does not currently have a database to automatically track rules, but is looking into developing a system of this kind.

One agency reported that it must enter rule data into a Department-level tracking system that parallels its own agency-level system. In fulfillment of a statutory requirement, another agency has created and maintains a separate database to track rulemakings connected with a specific class of regulatory actions.

Two of the agencies post at least some of their current rulemaking documents (e.g., proposed and final rule notices, transcripts of public meetings) on their agency web sites. One of the agencies also posts public comments on its agency web site, and uses e-mail alerts to inform the regulated community and public interest groups when items of interest have opened for comment. Agency staffers use e-mail to maintain Working Group relationships with employees in field offices, cutting down on agency travel costs by rulemaking team members.

Three of the four agencies participate in the U.S. Department of Transportation's interactive docket management system (<http://dms.dot.gov/>), a publicly available, web-accessible database that allows a visitor to read and comment on all documents in a given rulemaking docket. Visitors search for documents using docket numbers obtained from Federal Register notices or agency web sites. DOT's system also accepts comments, either *via* e-mail (an automated response form is provided) or *via* a file upload to the site (the method used on NRC's Rulemaking Forum web site).

All the responding agencies but one provide an e-mail address for public comments in their Federal Register notices; the remaining agency's notices refer readers to the DOT web site. One agency that accepts e-mail comments will not accept them as e-mail attachments; another agency provides a FAX number for comments, as well as an e-mail address.

On a related point, one agency noted that if it decides to accept a late-filed comment on any document open for public comment, it re-opens the comment period to allow other members of the public an equal opportunity to be heard. A different agency reports that it will accept early comments—comments filed before a rulemaking document on the subject is officially opened for comment. This agency simply puts such comments in a suspense file, and files them in the appropriate docket file as soon as one opens. A third agency accepts and docketed anonymous public comments on rulemaking documents.

Does your agency employ contractors to work on rulemaking or perform regulatory analysis?

The responding agencies reported little or no use of contract workers on rulemaking projects. One agency remarked that experiments with contract help had not proven cost-effective, as so much time was needed to get new workers up to speed. Another agency estimated that, at

most, 10 percent of its rulemaking workload was contracted out. All the agencies reported having trained economists and regulatory specialists on staff and available to prepare the various elements of a typical rulemaking package.

Is rulemaking efficiency a typical performance measure for staff and managers in your agency? If so, what specific measures are used?

All the agencies reported that rulemaking performance figured into the agency's assessment of staff and managerial success. Operating plans for individual offices involved in rulemaking typically include performance measures for rulemaking pegged to timely completion, clarity of presentation, and legal and technical adequacy, but no respondent mentioned a set of agency-wide standards or a particular scheme of quantitative assessment.

Congressional monitoring of one agency's rulemaking schedules has prompted that organization to put a high value on timely completion of rulemakings; this is the agency that developed the 60-day watch list mentioned above. Another agency stated that timely promulgation of rules was of increasing importance to it management, and noted that it was developing strategies to accelerate its rulemaking process. However, yet another agency reported that, though its leadership expects steady progress on rulemaking projects, there is a general understanding among management that many aspects of the Federal rulemaking process are unpredictable and largely beyond staff control. In this agency's view, strict application of quantitative performance measures in the rulemaking arena would be unreasonable.

New rulemakings often increase or change requirements on regulated entities, necessitating changes in existing systems, structures, and practices. Does your agency submit potential rulemakings to an internal review that focuses on (a) eliminating unnecessary regulatory burdens and costs to regulated entities, and (b) promoting cost-effective regulation in the public interest? If so, how does this affect the length of time your agency takes to complete rulemakings?

NRC's backfit review process is similar to the internal reviews that the responding agencies have established in response to Executive Order 12866 and the Regulatory Flexibility Act. Agency economists generate regulatory analyses demonstrating the cost-effectiveness of proposed rulemakings, along with analyses focusing on the potential effects on small businesses. Though these analyses are created concurrently with development of the rule, responding to OMB criticisms of agency analyses can add months to the time taken to issue a rule. Another agency reported that its need to coordinate with international standards-setting organizations in developing new regulations lengthened the rulemaking process considerably.

All the agencies are mindful of the need to minimize regulatory burdens and update rules as technology advances, but stress that their overriding concern is to address safety issues and reduce risks to the public. One agency reported that it attempts to ease transition costs to industry by including grandfather clauses or delayed effective dates in new rulemakings. Regulated companies are given a chance to use up existing supplies and make a gradual shift toward compliance with new standards.

Benchmarking Survey Package



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 11, 2002

XXXXXXXXXX
Deputy General Counsel
Office of the General Counsel
XXXXXXXXXXXXXXXXXXXXXXXXXXXX

Dear XXXXXXXX:

The Nuclear Regulatory Commission (NRC) has formed a Rulemaking Improvement Task Force to study our rulemaking process. As part of this project, the task force is gathering information about the rulemaking processes of other agencies. We will use this information both to benchmark our performance against that of counterpart agencies, and to learn from the successes of others. We are soliciting assistance from your agency, as well as others.

Our request, contained in Enclosure 1, seeks information about the steps in your regulatory process, as well as about the resources and time that your agency expends in the development of rulemakings. In order to provide a context for our request, Enclosure 2 presents a summary description of NRC's own regulatory process.

Although the rulemaking improvement report under development by our task force is intended for internal NRC use only, we cannot guarantee that it will not eventually be made publicly available. Therefore, any information from cooperating agencies used in our report will be summarized, and will not be identifiable by agency. The detailed information provided by each agency will remain available in internal NRC documents. We also will be pleased to share with your agency any insights gained through this study.

The task force may wish to arrange a follow-up call or meeting to insure that we fully understand the information provided by your agency. Please furnish us with the name, phone number, and e-mail address of a contact in your agency, in case such follow-up is needed.

The task force is asking for your response within 30 days. We recognize that this is a significant information request and greatly appreciate your agency's cooperation. If you have any questions, or would like to discuss this request, please contact Victoria Voytko, of my staff, at 301-415-6075. Also, to expedite receipt of your information, please e-mail your response to Ms. Voytko (VNV@nrc.gov), or phone her to arrange for courier service.

Sincerely,

Michael T. Lesar, Chief
Rules and Directives Branch
Division of Administrative Services
Office of Administration

Enclosures: 1. Information Request
2. Summary of NRC's Rulemaking Process

**Nuclear Regulatory Commission
Rulemaking Improvement Task Force
Request for Information from Counterpart Federal Agencies**

This request has three parts:

- VI. A general request for information about your agency's current rulemaking procedures.
- VII. A request for specific data about proposed and final rules that your agency has published in the last five years.
- VIII. A series of questions about specific elements of your agency's current rulemaking practices.

Please respond to any or all parts of this survey as your agency records allow. We would appreciate a response within 30 days. Questions about this request may be directed to:

Victoria Voytko, Regulations Specialist
Rules and Directives Branch
Office of Administration
Phone: 301-415-6075
Fax: 301-415-5144
E-mail: vnv@nrc.gov

Responses may be sent to Ms. Voytko (a) by e-mail (preferred method) at the address given above, (b) by facsimile at the number given above, or (c) by post at the following address:

Victoria Voytko
ADM/DAS/RDB
Mail Stop: T-6, D59
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Part I – Request for Information about Rulemaking Procedures

Our task force is reviewing both the NRC's rulemaking procedures and our guidelines for performing regulatory analyses. We would like to compare our practices to those of other Federal agencies that are similar either in administrative structure or in mission.

We would appreciate receiving a copy of any procedures manual, agency handbook, guidance document or comparable material that details your agency's rulemaking and/or regulatory analysis procedures. For purposes of comparison to our own procedures, we are particularly interested in material which—

- Describes how the rulemaking function is structured in your agency (e.g., is it centralized in a single office?);
- Indicates who has chief responsibility for rulemaking in your agency;
- Outlines the main stages in your agency's rulemaking process; and
- Details the levels of management approval required at various stages of rulemaking.

**Part II – Request for Data about Proposed and Final Rules
Published in the Last Five Years**

As part of our analysis, the task force is collecting data on the number of rules processed by the NRC yearly, the staff resources devoted to NRC rulemaking, and the average length of time required to complete each of the major phases of a typical NRC rulemaking. On a few key measures of efficiency, we would like to benchmark our performance against that of counterpart Federal agencies.

Your agency may use different measures of efficiency in rulemaking than those we have chosen. If so, we would welcome data on comparable measures used by your agency. Please characterize the data your agency is able to provide by annotating the chart below or, as necessary, summarizing the information on a separate sheet.

Taking the last five years as the range for data collection, please fill in the chart below. Indicate whether the figure provided for each performance measure represents hard data or an estimate by marking the appropriate column. Where no data is available, please write “Unavailable” in the “Data” column.

Performance measures		Data	Hard data	Estimate
1	Average annual FTEs budgeted for rulemaking			
2	Average number of final rules published yearly			
3	Average number of proposed rules published yearly			
4	Average number of APA-exempt rules published yearly			
5	Average number of direct final rules published yearly			
6	Average number of days from initiation of rulemaking to publication of proposed rule			
7	Average number of days from publication of proposed rule to publication of final rule			
8	Average number of days to obtain OMB clearance			
9	Number of rules published yearly which aim to:			
	a Enhance public safety			
	b Reduce regulatory burden			
	c Other			

**Part III – Request for Additional Information about Specific Elements
of the Rulemaking Process**

Please provide brief answers to the questions below. Where appropriate, please reference detailed discussions in the material your agency is sending us in response to Part I of this request.

- (1) How and when is rulemaking formally initiated in your agency?

- (2) How does your agency use information technology to track or facilitate rulemaking?

- (3) Does your agency employ contractors to work on rulemaking or perform regulatory analysis? To what extent?

- (4) Is rulemaking efficiency a typical performance measure for staff and managers in your agency? If so, what specific measures are used?

- (5) New rulemakings often increase or change requirements on regulated entities, necessitating changes in existing systems, structures, and practices. Does your agency submit potential rulemakings to an internal review that focuses on (a) eliminating unnecessary regulatory burdens and costs to regulated entities, and (b) promoting cost-effective regulation in the public interest? If so, how does this affect the length of time your agency takes to complete rulemakings?

AN OVERVIEW OF THE NRC'S RULEMAKING PROCESS

The NRC has attempted to establish an independent, open, efficient, clear, and reliable rulemaking process that allows the agency to meet its goals of maintaining safety, reducing regulatory burden, increasing public confidence, and improving the NRC's regulatory efficiency and effectiveness.

- II. **Triggers for Rulemaking.** NRC's regulations are developed in response to—
 - A. Congressional mandate,
 - B. Internal initiation,
 - C. Petitions from outside the NRC, or
 - D. The need for a conforming, corrective, or other type of administrative action.

- III. **The Rulemaking Plan.** Typically, the staff seeks the Commission's approval to begin work on a rulemaking by submitting a rulemaking plan which—
 - A. Describes the existing problem,
 - B. Details how the problem would be addressed by the rulemaking,
 - C. Sets out and—via an initial cost-benefit analysis—evaluates options for attaining the rulemaking's objective, and
 - D. Projects a schedule for completion of the rulemaking and an estimate of resources needed to complete the process.

- IV. **Development and Publication of Rules.** After Commission approval of the plan, the rulemaking proceeds accordingly. Also, at this point **the "clock" starts** to keep the time spent on the completion of the rule.
 - A. If necessary, an **advance notice of proposed rulemaking** or other of notice of enhanced public participation, such as a public workshop or meeting with Agreement State representatives, is prepared and published for public comment.
 - B. Then, a **proposed rule** is prepared and published for public comment. The length of time from the approval of the rulemaking plan to the publication of the proposed rule notice in the *Federal Register* is generally one year.
 - C. After the public comment period for the proposed rule ends, a final rule addressing comments on the proposed rule is prepared and published. Most often, the schedule calls for the **final rule** to be published one year after the proposed rule, or approximately two years after approval of the rulemaking plan.
 - D. The length of these schedules will vary depending upon the complexity of or the degree of public interest in the rule. Under certain very narrow conditions, the Commission may waive publishing a proposed rule for public comment. In that case, a **direct final rule** including a proposed rule is prepared and published. Direct final rules are generally finalized within 12 months.

- V. **Structure of NRC Rulemaking.** Responsibility for overseeing the development of a given rule generally falls to the cognizant program office—usually the Office of Nuclear Reactor Regulation or the Office of Nuclear Material Safety and Safeguards.
 - A. The responsible office typically forms a **working group** with members drawn from appropriate NRC organizations. The working group usually includes a member from the Office of the General Counsel; sometimes members are drawn from NRC regional offices or the Office of Nuclear Regulatory Research.
 - B. The main tasks of the working group are to—
 - 1. Prepare the rulemaking documents,

An Overview of the NRC's Rulemaking Process

2. Prepare the necessary supporting documents (environmental assessment, regulatory analysis, etc.),
3. Keep management informed about progress of the rulemaking, and
4. Facilitate final management review and approval of the complete rulemaking package.

- VI. Rulemaking Packages.** The rulemaking packages must address the standard requirements imposed by statute (e.g., review under the National Technology Transfer and Advancement Act of 1994, the National Environmental Policy Act, and the Paperwork Reduction Act). Although the NRC is an independent agency, it does require **regulatory analyses** to be performed on rulemakings.
- A. As part of the regulatory analysis, the NRC has established the requirement for the inclusion of a **backfit analysis**. Backfitting is defined as the modification of or addition to the systems, structures, components or design of a facility; or to the design approval or manufacturing license for a facility; or to the procedures or organization required to design, construct or operate a facility.
 - B. Backfits may be required by a new or amended provision in the Commission rules, or by a new interpretation of Commission rules by the regulatory staff. The NRC has established standards for the management of backfitting requirements on power reactors, gaseous diffusion plants, independent spent fuel storage installations and monitored retrievable storage installations.
 - C. Consideration of backfit issues can increase the time needed to complete the regulatory analysis for a rulemaking.
- VII. Concurrence Chain.** NRC rulemaking packages undergo **review and approval** at a number of levels, both within and without the agency.
- A. A typical concurrence chain—
 1. Begins with the originator of the package;
 2. Includes the **rule writer's chain of management** up to the Office Director level; and
 3. Continues to the Office of the **Executive Director for Operations** (EDO).
 4. The EDO transmits the package to the **Commission** for final consideration and approval.
 - B. Depending on the substance of the rule, the concurrence of other NRC offices may be necessary, and some offices need to concur on all packages.
 1. Each rulemaking must be awarded a finding of "no legal objection" from the **Office of the General Counsel**.
 2. The **Office of the Chief Financial Officer** reviews and concurs on the packages to ensure that the resources required to complete and implement the rulemaking have been properly addressed and to ensure that rulemakings that could affect the NRC's license and annual fee schedules have been coordinated.
 3. The **Office of the Chief Information Officer** reviews rulemaking actions to ensure that potential information technology impacts have been properly addressed and to coordinate OMB approval of any new or amended information collection requirements.
 4. The **Office of Enforcement** reviews rulemaking actions to ensure that an appropriate criminal penalty statement is included.
 5. The **Rules and Directives Branch** in the Office of Administration reviews

An Overview of the NRC's Rulemaking Process

rulemaking actions to ensure that the rulemaking document meets Office of the Federal Register publication requirements and complies with the Regulatory Flexibility Act, the SBREFA, and the Commission's Plain Language Initiative.

- C. Lastly, although the **Office of the Inspector General** does not concur on rulemaking actions, a copy of each rulemaking action is sent to OIG for review.
- VIII. Additional Levels of Review.** For certain rules, further reviews may be needed.
- A. To enhance Agreement State participation, the NRC may solicit input from **Agreement States**. Based on the complexity of the rule, Agreement State involvement may be sought on preliminary versions of the rulemaking plan, draft versions of the rule, and through participation on working groups.
 - B. Also, if a rule affects Indian tribes or receives comments from **Indian tribes or Tribal organizations**, the comments must be presented as a readily identifiable portion of the general discussion concerning any substantive comments received in the Supplementary Section of either the proposed or final rule.
 - C. An internal review may be required by the **NRC's Committee to Review Generic Requirements (CRGR)**. The CRGR has the responsibility to review and recommend to the EDO approval or disapproval of proposed NRC requirements or staff positions on one or more classes of nuclear power reactors and on selected nuclear materials issues. The CRGR's main focus relates to the staff's proper disposition of the rulemaking as it relates to the backfit rule. NRC has developed guidance so that regulatory analyses will meet the requirements of the backfit rule and provisions of the CRGR Charter.
 - D. NRC has established various **advisory committees** to enhance the agency's mission. Some rulemakings may require review by advisory committees, although the advisory committees and the CRGR may decline the opportunity to review a rulemaking package at their discretion. Depending upon the nature of the rulemaking, it may be reviewed by—
 - 1. The Advisory Committee on **Reactor Safeguards**,
 - 2. The Advisory Committee on **Nuclear Waste**, or
 - 3. The Advisory Committee on **Medical Uses of Isotopes**.
- IX. Final Approval and Signature Authority.** Most rules are approved by the **Commission** and signed by the Secretary to the Commission prior to publication.
- A. For certain types of rules, the Commission has **delegated approval and signature authority** to—
 - 1. The **Executive Director for Operations (EDO)** or
 - 2. The **Chief Financial Officer (CFO)**.
 - B. The authority delegated to the EDO and CFO extends only to rules which—
 - 1. Do not have significant policy implications;
 - 2. Do not substantially alter established agency practices; and
 - 3. Are within the purview of the EDO or the CFO.