

POLICY ISSUE (Information)

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FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: CONSIDERATION OF THE CUMULATIVE EFFECTS OF REGULATION
IN THE RULEMAKING PROCESS

PURPOSE:

The purpose of this paper is to inform the Commission of the staff's plans to make enhancements to the Nuclear Regulatory Commission (NRC) rulemaking process to enable explicit consideration of "cumulative effects of regulation" (CER).

SUMMARY:

In Staff Requirements Memorandum (SRM) M091208, "Briefing on the Proposed Rule: Enhancements to Emergency Preparedness Regulations," dated January 13, 2010, the Commission directed the staff to consider whether the schedule for implementing the new emergency preparedness rulemaking and future rulemakings should be influenced by the aggregate impact (now referred to as CER) of the new and recently issued regulations already scheduled for implementation. In response to this direction, the staff is making rulemaking process enhancements that include (1) increased interaction with external stakeholders throughout the rulemaking process, (2) issuance of draft and final supporting guidance with the proposed and final rulemakings, respectively, and (3) requesting stakeholder feedback as part of the rulemaking process so that CER can be addressed, when warranted.

BACKGROUND:

Through its various interactions with power reactor licensees, State partners, and external stakeholders, the NRC staff has been made aware of a concern about the impact of certain

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regulatory actions. This concern is not entirely new. To address similar concerns expressed by the nuclear power industry in the past, the staff has sponsored initiatives to review regulatory requirements to ensure that NRC's regulations and practices do not result in unnecessary regulatory burden (e.g., SECY-02-0081, "Staff Activities Related to the NRC Goal of Reducing Unnecessary Regulatory Burden on Power Reactor Licensees"). The nuclear power industry most recently voiced concerns during the implementation stages of two significant rulemakings: (1) the power reactor security rulemaking that amended Title 10 of the *Code of Federal Regulations* (10 CFR) Part 73, "Physical Protection of Plants and Materials" and (2) the fitness for duty rulemaking that amended 10 CFR Part 26 "Fitness for Duty Programs." The staff refers to this concern in this paper as CER¹ and has established the following working definition that reflects stakeholder feedback:

CER describes the challenges licensees, or other impacted entities such as State partners, face implementing new regulatory positions, programs, and requirements (e.g., rules, generic letters, backfits, inspections). CER is an organizational effectiveness challenge that results from a licensee or impacted entity implementing a significant number of new and complex regulatory actions stemming from multiple regulatory actions, within a limited implementation period and with available resources (which may include limited available expertise to address a specific issue). CER can potentially distract licensee or entity staff from executing other primary duties that ensure safety or security. CER can be aggravated if the new requirements lack clarity.

In SRM M091208, the Commission directed the staff to address the following concern:

For this and future rulemakings, the staff should consider if the schedule for implementing those new regulations should be influenced by the aggregate impact of the new regulation(s) and others that may already be scheduled for implementation.

Stakeholder Involvement and Feedback

The current rulemaking process does not consider the impact of multiple regulatory actions on licensees; i.e., each regulatory action is judged on its own merits and the supporting regulatory analysis examines only that specific regulatory action, not other ongoing actions currently being implemented by licensees. Recognizing this, and to implement the Commission direction through informed and effective process enhancements, the staff elected to engage external stakeholders to gain a better understanding of the scope of CER and stakeholder views on how the NRC might best address this issue. The staff held a Category 3 public meeting on CER on November 16, 2010. The meeting summary is available at Agencywide Documents Access and Management System (ADAMS) Accession No. ML103270231. Following the public meeting, the

¹ Some external stakeholders would prefer to use the term "Integrated Planning for Regulatory Activities." For the purposes of this paper the staff is continuing with the present terminology so that it does not create confusion with external stakeholders who either participated in the November 16, 2010, public meeting, or are otherwise following the agency's efforts on this matter.

Nuclear Energy Institute (NEI) sent the NRC a letter (ADAMS Accession No. ML103410341) dated December 7, 2010, that documents the key points that the nuclear power industry communicated during the public meeting. The staff has summarized the significant elements from both the public meeting and the NEI letter as follows:

- The nuclear power industry generally agrees that the rulemaking process enhancements outlined at the November 16, 2010, public meeting would help address CER and that the NRC should pursue them.
- The CER issue is broader than rulemaking; the impacts of CER can arise from any regulatory action, including actions such as generic communications, new or revised guidance or other supporting documents, license amendment requests, and inspection findings that have generic applicability.
- CER has the potential to impact all licensees including power reactor licensees, fuel cycle facilities, and byproduct material licensees.
- The NRC should assess regulatory actions currently under development against the principles of good regulation to ensure a thorough examination and coordination of the proposed action with other regulatory actions.
- The NRC should issue rules that would make previously issued order requirements generically applicable (already imposed and in place) separately from those that impose new requirements (i.e., rules that include new requirements would typically require supporting guidance, more interaction with stakeholders, and a much longer rulemaking process as compared to a rule that makes generically applicable previously imposed order requirements).
- The NRC should issue draft and final guidance documents in conjunction with proposed and final rules, respectively, and should hold public meetings at each rulemaking stage to obtain feedback on implementation issues and cost.
- Rulemakings imposing requirements that require facility modifications should allow for a minimum of 30 months for implementation.
- The use of risk insights to prioritize regulatory actions and to re-interpret current requirements would help address CER.
- A formal “lessons learned” process or feedback process would help routinely capture experience for developing and finalizing future amendments to the regulations.
- The application of NEI’s Regulatory Issue Resolution Protocol to regulatory actions involving CER would assist stakeholders to reach a shared understanding of the issue, success criteria, and regulatory process to be used. This would in turn help to improve the identification, resolution, and closure of generic issues.

- The use of an integrated multiyear schedule that identifies all new regulatory actions, and is made publicly available, would provide external stakeholders both an increased awareness of scheduled regulatory actions and an opportunity to provide feedback on the schedule as it relates to CER.

CER is an issue that could also impact entities other than operating power reactor licensees. To date, the staff has heard concerns from various stakeholders, although the majority of attendees at the November 16th public meeting represented the power reactor industry. For example, fuel cycle industry representatives raised issues of prioritizing and balancing NRC regulatory initiatives, and the timeliness of those initiatives, at the April 29, 2010, Commission briefing on Fuel Cycle Oversight Process Revisions. Applicants for new reactor design certifications and combined licenses may also to some extent, be impacted by CER. Specifically, as new requirements become effective, they could impact the staff's review of such applications. However, if timing of the new requirements imposes a schedule challenge to the applicant, the staff can address these concerns through regulatory vehicles such as issuance of license conditions.

During the public meeting, the nuclear power industry representatives stated that it does not currently provide significant feedback on the NRC's draft regulatory analyses, which are published as part of the proposed rule package in the *Federal Register* (FR). The nuclear power industry is reluctant to spend resources estimating costs at the proposed rule stage because the requirements may change significantly by the time the Commission issues the final rule, invalidating the industry's cost estimate. However, the staff notes that its estimates of costs and other impacts, such as dose, often differ substantially from the estimates and reported results that industry provides. More importantly, lacking accurate and informed feedback on the estimated costs and impacts from external stakeholders challenges the staff in its efforts to provide the Commission an accurate estimate of the impacts of the final rule.

Based on the information discussed at the public meeting, the staff and industry recognize that a complete treatment of CER would require the NRC to revise processes, including, but not limited to rulemaking, that govern significant regulatory actions. To that end, the external stakeholders at the November 16, 2010, public meeting agreed that much could be gained by first addressing CER in rulemakings and then applying insights to other regulatory processes once the NRC has gained sufficient experience in rulemaking. The staff agreed, and suggested that the NRC should first address CER in rulemaking because of the substantial impact that it imparts on licensees. After the NRC gains experience with addressing CER in rulemaking, it can decide whether to address CER in other processes.

The staff believes that the enhanced rulemaking process discussed in this paper to address CER is well aligned with both the Open Government initiative and the January 18, 2011, Executive Order "Improving Regulation and Regulatory Review – Executive Order." Although, the staff currently believes that the NRC's rulemaking process is already in the spirit of both the Executive Order and the Open Government initiatives, the staff believes that the noted rulemaking process enhancements should improve the NRC's alignment with these recent directives and initiatives but could delay promulgation of rules and their implementation dates.

It is important to recognize, that once the NRC has determined that the new or amended requirements meet the backfit requirements for imposition on licensees, mitigation of CER concerns associated with new rule requirements will be accomplished, if appropriate to do so, by providing licensees more time to implement new or amended requirements. In other words, CER mitigation will not be achieved through a reduction or elimination of requirements that the Commission judges to be appropriate for imposition on licensees.

DISCUSSION:

Based on feedback from external stakeholders, the NRC staff understands that CER can adversely impact a licensee's or impacted entity's effectiveness. This impact can occur regardless of the rulemaking process duration or level of interaction that occurred during the rulemaking, because final rule requirements can change late in the rulemaking process and thereby cause unanticipated implementation challenges for licensees or impacted entities.

The staff has considered whether extending the implementation or compliance period for a rule creates a safety or security issue. The staff concludes that extension of implementation periods for rulemakings is not generally a safety or security concern because in most cases the requirements that are in place before the NRC issues the new rule ensure adequate protection of public health and safety and the common defense and security. For new requirements that relate to adequate protection or common defense and security, if the issue is time sensitive, it may not be possible to mitigate the cumulative impacts on licensees.

Rulemaking Process Changes to Address Cumulative Effects of Regulation Concerns

The staff will revise the rulemaking process as described below to address CER. The staff will apply these rulemaking enhancements to rules that potentially create CER as defined previously in this paper. The staff will typically not apply CER rulemaking process enhancements to efforts that do not impose new requirements on existing licensees, including those that provide voluntary alternatives, those that adopt consensus standards, or those involving approval or certification of standard designs. The following enhancements are designed (1) to encourage increased interaction with external stakeholders throughout the rulemaking process in order to resolve issues that can lead to implementation challenges and contribute to CER, (2) to explicitly solicit feedback on CER concerns to increase stakeholder awareness and enable the NRC to make better informed decisions on how to mitigate CER, and (3) to improve the process for establishing the time allowed for implementation by seeking additional information on CER:

- (1) Regulatory Basis Development Interaction. The rulemaking process will require² that the NRC staff interact with external stakeholders during development of the rulemaking regulatory basis. The process will be flexible as to how, and under what circumstances, the staff will interact with external stakeholders. This could include interactions during

² In all cases use of "require" with respect to the CER rulemaking procedure enhancements should be understood to mean that it applies only to those rulemakings where there is potential for CER. The procedure will direct these process enhancements to be followed unless otherwise modified and approved by NRC management on a case-by-case basis. A conclusion that a CER potential does not exist, or that management has decided to not use the enhanced CER processes, will be documented as part of the rulemaking regulatory basis, and proposed and final rule SECY papers.

development of the regulatory basis, as well as making the regulatory basis, or a portion thereof, publicly available. Feedback from external stakeholders during the regulatory basis stage will assist the NRC staff in reaching a common understanding of the safety, security, or other issues associated with the regulatory basis, and the feasibility and practicality of suggested regulatory approaches. This interaction will also elicit public stakeholder feedback concerning the costs and other impacts of the rulemaking action under consideration. This interaction (1) leads to a more informed regulatory basis for the rule, (2) can identify and potentially resolve issues that ultimately may result in implementation problems, (3) can identify areas where implementation guidance is needed, (4) could focus stakeholder interaction on the proposed rule, resulting in a reduced number of public comments, and (5) can lead to a better-informed NRC decision on whether it should pursue rulemaking.

- (2) Draft Guidance Interaction. Consistent with current practice, the rulemaking process will require the NRC to interact with external stakeholders during the development of implementation guidance. The staff will remain flexible on how this interaction will occur. This interaction could involve fairly simple interactions on drafts of implementation guidance, making the complete draft guidance publicly available, or holding public meetings on industry developed guidance if the industry is supporting the rulemaking guidance development. The staff will use the feedback from these interactions to develop more effective guidance that meets the needs of the NRC and licensees. This interaction helps identify, and possibly resolve, issues that can lead to implementation challenges, and thereby, can help mitigate CER.
- (3) Publication for Comment of Draft Guidance with the Proposed Rule. The staff will revise the rulemaking process to coordinate publication of draft implementation guidance in parallel with the proposed rule for public comment. Unless otherwise directed by the Office of the Executive Director for Operations (EDO), the staff will not provide the proposed rule package to the Commission or EDO, as applicable, until draft guidance is complete. The draft guidance could then be published in parallel with publication of the proposed rule so external stakeholders can gain a better understanding of both the proposed new or amended requirements and associated guidance. In turn, stakeholders will have a better understanding of the implementation actions recommended to comply with the proposed new requirements including engineering, procurement, installation, testing, and analysis. This level of detail will enable licensees to provide feedback on CER at the proposed rule stage, including improved licensee estimates for the cost and time to implement the new requirements.
- (4) Explicit Stakeholder Request for CER Feedback. Each proposed rule published in the FR will contain a specific request for comment that solicits feedback on CER. These requests will be designed to elicit stakeholder input on the potential for CER with respect to the proposed rule, and to obtain suggestions on how best to address the situation. The request will use a standard set of questions, similar to the following, and adapted to the specifics of the rule:
 - Does the proposed rule’s [effective date, compliance date, or submittal date(s)] provide sufficient time to implement the new proposed requirements including

changes to programs, procedures, and the facility, in light of any current or projected CER challenges?

- If current or projected CER challenges exist, what do you suggest as a means to address this situation (e.g., if more time is required for implementation of the new requirements, what period of time is sufficient)?
- Are there unintended consequences? Does the proposed rule create conditions that would be contrary to the proposed rule's purpose and objectives? If so, what are the unintended consequences and how should they be addressed?
- Please comment on the NRC's cost and benefit estimates in the regulatory analysis that supports the proposed rule.

The fourth question differs from the three previous questions in that it focuses on areas within the regulatory analysis where uncertainty may exist. Its objective is to obtain feedback and data that will enable a more complete and accurate regulatory analysis to support the final rule. This feedback could potentially cause the NRC to revise its position with regard to the imposition of one or more new or amended requirements as proposed.

- (5) Consideration of CER Feedback. The final rule SECY paper and *Federal Register* notice (FRN) will summarize the CER feedback received and provide the Commission with the staff's recommended approach for addressing any existing CER challenges. Typically, if the staff concludes that a CER challenge exists, it could recommend an extended schedule for implementing the final rule requirements to reduce the impact depending on the nature of the challenge. For example, if a CER concern stems from the proposed implementation of new requirements that would result in facility modifications that require detailed engineering support and procurement of equipment, or require particular timing (such as a plant outage) for installation, testing, and commissioning, the staff will recommend a compliance date that would reasonably accommodate the modifications. The draft final rule FRN, enclosed with the final rule SECY paper, will provide the details for how the staff would implement the schedule extension consistent with its recommendation to the Commission.
- (6) Publishing Final Regulatory Guidance with the Final Rule. The staff will revise the rulemaking process to coordinate publication of final regulatory guidance in parallel with issuance of the final rule. The staff will provide the draft final rule package to the Commission or EDO after all draft final guidance is complete and available, unless directed otherwise by the EDO. This process revision is intended to ensure that the regulatory framework is in place, is consistent with the governing new requirements, and is predictable. It supports licensee implementation, in conjunction with the implementation period that the Commission judges to be adequate.
- (7) Public Meeting on Implementation During the Final Rule. The rulemaking process allows the staff the option to structure the rule requirements such that compliance dates may not always coincide with the rule's effective date. The staff can hold a public meeting on

implementation during the final rulemaking stage to better understand and clarify CER concerns. The staff will typically exercise this approach when the CER concern may be significantly changing such that the feedback obtained at the proposed rule public comment stage may not have properly characterized the CER concern, leading the staff to conclude that the Commission must obtain more updated CER feedback to support a decision on final rule implementation dates.

- (8) Revised Common Prioritization of Rulemaking (CPR) Process. The staff recently revised its internal process for prioritizing its rulemaking activities on a common basis agency wide. As part of this revision, the staff, where appropriate, may project potential future rulemaking activities beyond the normal two-year budget formulation horizon. The staff uses the CPR process as a scheduling and budgeting tool for internal NRC resources, and as such, it is separate and distinct from CER. However, the staff, under some circumstances could decide to make some of the longer-term projections in the CPR publicly available as a means to increase external stakeholder awareness of scheduled rulemaking-related actions. In this regard, the staff notes that rulemaking information is currently made publicly available (published in the FR) on a semiannual basis through the Unified Regulatory Agenda.

Schedular Process Changes to Support CER Enhancements

A fundamental cornerstone of the enhanced rulemaking process described above is additional interaction with external stakeholders at several points during the rulemaking process. A central element of the enhanced process is the issuance of all supporting draft guidance in parallel with the proposed rule to support better informed stakeholder comment. The staff concluded that rulemaking schedule metrics need to be adjusted to reflect: (1) that a substantial percentage of the overall rulemaking effort will occur before, and up to, the issuance of the proposed rule, (2) the size and complexity of the rulemaking (including the rule language, supporting statement of considerations, and supporting guidance), the anticipated external stakeholder interest and participation in the rulemaking, and (3) that much of the rulemaking guidance will be developed by the same staff that prepare the rulemaking documents creating a resource challenge. As such, the staff is developing a strategy for rulemakings that incorporates the following basic schedule elements:

- A nominal 1-year period will be the baseline schedule for development and completion of the rulemaking regulatory basis. The staff will adjust the specific rulemaking schedule based on (1) any research required (including analytical analysis, testing, and code development), (2) the number and complexity of anticipated regulatory basis issues, and (3) the anticipated level of interaction with external stakeholders. The schedule will also reflect any time period for which the staff elects to make the regulatory basis publicly available (i.e., the rulemaking process will be flexible on whether, and for what time period, the regulatory basis should be made publicly available, as well as how comments and feedback will be addressed). This regulatory basis public comment period, if included, will be adjusted depending on external stakeholder interest in the rulemaking action and previous interaction on the development of the regulatory basis.

- The proposed rule schedule will begin after a nominal 30-day acceptance review by the rulemaking staff of the regulatory basis developed by the technical lead organization, assuming the rulemaking staff accepts the regulatory basis and decides to pursue developing a proposed rule. As a baseline schedule, the staff will provide the proposed rule to the Commission within one year. Concurrently the staff will prepare and have ready the draft implementation guidance. The staff will adjust the specific rulemaking schedule based on (1) the size and complexity of the rulemaking, and (2) the size, number and complexity of supporting draft guidance documents.
- The baseline schedule will usually include a 75-day public comment period. The staff will adjust the specific rulemaking schedule based on the level of anticipated external stakeholder interaction, including the potential for an extended public comment period on the proposed rule and supporting guidance documents.
- The staff will establish the final rule schedule following closure of the public comment period on the proposed rule to avoid schedule impacts that stem from comment period extensions and increased external stakeholder outreach. As a baseline schedule, the staff will provide the final rule to the Commission one year following the end of the public comment period. Concurrently, the staff will prepare and have ready the final implementation guidance. The staff will adjust the specific rulemaking schedule based on the (1) number and complexity of public comments received, (2) number and complexity of guidance document comments received, and (3) anticipated need to hold a public meeting with external stakeholders to clarify CER feedback during the final rule stage.

The staff will establish specific schedule milestones at each juncture to better reflect the tasks that are within the staff's control and the enhanced rulemaking process described in this paper. The staff expects that the increased level of interaction with external stakeholders on the regulatory basis and supporting guidance will extend proposed rule schedules. However, this interaction should help resolve issues, including implementation issues that contribute to CER, and thereby, reduce public comment on both the proposed rule and draft guidance. The staff recognizes that the emphasis on effective interactions with external stakeholders throughout the enhanced CER process could contribute to an increased overall expenditure of staff resources through implementation of the rule. However, the enhanced CER process is expected to significantly reduce the expenditure of staff resources associated with unintended implementation consequences that can result in multiple exemption requests or the filing of petitions for rulemaking to address implementation issues resulting from CER issues. The staff anticipates that the resource implications will balance out, however, the staff will consider the net resource implications through implementation of the process and will inform the rulemaking budget through the planning, budgeting, and performance management process, as appropriate.

COMMITMENTS:

The staff will revise, within 12 months following the date of this paper, office-specific rulemaking procedures to reflect the rulemaking process enhancements, as well as the revised rulemaking schedule approach discussed in the section entitled "*Schedular Process Changes to Support CER Enhancements*." In the mean time, the staff will apply these enhancements to ongoing rulemakings, to the extent practicable.

RESOURCES:

The staff will request the additional necessary resources to implement the recommended revisions to the rulemaking procedures discussed in this paper for fiscal years 2012 and 2013 during the planning, budgeting, and performance management process.

COORDINATION:

The Office of General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

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