Rulemaking Process Innovation at the U.S. Nuclear Regulatory Commission

U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Division of Rulemaking, Environmental, and Financial Support

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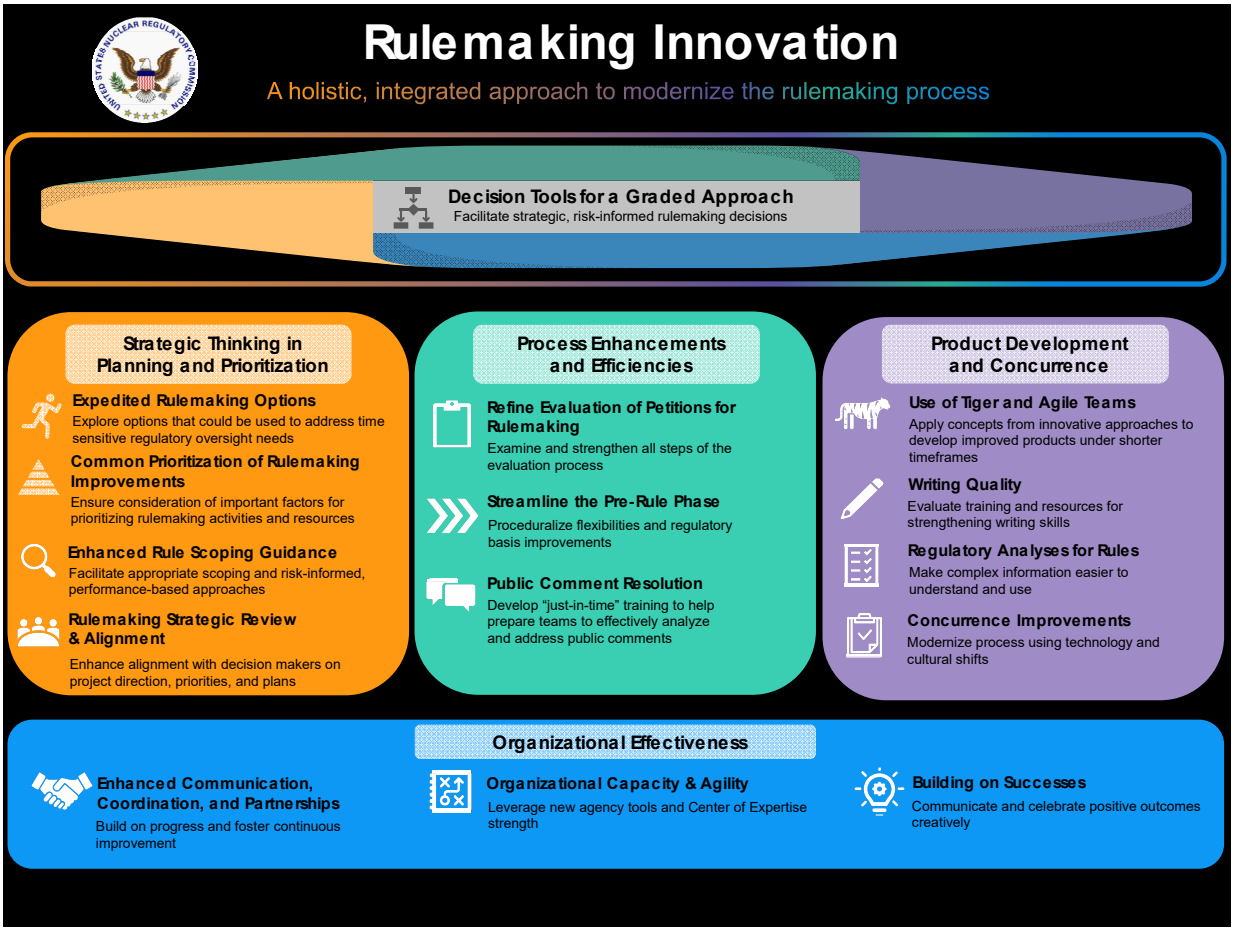

Figure 1. Enhancement Areas and Planned Activities

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SUMMARY

The U.S. Nuclear Regulatory Commission's (NRC's) Rulemaking Center of Expertise (COE)[1] is making improvements to the NRC's rulemaking process to align with the agency's vision of being a modern, risk-informed regulator. As illustrated in Figure 1 on page i of the frontmatter, this initiative takes a holistic, integrated review of all aspects of the rulemaking process to identify opportunities for improving quality, timeliness, and stakeholder engagement. To inform its evaluation, the staff reviewed a variety of inputs, including benchmarking with other Federal agencies, interviews with other NRC staff and managers, lessons learned from recent projects, project management best practices, and the agency's transformation activities. The changes identified by this evaluation are consistent with existing Commission policy and direction.

Based on its analysis, the staff identified several opportunities for improvement at both strategic and tactical levels and organized them into five key enhancement areas:

1. Decision tools for applying a graded approach to rulemaking;
2. Strategic thinking in planning and prioritization;
3. Process enhancements and efficiencies;
4. Product development and concurrence; and
5. Organizational effectiveness.

The first area establishes a framework for facilitating a strategic, risk-informed decision path for rulemaking and is expected to provide the most impact. The other four areas facilitate implementation of the path forward in more effective, efficient, and innovative ways. The full set of improvements are designed to operate together in advancing all aspects of the NRC's rulemaking process.

Staff has made notable progress in pursuing efforts in these areas. This report discusses recent accomplishments and additional actions NRC plans to take, the expected completion timeframes, and the approach for performance monitoring and tracking.

[1] The Rulemaking Center of Expertise is a group within the Division of Rulemaking, Environmental, and Financial Support in the NRC's Office of Nuclear Material Safety and Safeguards.

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1. PURPOSE AND OBJECTIVES

The purpose of this effort is to identify and implement changes to the NRC's rulemaking process to align it with the agency's vision of being a modern, risk-informed regulator. This staff-initiated effort takes a holistic, integrated review of all aspects of the rulemaking process to identify innovative ways to improve quality and timeliness of rulemaking products and further strengthen staff and stakeholder engagement.

The specific objectives are:

- Determine the most appropriate path for meeting a rulemaking need in a strategic manner;
- For long-term rulemaking projects, proactively identify and make needed course shifts;
- Improve the quality, resource expenditure, and timeliness of rulemaking processes and products;
- Strengthen collaboration and integration with relevant internal and external activities; and
- Leverage the COE's organizational agility and capacity to meet rulemaking needs.

2. BACKGROUND ON RULEMAKING PROCESS

The Federal rulemaking process is, by design, a thorough, deliberate, and transparent process. This process is constructed to produce technically and legally sound regulations that provide regulatory certainty and are informed by a full spectrum of stakeholder input. NRC's implementation of Federal requirements and Commission direction, that together inform its rulemaking policy and practices, is documented in Management Directive 6.3, "The Rulemaking Process." In conducting its rulemaking activities, the NRC must adhere to a number of statutorily mandated procedural requirements (e.g., the Administrative Procedure Act (APA), Paperwork Reduction Act, the Congressional Review Act, the National Environmental Policy Act) and follow direction issued by its Commission. Enclosure 1 provides a high-level overview of the rulemaking phases and the required and optional components of those phases.

3. EVALUATION AND IMPLEMENTATION APPROACH

To collect data for the evaluation in this report, the staff conducted benchmarking with several other Federal agencies and interviewed a sample of NRC staff and managers familiar with the rulemaking process. The staff also reviewed lessons learned from recent projects (including the recently completed Material Control and Accounting Rulemaking Case Study (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19235A010)), project management best practices, and the agency's transformation activities.

Based on these information sources, the staff identified several opportunities for improvement at both strategic and tactical levels and organized them into five key enhancement areas. The staff reviewed and integrated principles from the agency's Change Management Framework in formulating these areas and will continue to apply these concepts during implementation of these activities. The staff has made notable progress in implementing many of the efforts, and additional actions are described under each section below, along with anticipated timeframes for completion.[2] The COE is planning to conduct pilot operations projects in several areas, because these projects can be conducted at a low cost or low risk and provide helpful insights for adjustments and refinements to inform longer-term planning. In addition, as rulemaking covers a wide breadth of agency activities, the COE plans to be an early adopter of agency transformation and innovation advancements, including applicable Information Technology (IT) tools, and to collaborate closely with its partner organizations and business line leads.

Staff from across the COE organization have been engaged in this effort in order to leverage diversity in backgrounds and skillsets. The intent is to energize and empower all rulemaking staff to take ownership of the rulemaking process, so that innovation and continuous improvement become more fully integrated into the culture and routine operations of the COE. Plans for monitoring and tracking progress are discussed in Section 4.6.

4. KEY ENHANCEMENT AREAS

The first area establishes a framework for facilitating a strategic, risk-informed decision path for rulemaking and is expected to provide the most impact. The other four areas facilitate implementation of the path forward in more effective, efficient, and innovative ways. The full set of improvements are designed to operate together in advancing all aspects of the agency's rulemaking process and capabilities within its control.

4.1. DECISION TOOLS FOR GRADED APPROACH TO RULEMAKING

Strategic, risk-informed decisions

The staff plans to develop two decision tools to help guide the decision-making process for engaging in rulemaking and for identifying, in a strategic manner, the most appropriate path forward.

Rulemaking Entry–The first tool will help facilitate the decision for determining whether rulemaking is the appropriate solution to meet a regulatory need. Based on the factors involved, rulemaking may be warranted, but there could be other approaches that could address the issue (e.g., issuance of guidance or orders). This tool would contain information related to:

- Considerations for when to use rulemaking;
- Potential non-rulemaking options and factors to consider for evaluating those options; and

[2] Exact schedules may need to be refined if there are emerging factors or priorities that need to be accommodated during implementation.

- Resources for locating more information on potential non-rulemaking solutions.

Rulemaking Approach–If it appears rulemaking would be warranted, the second tool would help facilitate a "graded approach" to rulemaking to identify the most effective and efficient approach based on the complexity and maturity of the issue. That is, the level of effort and length of time needed for the development process should be commensurate with the significance of the issue and potential challenges involved. Examples of considerations in determining the appropriate path forward include:

- The complexity of the regulatory issue;
- Level of anticipated external interest;
- Type and timing of stakeholder involvement that would be useful; and
- Maturity of the regulatory problem under analysis.

The tool will help the staff evaluate these factors and develop a recommended rulemaking approach which will be provided in a rulemaking plan to the Commission for approval. Considerations for different rulemaking paths include:

- A typical notice and comment rulemaking versus a direct final rule approach;
- The need for a regulatory basis;
- The need for an advance notice of proposed rulemaking (ANPR) or other forms of enhanced public outreach in the pre-rulemaking phase; and
- The potential for seeking delegation of signature authority for approving the rule to a lower level.

During the development of these decision tools, staff will consider how to incorporate risk-informed decision-making into the tool (e.g., applying the Be riskSMART framework from the agency's transformation effort). Staff will also consider including guidance on how to design more performance-based rules, as well as references and resources for additional information.

Once completed, staff plans to conduct rollout activities within the agency to promote awareness and use of these new decision tools. Staff will incorporate their use in several other efforts, as described in later sections of this report. Staff also intends to make these decision tools publicly available, with the intent of helping to facilitate transparency and openness by clearly showing the agency's decision paths for rulemaking.

Additional Planned Activity	Target Completion Timeframe	Transformation Area Supported
4.1-1. Complete development and rollout of decision tools that ensure use of the most effective rulemaking approach	By FY 2020 Q4	Be riskSMART Innovate

4.2. STRATEGIC THINKING IN PLANNING AND PRIORITIZATION

Some of the key insights from the Material Control & Accounting rulemaking lessons learned case study were the importance of providing strategic direction for long-term projects, identifying course shifts needed, and providing emerging information or changes in circumstances in a timely manner to the Commission when needed. Staff has demonstrated notable progress in applying these insights to the management of rulemaking projects, and the staff has been reconsidering approaches to rulemaking and seeking additional Commission direction based on changes in factors or circumstances that could influence the previous direction. The staff will continue to proactively communicate with senior agency management and the Commission using appropriate means (e.g., Commission memos and papers, briefings) when needed to obtain alignment or seek direction to address emerging issues. The staff is also exploring options for expedited rulemaking approaches that could be used to address time-sensitive regulatory oversight needs.

Additional activities to support this focus are described below.

4.2.1. Common Prioritization of Rulemaking Process Improvements

The staff has recently strengthened the Common Prioritization of Rulemaking (CPR) process (https://www.nrc.gov/about-nrc/regulatory/rulemaking/rules-petitions.html) for conducting more strategic, probing reviews of all existing rulemakings to identify if shifts in direction are warranted. Specifically, during the FY 2021–2022 cycle, staff provided enhanced guidance and communication to offices to facilitate this more in-depth evaluation in a systematic manner.

Going forward, staff submitting new rules during CPR will be expected to provide their evaluation of non-rulemaking options included in the pre-rulemaking decision tool to show why rulemaking is the preferred option. The evaluation will be provided when staff present the new rule entry information and the rule's preliminary prioritization to the Rulemaking Coordinating Committee (RCC)-sponsored CPR working group.

The RCC includes NRC staff representatives from the Office of the General Counsel (OGC) and each of the technical and program offices involved in the rulemaking process. The RCC's focus is to ensure consistency in methods used to develop and issue rules and to initiate and implement improvements to the rulemaking process.

For the FY 2022–2023 cycle, staff plans to incorporate additional enhancements to support the evaluation of new and existing rules during CPR, including:

- Add in consideration of information from the Strategic Workforce Planning Process on external and internal factors that could impact the agency, in the evaluation.
- Increase engagement with senior managers during the evaluation to leverage their strategic planning experience.
- Program offices/business lines should vet rulemaking ideas through the RCC prior to the decision to pursue rulemaking and before presenting a new rule during CPR. The committee can help provide guidance and feedback on whether rulemaking is warranted and the most appropriate path forward.

- Once the decision tools discussed under Section 4.1 are completed, the discussion with the RCC should include results from applying the tools. The RCC-sponsored CPR working group would also work to develop knowledge management records of how issues were considered in rulemaking and what alternatives were identified and use such information to help inform future decisions.

- Incorporate additional focus on consideration of any potential impacts from external sources (e.g., statutes, Executive Orders, rulemaking bodies such as the Administrative Conference of the United States) and opportunities to leverage shared governmental resources (e.g., regulations.gov). These are currently considered in the prioritization process under CPR Factors C and D[3] but could be given more direct visibility to decision makers. The prioritization justification recorded in the tracking and reporting system and in rulemaking plans will be modified to include the Factor C and D information, if applicable.

4.2.2. Enhancing Guidance for Rule Scoping

Appropriately scoping a rule plays a critical role in being able to complete the development of the rule in a timely manner and to effectively reach alignment during the review process. As such, the rulemaking staff will work with its partner offices to establish clearer procedures, including roles and responsibilities, steps to appropriately scope a proposed rule, and instructions for applying risk-informed, performance-based approaches. Staff also plans to augment existing guidance on the development of rulemaking plans to include specific scoping related recommendations. The goal is to achieve alignment on an appropriately scoped rulemaking to ensure regulatory needs are appropriately addressed in a timely manner based on safety/security significance and to minimize risk of unnecessary scope expansion, which may slow down progress.

4.2.3. Enhance Methods for Conducting Strategic Review and Alignment

One major takeaway from benchmarking other government regulators is that they meet regularly with their decision makers to maintain alignment on their rulemaking actions. The staff has increased efforts to hold early alignment meetings at the beginning of project stages to ensure alignment on scope and approaches with decision makers and key stakeholders; this provides an opportunity to identify and apply any course changes needed. The staff has also been engaging with decision makers when there has been emerging information to determine if any adjustments may be needed. As discussed in the beginning of this section, staff has made progress in proactively identifying course shifts for several long-term projects and will continue to strengthen the focus in this area.

To make further advancements in this area, staff plans to enhance the ways it strategically engages with senior agency decision makers and other points of contact such as the Office of the General Counsel and Commission office staff to maintain situational awareness of the relevance and priority of active rulemaking efforts. This will help facilitate consideration of

[3] Factor C is “governmental priority,” and Factor D is “public priority.”

themes or trends from the full spectrum of NRC's regulatory areas and the identification of potential impacts across organizational boundaries. The timing for implementing these enhanced methods would align with the budget formulation process. The staff plans to pilot potential efforts and adjust as needed based on experience and feedback to inform longer term plans.

Additional Planned Activity	Target Completion Timeframe	Transformation Area Supported
4.2-1. Explore options for expedited rulemaking approaches that could be used to address time sensitive regulatory oversight needs	FY 2021 Q2	Innovate
4.2-2. Incorporate additional enhancements for the FY 2022–2023 CPR cycle that ensure consideration of important factors for prioritizing rulemaking activities and resources.	FY 2020 Q4–FY 2021 Q1	Innovate
4.2-3. Develop enhanced guidance to ensure the scope of each rulemaking is clearly established and meets its strategic objectives	By FY 2021 Q1	Innovate
4.2-4. Enhance opportunities for conducting strategic review and alignment to bring decision makers together to align on project direction, priorities, and plans. Use the experience to inform longer term plans.	During FY 2021 Q3/Q4	Innovate

4.3. PROCESS ENHANCEMENTS AND EFFICIENCIES

The COE has identified and taken steps to make progress in several process areas to improve quality, efficiency, and timeliness.

4.3.1. Enhancements to the Petition for Rulemaking (PRM) Process

Staff have made recent improvements in its PRM review process consistent with Title 10 of the *Code of Federal Regulations*, Section 2.802, "Petition for rulemaking—requirements for filing," and Section 2.803, "Petition for rulemaking—NRC action." This efficiency measure has already demonstrated a shortened sufficiency review time for petitions. Other enhancements include development of additional procedures and holding a first-of-a-kind workshop for staff to learn about recent developments and novel approaches to dispositioning petitions. In addition, the COE has creatively applied resources to work through a PRM backlog, including recruiting and onboarding a cohort of rotational assignees and leveraging available staff across branches. When the decision tools described in Section 4.1 are completed, staff will apply them when evaluating and dispositioning PRMs.

4.3.2. Streamlining the Regulatory Basis Stage

The staff recently completed two streamlining improvements to the regulatory basis stage of the rulemaking process:

- Staff will include a recommendation about the need for regulatory basis development in rulemaking plans for Commission approval. Several years ago, the Commission directed the staff to prepare rulemaking plans and obtain Commission approval for all new rulemakings (unless already explicitly delegated to the staff). The template for rulemaking plans included estimated dates for the draft and final regulatory basis. However, development of a regulatory basis document may not be necessary in all cases.

- For rulemakings that involve the development of a regulatory basis, the staff will issue a regulatory basis document for public comment and resolve comments at the proposed rulemaking stage, instead of issuing a "draft regulatory basis" for public comment and then a "final regulatory basis," which had been the staff's practice. This change is expected to save approximately 3 months from the overall rulemaking schedule. Comments received on the regulatory basis will be considered in the proposed rule.

Staff have begun to apply these improvements, and these changes will be included in updates to the staff's policies and procedures.

4.3.3. Public Comment Resolution Training

The rulemaking staff and the OGC staff have developed a training course, "Advanced Training for Responding to Public Comments in Rulemaking," to provide guidance on efficient and effective approaches for addressing public comments received during the rulemaking process. This course was recently enhanced to include responding to comments on additional types of documents.

This course focuses on supporting:

- Improvement of the quality, accuracy, and consistency of NRC responses to rulemaking comments and the associated documentation for the underlying NRC regulatory decision or action.

- More efficient preparation of NRC comment response documents in rulemaking (i.e., timelier with less expenditure of resources devoted to comment response document preparation).

- Better documentation and communication of the bases for NRC's rulemaking actions, leading to increased public confidence in NRC's decision-making.

The staff plans to continue collaborating with the OGC staff to provide this training on a periodic basis and refine the materials based on incoming feedback. In addition, the staff plans to develop complementary "just-in-time" training using IT tools that would be available to support comment resolution activities.

Additional Planned Activity	Target Completion Timeframe	Transformation Area Supported
4.3-1. Apply decision tools in evaluating and dispositioning PRMs to ensure consideration of non-rulemaking options and, if appropriate, the most effective rulemaking approach	Starting FY 2021 Q1	Innovate
4.3-2. In updates to the staff's policies and procedures, incorporate regulatory basis stage flexibilities and improvements to ensure their continued and consistent application	By FY 2021 Q1	Innovate
4.3-3. Develop "just-in-time" training to help prepare teams to effectively analyze and address public comments	By FY 2021 Q1	Innovate Focus on Our People

4.4. PRODUCT DEVELOPMENT AND CONCURRENCE

4.4.1. Use of Tiger Teams and Agile Teams

Staff plans to develop guidance with criteria for the use of a "tiger team" of expert staff who will be tasked to develop rulemaking products on an accelerated schedule. The guidance will contain a set of steps for gaining alignment and approval from senior management and tools for the team to document their process, solutions, and learnings. The tiger team will be composed of a small number of select members who can be relieved of most collateral duties, and thus able to dedicate their time for a specified period to a single project in order to make quick progress. This approach would bring together staff with the highest skills and expertise from both the technical and administrative areas of the program, with special emphasis on placement of a strong writer on the team. An example where the agency used a dedicated team to complete a high priority rulemaking quickly is the NRC's Continued Storage of Spent Nuclear Fuel rulemaking (79 FR 56238; September 19, 2014), which was completed in about two years. Once the guidance is developed, the COE will select a rulemaking project to pilot the concept and refine the guidance based on the results.

The staff is also looking at incorporating Agile project management concepts into rulemaking development as an alternative to traditional project management with linear sequential phases, also known as waterfall project management. Agile project management has been widely used for IT product development for several decades, but some of the concepts could be useful in the rulemaking process. Waterfall project management is often more efficient if the requirements for the project are well-defined up front. An iterative approach using Agile concepts could be used on rulemaking projects where the desired regulatory framework may not be well-defined in the early stages. An iterative approach with a dedicated expert rulemaking team and a defined project owner who is accountable for delivering value could help the team be more responsive

to new information and to adjust course during development, which should reduce project risk. Although the NRC has not used Agile project management for rulemaking development yet, staff developed the rulemaking tracking and reporting system with a contractor following an Agile approach (https://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/active/RuleIndex.html). The staff will include guidance on the use of Agile concepts along with the guidance on tiger teams.

4.4.2. Writing Quality

To facilitate a streamlined concurrence process (discussed below), documents must be of high quality when entering the formal review process, as this minimizes the risk of significant revision and rework. Traditionally, written products are not reviewed by supervisors/managers until the concurrence process begins, although working group members are encouraged to provide regular updates to their management during the development process. The COE has begun taking steps to improve writing quality through efforts such as:

- Holding "Alignment and Assignment" meetings at the beginning of a project to reach common understanding of the format and content of the final product.
- Assigning complex or first-of-a-kind writing projects to the strongest writers within a group.
- Emphasizing and reinforcing the importance of having a single owner who has responsibility for developing and ensuring the quality of the document.
- Requesting development of an outline with a summary of key arguments for Branch Chief review and feedback before writing of the full document begins.
- Conducting progress check-ins with Branch Chiefs to review early drafts.
- Developing capabilities for conducting peer reviews.
- Using IT tools like PerfectIt to assist authors to proof and edit their documents.

In addition to these efforts, the COE plans to evaluate availability of additional training and resources for strengthening writing skills.

4.4.3. Regulatory Analyses for Rules

The staff has taken action to improve the quality of cost-benefit analyses for rulemaking and other regulatory actions by revising NRC's Regulatory Analysis Guidelines to capture cost-estimating best practices, improve instruction for considering uncertainty, and add methods for assessing factors that are difficult to quantify. These actions provide the methodologies and tools for staff to develop realistic estimates that are consistent with the cost-estimating best practices identified in U.S. Government Accountability Office guidance. The staff has provided the revised cost-benefit guidance for Commission approval and is using the best practices that are included in the revised guidance when preparing regulatory analyses for rulemaking

products. Other steps to improve the quality of regulatory analyses for rulemaking actions include:

- Seeking stakeholder input on regulatory costs and impacts early in the rulemaking process to better inform the draft regulatory analysis of proposed rules.
- Including questions in the ANPR or proposed rule for stakeholder consideration that specifically focus on the economic impacts of a proposed regulatory solution.
- Adding an Executive Summary in lengthy or complex regulatory analyses to assist decision makers.
- Providing basic and advanced training to NRC staff on NRC's regulatory analysis guidance for both legislative rules that amend the *Code of Federal Regulations* and interpretive rules.[4]

In addition to these efforts, the staff are developing new templates for regulatory analysis documents with the goal of presenting portions of these complex data analyses in a manner that is reader-friendly and more accessible to the public.

4.4.4. Concurrence Improvements

Due to the nature of the work involved, the COE produces a high volume of documents on a consistent basis for delivery to the Executive Director for Operations and to the Commission. Concurrence helps to facilitate the development of high-quality products that are technically and legally sound, meet applicable requirements, and gain broad support. A streamlined process is critical due to the multiple areas of responsibilities involved and extensive coordination needed. A significant portion of the document development process is spent in the concurrence process, and this has been identified as an important opportunity for improvement. As such, staff has recently implemented several innovations and efficiency measures in conducting concurrence, and several are described below.

Areas of notable progress include:

- Staff has increased focus on identifying who should be included on concurrence and making efforts to expand the practice of providing courtesy copies for information only, if there is not a specific reason for someone to be on concurrence but awareness would be helpful. Reviewers are also being encouraged to opt-out of being on concurrence formally if they do not have a direct role in the product being developed. These efforts should help refine the concurrence chain to only necessary parties.
- Once individuals who need to be on concurrence have been identified, staff has been making efforts to better define roles and responsibilities, such as clarifying if an individual only needs to review certain portions of documents or only from a specific perspective. One tool staff has started using more frequently is a concurrence plan.

[4] "Interpretive rules" are a subset of "guidance documents." For more information, see "Guidance Documents Versus Interpretive Rules" in Enclosure 1.

Instead of sending a broad request for concurrence (which may give the impression that the reviewer needs to review everything), staff are suggesting focus areas for each reviewer based on their organizational responsibilities. For requests involving multiple documents, the staff often include a matrix showing which reviewer(s) is responsible for a particular document or section.

- Staff has been offering early briefings to individuals on concurrence, before they receive the document formally, to help familiarize them with the topic to facilitate their review. Staff has also been providing early drafts of documents for awareness. The COE leadership has been working to shift mindsets to being comfortable with higher levels of management seeing draft products (e.g., that meet an 80/20 threshold) that are not completely polished in order to facilitate early feedback.

- Staff has been making broader use of parallel concurrence when possible. Traditionally, concurrence has been sequential. Depending on project and schedule needs, staff has been trying new ways of sequencing reviews that are not always in strict alignment with reporting structure (e.g., Branch Chiefs and Division Directors reviewing in parallel, or Division Directors potentially reviewing before Branch Chiefs, based on availability).

- In support of parallel concurrence, staff has been incorporating broader use of IT tools for more efficient collaborative review and consolidation of staff input. Using these tools allows reviewers to see and respond to each other's comments in real time, and staff can get started responding to comments during the review period instead of waiting until the end. This has helped to cut down on time and work needed to merge different sets of comments. To increase awareness of these tools and strengthen staff's IT capabilities, staff has started holding Skype sessions to discuss best practices, demonstrate tools, and exchange ideas.

- Staff has started using concurrence meetings when multiple concurrences are needed under tight timeframes. The focus of these meetings is to obtain high-level verbal agreement on any changes needed on documents. The written changes can then be quickly provided after the meeting to confirm concurrences.

- Staff has developed a running list of concurrence best practices, tips, and tools, and discussions are held during staff meetings periodically to review and update the list and share experiences.

Many of these innovations are significant departures from past practices and will require a willingness and commitment from staff and management to effectively implement. Staff plans to continue communicating with reviewers about innovations and improvements being implemented and requesting their support and flexibility, as their buy in is critical to being able to achieve positive results. The COE leadership has been providing communications, reinforcing expectations, and gaining buy in and will continue to facilitate evolving expectations and practices in this area.

In implementing all these activities, the COE has been coordinating closely with the Process Simplification futures team, and a COE staff member has been serving on that team on a collateral basis. With this arrangement, the COE has been able to share its recent progress

with the future teams to factor into their efforts. The COE has agreed to serve as a pilot for the Process Simplification team's concurrence improvement efforts, including use of the e-Concurrence system when that is available.

Additional Planned Activity	Target Completion Timeframe	Transformation Area Supported
4.4-1. Create guidance for use of innovative concepts from tiger and Agile teams to develop improved products under shorter timeframes and conduct a pilot project	By FY 2021 Q1 (pilot depends on project needs and timing)	Innovate
4.4-2. Evaluate training and resources for strengthening writing skills to produce higher quality products and minimize the need for significant revision and rework	By FY 2020 Q4; timing for implementation to be determined (TBD) based on activity	Focus on Our People
4.4-3. Develop templates for Regulatory Analyses to help make complex information easier to understand and use	By FY 2021 Q1	Use Technology
4.4-4. Develop and conduct communications on evolving expectations, tools, and practices for concurrence to increase awareness and adoption	Initial communications during FY 2020 Q3; reminders periodically thereafter	Focus on Our People Innovate Use Technology
4.4-5. Serve as a pilot for e-Concurrence and other innovative practices identified by the Process Simplification team to help advance agency improvement efforts	TBD depending on timing of the Process Simplification team's efforts	Innovate Use Technology

4.5. ORGANIZATIONAL EFFECTIVENESS

Staff has identified and made progress in several organizational effectiveness areas to meet rulemaking needs as discussed in the following sections.

4.5.1. Enhanced Communication, Coordination, and Partnerships

Staff has increased focus on, and plans to continue strengthening, communications, collaboration, and integration with agency activities. Specific examples include:

- Holding earlier and more frequent alignment meetings and check-ins with senior agency management during the development of projects and using steering committees to address emerging needs or challenges more proactively. This has allowed staff to gain valuable input and guidance to shape the trajectory of projects and to minimize the need

for course corrections later, which has led to more effective and efficient management of projects.

- Evolving the focus of periodic rulemaking briefings with business line lead organizations to be more focused on cross-cutting and strategic areas of interest. Holding periodic coordination meetings with other groups that contribute to the rulemaking process, such as the Office of Nuclear Regulatory Research, the OGC, the Regulatory Guidance and Generic Issues Branch in the Office of Nuclear Regulatory Research, and the Standing Committee on Compatibility.

- Prioritizing rulemaking and petition for rulemaking activities with the appropriate business line lead offices and obtaining alignment and approval of schedules early in the process. This has helped to identify resource needs and achieve clear alignment on priorities.

- Ensuring that the OGC is represented at all working group meetings, to the extent practicable, so legal considerations are included early during the rule development process.

- Identifying and addressing potential backfitting issues as early as possible, including engaging with the backfitting and forward fitting community of practice (CoP) and the Committee for the Review of Generic Requirements, as needed. Staff continues to closely monitor developments in this area and will apply any new guidance or practices in this area as they become available. The staff will continue recent progress on backfit discipline.

- Engaging with agency and government wide efforts, such as with Embark Venture Studios and the General Services Administration effort to improve the public comment process and address issues involving mass and fake commenting.

- Enhancing Agreement State interactions in the rulemaking process, in accordance with procedure SA-801A, Agreement State Participation in Rulemaking Working Groups (https://scp.nrc.gov/procedures/sa801a.pdf). The COE has received positive feedback from both the Organization of Agreement States as well as from the NRC's Agreement State Program staff about the progress in this area.

- Actively participating in and coordinating with agency wide transformation and innovation efforts; serving as early adopters of innovation efforts and tools where possible.

The COE will continue to actively engage in these efforts and use feedback and new information gained to inform its improvement efforts.

4.5.2. Organizational Capacity and Agility

When the rulemaking COE was initially formed in 2017, some of the anticipated benefits included enhanced ability to shift resources or work assignments to meet the demands of a changing environment and more effective knowledge management and maintenance of critical skill sets. Since its creation, the COE has continued to increase agility and organizational capacity through efforts such as:

- Assigning staff to work across branches and functional areas
- Cross training staff to serve as both cost analysts and rulemaking project managers
- Providing opportunities for collateral assignments for individuals from other organizations based on workload needs and professional interests
- Actively recruiting and maintaining a continuous stream of rotational assignees
- Supporting staff engagement on agencywide efforts such as Futures Initiative teams

As a result, there is strong teamwork and collaboration across the COE organization. The COE will continue to closely monitor and track progress in maintaining an agile organization and in providing engaging opportunities for professional development. The COE will review results from the Strategic Workforce Planning closely each year and proactively develop effective gap closure strategies. In addition, the COE plans to be early adopters of the NRC Open Opportunities platform (https://openopps.usajobs.gov/) and will post opportunities to meet emerging needs and provide meaningful apprenticeship opportunities by using NRC's Nuclear Regulator Apprenticeship Network.

4.5.3. Building on Successes

The COE has recently increased focus on recognizing and highlighting examples of staff achieving different types of successful outcomes during the rulemaking development process, from "quick wins" to more significant accomplishments. Examples being recognized include improved efficiency during the concurrence process, applying innovative thinking in implementing project management activities, and applying new technology tools. The COE leadership has leveraged diverse tools such as group emails, shout-outs in newsletters, and formal awards, and plans to continue explicitly recognizing applications of innovations and creativity.

In addition, staff is in the process of developing publicly available "success story" case studies to illustrate how specific rulemakings have contributed to the agency's mission and how staff applied innovations and efficiency measures during the development process. Staff plans to design these case studies to be visually appealing and will coordinate with the Office of Public Affairs to ensure effective messaging for a public audience. The intent of this effort is to help provide further transparency and strengthen public confidence in the rulemaking process. Staff recently issued two "Rulemaking Highlights" case studies (ADAMS Accession No. ML20099A094 and ML20205L609) and plans to use experience from this to determine longer term plans. Staff also plans to identify and pursue other innovative methods of enhanced public communications about rulemaking accomplishments as opportunities arise.

Additional Planned Activity	Target Completion Timeframe	Transformation Area Supported
4.5-1. Leverage the NRC Open Opportunities platform and provide apprenticeships using the Nuclear Regulator Apprenticeship Network to	Open Opportunity pilot currently in progress. Plan to offer apprenticeship to	Innovate Use Technology Focus on Our People

continue building organizational capacity using new methods	Nuclear Regulator Apprenticeship Network cohort in FY 2021.	
4.5-2. Incorporate lessons learned from first "Rulemaking Highlights" case study to inform development of future products to provide transparency and increase public confidence by illustrating rulemaking contributions to the agency's mission and specific applications of innovations and efficiency measures.	FY 2020 Q4	Innovate

4.6. PERFORMANCE TRACKING AND MONITORING

The Division of Rulemaking, Environmental, and Financial Support, where the rulemaking COE resides, recently began incorporating the use of Objectives and Key Results (OKRs) to set focus areas for the division and monitor progress. The OKRs are monitored on a biweekly basis and updated as needed on a quarterly basis using available IT tools. For consistency and efficiency, the COE plans to incorporate aspects of activities described in this report into the division's OKRs as applicable to track and monitor progress. This approach will also facilitate the integration of a continuous improvement focus into the routine operations of the division.

5. CONCLUSION

In planning and implementing future actions, the rulemaking COE is continuously scanning the environment, both within and outside the NRC, to build on the progress and momentum already underway. The efforts described in this report are not a one-time, siloed initiative, but are intended to facilitate a continuous improvement focus to meet evolving needs. They are expected to mature, grow, and adapt over time. The staff is committed to continuously improving the NRC's rulemaking process and serving as a model of Federal rulemaking excellence in service of our mission to protect public health and safety, promote the common defense and security, and protect the environment.

The following table is a consolidated list of the additional planned activities described in this report.

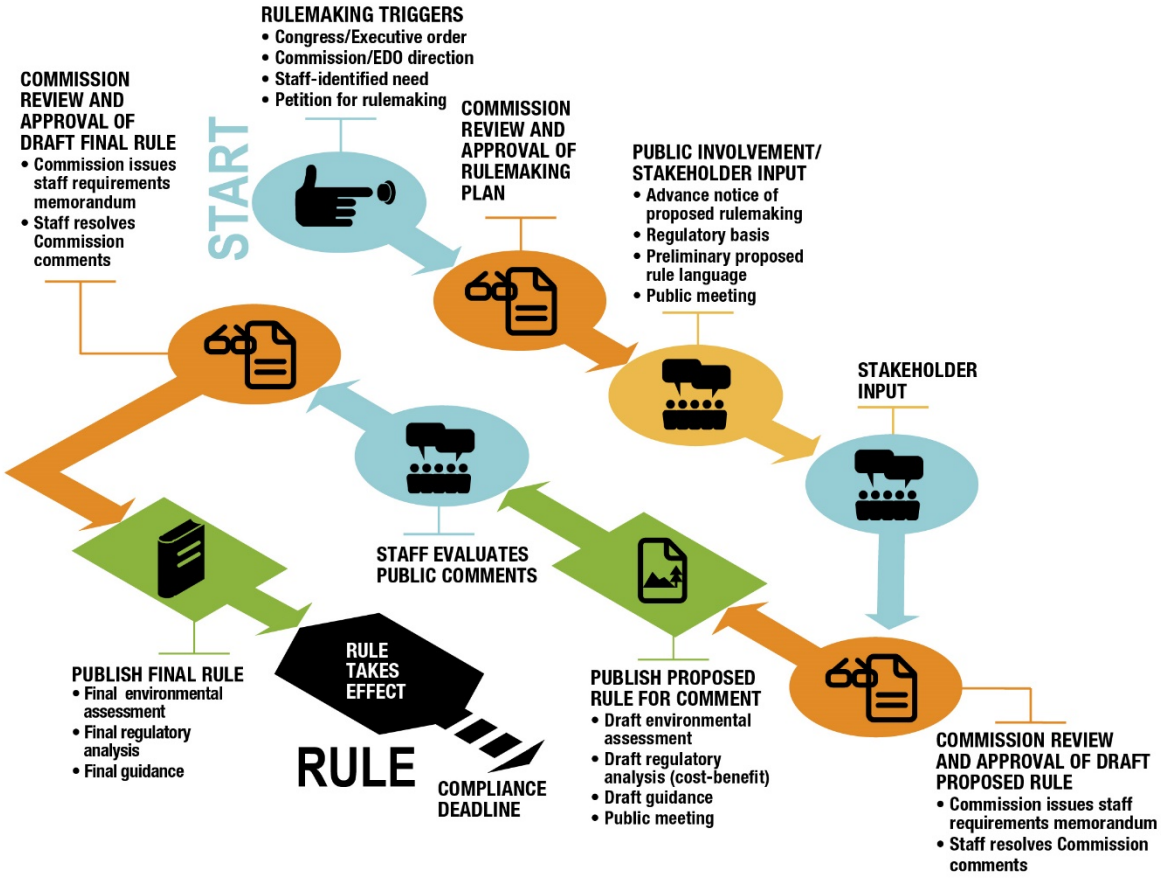
Additional Planned Activity	Target Completion Timeframe	Transformation Area Supported
4.1-1. Complete development and rollout of decision tools that ensure use of the most effective rulemaking approach	By FY 2020 Q4	Be riskSMART Innovate
4.2-1. Explore options for expedited rulemaking approaches that could be used to address time sensitive regulatory oversight needs	FY 2021 Q2	Innovate

4.2-2. Incorporate additional enhancements for the FY 2022–2023 CPR cycle that ensure consideration of important factors for prioritizing rulemaking activities and resources	FY 2020 Q4–FY 2021 Q1	Innovate
4.2-3. Develop enhanced guidance to ensure the scope of each rulemaking is clearly established and meets its strategic objectives	By FY 2021 Q1	Innovate
4.2-4. Enhance opportunities for conducting strategic review and alignment to bring decision makers together to align on project direction, priorities, and plans. Use the experience to inform longer term plans.	During FY 2021 Q3/Q4	Innovate
4.3-1. Apply decision tools in evaluating and dispositioning PRMs to ensure consideration of non-rulemaking options and, if appropriate, the most effective rulemaking approach	Starting FY 2021 Q1	Innovate
4.3-2. In updates to the staff's policies and procedures, incorporate regulatory basis stage flexibilities and improvements to ensure their continued and consistent application	By FY 2021 Q1	Innovate
4.3-3. Develop "just-in-time" training to help prepare teams to effectively analyze and address public comments	By FY 2021 Q1	Innovate Focus on Our People
4.4-1. Create guidance for use of innovative concepts from tiger and Agile teams to develop improved products under shorter timeframes and conduct a pilot project	By FY 2021 Q1 (pilot depends on project needs and timing)	Innovate
4.4-2. Evaluate training and resources for strengthening writing skills to produce higher quality products and minimize the need for significant revision and rework	By FY 2020 Q4; timing for implementation TBD based on activity	Focus on Our People
4.4-3. Develop templates for Regulatory Analyses to help make complex information easier to understand and use	By FY 2021 Q1	Use Technology
4.4-4. Develop and conduct communications on evolving expectations, tools, and practices for concurrence to increase awareness and adoption	Initial communications during FY 2020 Q3; reminders periodically thereafter	Focus on Our People Innovate Use Technology
4.4-5. Serve as a pilot for e-Concurrence and other innovative practices identified by the Process Simplification team to help advance agency improvement efforts	TBD depending on timing of the Process Simplification team's efforts	Innovate Use Technology
4.5-1. Leverage the NRC Open Opportunities platform and provide apprenticeships using the Nuclear Regulator Apprenticeship Network to continue building organizational capacity using new methods	Open Opportunity pilot currently in progress. Plan to offer apprenticeship to Nuclear Regulator Apprenticeship Network cohort in FY 2021.	Innovate Use Technology Focus on Our People
4.5-2. Incorporate lessons learned from pilot case study to inform development of future products to provide transparency and increase	FY 2020 Q4	Innovate

public confidence by illustrating rulemaking contributions to the agency's mission and specific applications of innovations and efficiency measures.		

ENCLOSURE 1 – RULEMAKING PROCESS OVERVIEW

A TYPICAL RULEMAKING PROCESS



PRE-RULEMAKING PHASE

The staff has long recognized the benefits of conducting focused public outreach before entering the proposed rule phase, and the Commission routinely approves rulemaking plans with schedules that dedicate time and resources to engage with the public. The value of this engagement is two-fold: it allows staff to gather data and cost attributes from the affected entities that staff will need to conduct a preliminary cost-benefit analysis. If staff gains enough information to determine that a planned rulemaking is not cost-justified and new requirements are not necessary for safety and adequate protection, the project is ended. If the rule is found to be quantitively and qualitatively justified, the early input contributes to a product that is more readily accepted by the stakeholders.

Public comments collected during the pre-rulemaking phase (such as in an ANPR) are used to inform the regulatory recommendations that staff will provide to the Commission at the proposed rule phase. Unlike public comments received during the APA-directed public comment phase of rulemaking, staff does not need to provide a written response to each comment received on the

docket from pre-rulemaking engagements with the public. As a best practice, the *Federal Register* notice soliciting public comments in pre-rulemaking should clearly state that NRC will not respond in writing to the comments received at this stage. However, staff should provide decision makers a summary of the input and staff's general response to comments; in particular, staff should detail those comments that have influenced the proposed rule.

Staff has considerable flexibility in how to conduct early public outreach and can choose to:

- Issue an ANPR. This document can describe the need for action and broad concepts. This approach is useful for gauging public appetite for change when a regulatory solution is not clear-cut or concerns areas of controversy. An ANPR also may outline regulatory responses the NRC is considering, propose alternatives, including non-rulemaking solutions, include preliminary rule language (with prior Commission notice), and solicit public comment on specific questions. As stated in MD 6.3, Commission approval of a rulemaking plan is required before drafting an ANPR.

- Issue a regulatory basis, white paper, or issues paper for public comment. These researched studies conducted by staff vary in the level of detail, and generally address scoping concerns or lay out various options for handling emergent technical, legal, economic, or policy issues or problems.

  A regulatory basis will be the narrowest of these documents, as it is usually prepared specifically for a planned rulemaking. See Section 4.3.2, *Streamlining the Regulatory Basis Stage*.

- Post for public comment preliminary proposed rule language. Staff must notify the Commission before using this process, but authority to issue preliminary rulemaking language is delegated to the office director level. This tool can be useful when there are specific requirements identified for amendment or issuance. Staff issues an informal document for comment, often a simple redline or markup of existing regulatory text. Staff can hold public meetings to receive feedback or issue subsequent versions and work collaboratively with the affected entities to fine-tune the language prior to issuing the entire proposed rule for comment. This iterative process can prevent the need to issue a supplemental proposed rule.

- Conduct general public outreach to explain the planned rulemaking. Public meetings can help stakeholders understand what specific information to provide the NRC in their comments on the planned rulemaking. Conducting workshops, public meetings, and webinars require staff time and resources, but providing opportunity for the public to ask questions, ideally before the end of a comment period, will result in better-informed comments. It is a good practice to transcribe these public meetings but not required for pre-rulemaking engagements.

After the inception of the COE, rulemaking staff has been consciously reviewing and exercising these pre-rulemaking options for obtaining early public input and will monitor the pros and cons of each approach as we gain experience going forward.

PROPOSED RULE AND FINAL RULE PHASES

Congress has placed certain minimum requirements for the conduct of rulemaking on all Federal agencies in Section 553 of the APA. Like other agencies, NRC provides public notice and requests comment on proposed rules by publication in the *Federal Register*. Staff has limited flexibility in the rulemaking process at the proposed and final rule phases but has taken efforts that result in modest efficiency improvements. These include:

- Public Comment Period: The length of time for public comment is not specified by the APA. NRC practice is to allow 75 days for the public to comment on a technical proposed rule. When justified, COE staff has carefully assessed the level of public interest and adjusted to allow for a shorter or longer comment period.

- Transparency for Decisions: The APA requires agencies to identify the terms or substance of a proposed rule or a description of the subjects and issues involved. COE staff strive to make available complete and accurate workpapers and supporting data. For example, the NRC practice is to perform regulatory analyses for proposed and final rules, which contain detailed uncertainty analyses.

- Responding to Public Comments: The APA requires agencies to consider public comments when issuing a final rule. As discussed further in Section 4.3.3, *Public Comment Resolution Training,* staff has developed training and tools to standardize the comment response documentation for final rules. In addition, for controversial rules that have large volumes of public input, the COE augments the rulemaking working groups with contractors to help evaluate and bin comments and assist in the development of comment responses.

GUIDANCE DOCUMENTS VERSUS INTERPRETIVE RULES

“Guidance” is an umbrella term describing non-legally binding rules. The NRC issues numerous types of guidance documents. “Interpretive rules” are a subset of “guidance” that interpret NRC requirements and offer NRC staff advice on one or more possible methods licensees and applicants may use to meet regulatory requirements (see U.S. Dep’t of Justice, Attorney General’s Manual on the Administrative Procedure Act (1947) at 30, footnote 3 (defining “interpretive rule” as referring to “rules or statements issued by an agency to advise the public of the agency’s construction of the statutes and rules which it administers”). In contrast, certain “guidance documents” are not “interpretive rules” when they solely describe internal agency procedure or reiterate existing agency interpretations. The NRC routinely provides for notice and comment prior to issuing interpretive rules, whereas notice and comment is less common for issuance of guidance documents that are not interpretive rules.