

POLICY ISSUE NOTATION VOTE

October 5, 2012

SECY-12-0137

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: IMPLEMENTATION OF THE CUMULATIVE EFFECTS
OF REGULATION PROCESS CHANGES

PURPOSE:

To obtain Commission approval on the staff actions to implement the Commission direction related to the cumulative effects of regulation (CER) process.

SUMMARY:

In the Staff Requirements Memorandum (SRM) to SECY-11-0032, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," dated October 11, 2011 (NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML112840466), the Commission provided direction to the staff on issues related to the implementation of the CER process enhancements. This paper builds upon the staff's proposals in SECY-11-0032 and contains the staff's response to the Commission direction. Specifically, the "Discussion" section describes interactions with stakeholders throughout all stages of the rulemaking process, guidance publication, the common prioritization of rulemaking (CPR), the staff's consideration of applying risk insights to prioritize regulatory actions, the impact of CER implementation on other regulatory actions, and the staff's consideration of the need to quantify cumulative impacts of regulation. In addition, this paper addresses feedback from external stakeholders received at the May 2012 public meeting on CER.

BACKGROUND:

In SRM M091208, "Briefing on the Proposed Rule: Enhancements to Emergency Preparedness Regulations," dated January 13, 2010 (ADAMS Accession No. ML100130067), the Commission directed the staff to consider if the schedule for implementing the emergency preparedness rulemaking and future rulemakings should be influenced by the "aggregate impact" (now more commonly called "cumulative effects of regulation" or CER) of the new and recently issued regulations already scheduled for implementation.

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In response to this direction, the staff prepared SECY-11-0032 (ADAMS Accession No. ML110190027), which included rulemaking process changes and several enhancements designed to: 1) 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) explicitly solicit feedback on CER concerns to increase stakeholder awareness and enable the NRC to make well-informed decisions on how to mitigate CER, and 3) improve the process for establishing the time allowed for implementation by seeking additional information on CER. Specifically, SECY-11-0032 described the following rulemaking process enhancements:

- Interaction (with stakeholders) throughout all phases of the rulemaking process;
- Public meeting on implementation during the final rule;
- Concurrent publication of draft guidance with the proposed rule and final guidance with the final rule;
- Explicit request for stakeholder feedback on CER; and
- Scheduler process changes.

In its SRM to SECY-11-0032, the Commission approved the process enhancements and directed the staff to provide its final strategy to implement the changes. In addition, the Commission directed the staff to:

- Revise office-specific rulemaking procedures to reflect the rulemaking process enhancements;
- Consider application of risk insights to prioritize regulatory actions;
- Consider other regulatory instruments when incorporating the CER process changes; and
- Consider the need to quantify the cumulative impacts of regulation.

On March 20, 2012, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs issued a memorandum to the heads of executive departments and agencies entitled "Cumulative Effects of Regulation."¹ The memorandum stated that "agencies should take active steps to take account of the cumulative effects of new and existing rules and to identify opportunities to harmonize and streamline multiple rules." While the memorandum is not binding on the NRC, the staff plans to implement, or has already implemented, the steps suggested in the memorandum through existing NRC processes, including the CER process, as described herein.

On May 31, 2012, the staff held a Category 3 public meeting to obtain external stakeholder feedback on the CER process changes described in SECY-11-0032 and its corresponding SRM. Forty individuals participated in the meeting, including members of the industry (power reactors and materials), agreement states, and the NRC staff. That feedback is contained in the topic-specific portions of the "Discussion" section of this paper, and the meeting summary is available in ADAMS under Accession No. ML12165A720. In addition to the comments specific to the additional directives contained in the SRM to SECY-11-0032, external stakeholders provided the following concerns and recommendations regarding the generic application of the

¹ Available at <http://www.whitehouse.gov/sites/default/files/omb/assets/inforeg/cumulative-effects-guidance.pdf>

CER process:

- A CER template could be used early on in the rulemaking process to determine the viability and priority of a new rulemaking.
- Rulemaking is just one part of the regulatory picture; relative prioritization of activities should include all regulatory actions, including inspections.
- Implementation challenges vary at different levels; therefore, the CER process should consider the impact on individual plants, a fleet of plants, and industry as a whole.
- A well-defined problem statement early in the process is a must.

The attendees also suggested that there are three possible actions to address a CER issue: 1) delay issuance of the rule, 2) consider site-specific implementation timelines, and 3) use enforcement discretion or exemptions. The staff does not consider the use of enforcement discretion to be the optimal regulatory vehicle to address a CER issue. Further, the staff notes that this decision process will be applied on a case-by-case basis, but, in all cases, safety and security concerns take priority over CER concerns.

Following the public meeting, the Nuclear Energy Institute (NEI) sent a letter (ADAMS Accession No. ML12170A660) dated June 15, 2012, which reiterates key points made by industry representatives during the public meeting.

DISCUSSION:

In its SRM to SECY-11-0032, the Commission directed the staff to submit the results of its final strategy to implement the CER process changes for Commission review and approval. The following subsections build upon the staff's initial proposal in SECY-11-0032, respond to the additional direction contained in the SRM, and address the public feedback from the May 31, 2012, public meeting.

The staff has developed the following definition of CER:

Cumulative Effects of Regulation describes the challenges that licensees, or other impacted entities (such as State partners) face while implementing new regulatory positions, programs, or requirements (e.g., rules, generic letters, backfits, inspections). Cumulative Effects of Regulation is an organizational effectiveness challenge that results from a licensee or impacted entity implementing a number of complex regulatory positions, programs or requirements within a limited implementation period and with available resources (which may include limited available expertise to address a specific issue). Cumulative Effects of Regulation can potentially distract licensee or entity staff from executing other primary duties that ensure safety or security.²

CER will not apply to administrative rules, direct final rules, interim final rules, design certification rules, consensus standards rules, and other similar types of rulemakings that will be identified in a pending revision to Management Directive (MD) 6.3, "The Rulemaking Process." Accordingly, the described process enhancements will be applied to CER-applicable rules.

² The staff has revised the CER definition in SECY-11-0032 by making editorial changes.

At the May 31, 2012, public meeting, the stakeholders requested staff revisit whether CER should be applied to rulemakings that incorporate voluntary consensus standards. Specifically, stakeholders believe CER should be applied to rulemaking amendments to Title 10 of the *Code of Federal Regulations* (10 CFR) 50.55a because industry does not always agree with the consensus standards, and because these rules can be burdensome to implement.

The staff revisited this issue and determined that no change is necessary. The staff does not intend to apply the CER process changes to rulemakings that incorporate voluntary consensus standards because: 1) consensus standards already incorporate stakeholder input early on in development of the standards, and 2) industry stakeholders historically have advocated for expedited processing of these rulemakings to avoid relief requests and to reduce proposed alternative submissions (licensing actions) to the NRC. Furthermore, the staff does not interpret the concerns raised by external stakeholders during the public meeting to be CER concerns. These concerns, which are technical in nature and are not related to implementation, are more appropriately raised through the standard notice and comment rulemaking process.

CER Template

At the May 31, 2012, public meeting, industry stakeholders recommended that the staff use a “CER template” in the early stages of rulemaking to determine the viability and priority of a new rulemaking, as compared to ongoing regulatory actions. The CER template, as described by the industry, would suggest criteria (e.g., safety, risk, compliance, regulatory relief) that would be applied to a prospective rulemaking to facilitate obtaining stakeholder feedback to support the NRC’s decision on whether and when to proceed to rulemaking. The NEI volunteered to take the lead on developing the CER template and coordinating in a public forum with the NRC throughout its development. This concept was not envisioned in SECY-11-0032, nor directed by the Commission in the corresponding SRM.

The staff will begin the dialogue with external stakeholders to gain a better understanding of the content of a CER template and how the template could be used. This dialogue, the development of a CER template, and, if adopted, the application of the CER template to an individual rulemaking, would take place in an open, transparent process (i.e., public meetings). The NRC retains the ultimate decisionmaking authority on whether and when to proceed with a rulemaking.

The regulatory basis stage may be the optimal point in the rulemaking process to apply a CER template. During that stage staff develops the necessary details about the rulemaking, and evaluates whether issuing a proposed rule is the appropriate action. A CER template might support the goals of the CER process enhancements, in particular the goal to increase external stakeholder interaction, by providing a structured tool that the staff could use to obtain external feedback.

Interacting with Stakeholders during the Regulatory Basis Stage

The NRC's current regulatory process encourages stakeholder interaction during the early stages of the rulemaking process, which begins with the development of the regulatory basis and may include an advance notice of proposed rulemaking. The staff believes that early stakeholder interaction leads to a more informed regulatory basis, identifies issues earlier that could result in implementation problems, and reveals areas where guidance is needed. This early interaction also improves the quality and completeness of problem statements for the rulemaking. In the past, stakeholder interactions did not always occur at the regulatory basis stage. Going forward, stakeholder interactions will be conducted routinely at the regulatory basis stage of a rulemaking.

In its SRM, the Commission directed the staff to keep the Commission informed of the outcome of the regulatory basis development interactions and to provide the Commission with general conclusions based on these interactions via a Commissioners' Assistants (CA) note for each rulemaking as soon as practical. The staff intends to implement this direction by submitting a CA note following public interactions that convince the staff to substantively change the content, scope, or schedule of the rulemaking. If a CER template is adopted, a CA note would be developed when significant areas of disagreement exist during application of the CER template to a specific regulatory basis.

Interacting with Stakeholders during the Proposed Rule Stage

The Commission directed the staff to seek and consider stakeholder feedback on the CER considerations related to a proposed rule. Each rulemaking program office revised its rulemaking procedures and templates to include a list of generic questions that apply to rulemakings. Optional rule-specific questions may be developed in some cases. Questions related to CER will be included in future proposed rules.

In the May 2012 public meeting, the staff received positive feedback from external stakeholders on the CER-related questions. One attendee did note, however, that the NRC should request comment on the regulatory activities of other agencies that may impact an NRC rulemaking. The staff agreed and revised the CER-related questions accordingly.

Interacting with Stakeholders during the Final Rule Stage

The staff incorporated a public meeting into the final rule stage, and has held these meetings for three recent rules on generic environmental impact statement for nuclear power plant license renewal, research and test reactor employee fingerprinting, and emergency power preparedness. The purpose of this type of meeting is to better understand and clarify any CER concerns and to provide an opportunity to properly structure the implementation dates of the final rule requirements. The May 2012 public meeting attendees indicated that the public meeting on implementation could aid in identifying implementation issues for specific licensees. The staff notes that, in order for these implementation meetings to be successful and effective, it is imperative that preliminary final rule language and draft final guidance documents are publicly available. This ensures that external stakeholders will be aware of the requirements and can make informed assessments on implementation challenges.

Although the staff plans to conduct public meetings on implementation during the final rule stage for most rules, there may be some rules for which a public meeting might not be held. For example, a public meeting would not be necessary for a rule that extensively considered the implementation date (external stakeholder interaction included) during the regulatory basis and proposed rule phases. A rule that includes a straightforward, noncontentious implementation date or a rule for which no CER input was received may not warrant a public meeting at the final rule stage. External stakeholders expressed general agreement with this approach during the May 2012 public meeting and agreed that in these cases, it was not worth delaying issuance of the final rule (nominally by about one month) to hold the public meeting. Stakeholders did note, however, that frequent (especially early) interaction is key.

Guidance Associated with Rules

The CER process requires that draft guidance be published for comment concurrently with proposed rules and that final guidance be published concurrently with final rules. The SRM to SECY-11-0032 directed the Executive Director for Operations to promptly inform the Commission of any instances (and the associated reasons) for which a proposed rule package will be provided to the Commission without having completed the draft guidance. In the event that guidance cannot be published in accordance with the current schedule for the rule, the staff will request a schedule extension to allow for the concurrent publication of the rule and associated guidance. For future rulemakings in which CER applies, the staff will develop project plans to issue rules and guidance concurrently, and it will budget additional time and resources accordingly.

During the public meeting, external stakeholders noted that the concurrent publication of guidance and rules is working well, and they highlighted the recent 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," rulemaking as an example. The meeting attendees expressed frustration when, despite stakeholder interactions throughout the process, final generic communications and rules are published with significant changes that have been made during concurrence. With the new CER process, stakeholders will see the preliminary final rule language during the public meeting on implementation at the final rule stage.

Common Prioritization of Rulemaking

The Commission directed the staff to use the common prioritization of rulemaking process for prioritizing its rulemaking activities and, where appropriate, project potential future rulemaking activities beyond the normal 2-year budget horizon. The Commission also noted that the staff should consider making this information public.

The CPR process considers four factors and assigns a score to each factor. Those factors include support for the NRC's Strategic Plan goals; support for the Strategic Plan organizational excellence objectives; a governmental factor representing interest to the NRC, Congress, or other governmental bodies; and an external factor representing interest to members of the public, non-governmental organizations, the nuclear industry, vendors, and suppliers. This process is used primarily for the development of rulemaking budget estimates, but the staff also can use the process as a means for deciding the relative priorities of rulemaking projects during budget execution.

In addition, the staff includes all planned and active rulemakings in the CPR regardless of their planned start dates. Many of the rulemakings in the CPR process are active or near-term activities, but the process allows staff to include rulemakings that may not begin for several years.

The staff concluded that elements of the CPR should be made public, and that the Unified Agenda is the most efficient and effective vehicle to communicate rulemaking priorities. The Unified Agenda, which the NRC and all Federal agencies publish semiannually, provides an update on all active rulemaking activities. The fall edition of the Unified Agenda contains the NRC's regulatory plan, which contains a statement of the major rules that the Commission expects to publish in the coming FY and a description of the other significant regulatory priorities from the CPR that the Commission expects to work on during the coming fiscal year (FY) and beyond. To further promote openness and transparency, the spring 2013 Unified Agenda, published in mid- 2013, will include a brief description of the NRC's CPR process.

The public meeting attendees were interested in the four factors used to prioritize rules in the CPR, and they suggested that the process include a weighting factor for rules that provide regulatory relief. The staff noted that regulatory relief is currently considered in the external factor of the CPR process. The attendees also suggested that the rulemaking priorities be reevaluated at several points in the rulemaking process. The staff notes that it currently updates the CPR on an annual basis, at which time rule priorities are re-considered. The attendees expressed interest in the NRC making the CPR process visible. As noted above, the staff will add additional information on the CPR process to the Unified Agenda.

The SRM to SECY-11-0032 stated that CPR updates also should be provided via CA notes on a periodic basis at an appropriate interval determined by the staff. As described above, the staff updates the CPR annually during the budget formulation process, and includes these updates in the budget submittal to the Commission. Staff notes that the CPR informs the budget process and is striving to ensure future consistency between the CPR and the budget. Considering these factors, the staff intends to maintain the annual update process.

Applying Risk Insights to Prioritize Regulatory Actions

In its SRM to SECY-11-0032, the Commission directed the staff to consider whether the revised process should apply risk insights to prioritize regulatory actions, whether such a prioritization is practical, and, if so, how it might be pursued.

The CPR process, as previously described, considers the extent to which a rulemaking could enhance safety or security. This is part of the staff's consideration of how the rule would support the NRC's safety and security strategic goals and organizational excellence objective of effectiveness, all of which are factors in determining the rulemaking's priority. The staff's judgment that a rulemaking could considerably enhance safety or security could justify a higher priority. Risk information or insights are considered when available and as appropriate to prioritize rulemaking actions. The staff notes that this prioritization is used for budgeting purposes and informs the initial rulemaking schedule. In general, the timeline for completing the rulemaking is determined once the staff has begun work on the regulatory basis and is driven by scope, complexity, Advisory Committee on Reactor Safeguards interest, level of public engagement, number of guidance documents, OMB reviews, etc.

Beyond CPR's consideration, the staff does not recommend a different approach for applying risk insights to prioritize regulatory actions. For example, quantitative risk information is often very limited (if available) during the early stage when the staff is prioritizing rulemakings. Obtaining detailed risk information prior to the regulatory basis stage may require significant staff resources at a point in time when the staff has not yet determined whether rulemaking is the appropriate regulatory action. In addition, efforts to obtain this information could delay the rulemaking schedule.

However, the staff believes that risk insights, when available, can also be applied to a rulemaking in appropriate circumstances when determining implementation date(s) for competing regulatory requirements. The CER template described previously, if adopted, could identify qualitative risk information for rulemaking activities early in the rulemaking process, although the primary purpose of CER is focused on unintended consequences to licensees implementing regulatory programs and not on risk analysis of the regulatory program. Because CER template discussions would occur in a public setting, external stakeholder feedback on associated risk could be obtained and incorporated in the assessment. Further, the staff expects that the specific request for comment on CER in the proposed rule will gather feedback on other regulatory actions and their relative significance to the proposed regulatory action that may impact the implementation of the subject rule. Additionally, the public meeting on implementation held during the final rule stage could be used to assess the relative change in risk associated with the rulemaking compared to the other ongoing and near-term regulatory actions. At that stage of the rulemaking process, the draft final rule requirements would be known, and a better view of other ongoing and near-term regulatory actions would be available. For rulemakings and associated regulatory actions where no or limited risk information is available or is not otherwise considered, the rulemaking implementation date(s) would be determined based on a qualitative assessment of factors such as the relative benefits of the actions (e.g., if the rule provides regulatory relief), the number and complexity of the actions, the flexibility of implementation dates for other actions, etc. In contrast, for rules where risk information is available, it could be used as an additional factor in determining the rulemaking implementation date(s).

Schedule Process Changes

The CER process enhancements may impact rulemaking schedules due to increased stakeholder interaction and the requirement to publish draft guidance with proposed rules and final guidance with final rules. The staff will discuss the schedule with external stakeholders at public meetings held during the rulemaking process as appropriate. As directed in the SRM to COMSECY-12-0007, "Impact of the Cumulative Effects of Regulation on Existing Rulemaking Due Dates," the staff will use the existing rulemaking schedule change process to request schedule revisions, as necessary.

Impact of CER Implementation on Other Regulatory Instruments

The Commission indicated that the implementation of CER should consider other regulatory instruments and that the staff's procedures should be revised to include provisions accounting for other regulatory actions that may influence implementation dates for new rules. The staff intends to consider the impact that other ongoing regulatory actions (orders, generic communications, etc.) may have on implementation of the new rule requirements. In those specific cases, the *Federal Register* notice of the proposed rule will specifically request public

comment on how those other activities may impact the proposed rule. The impact other regulatory actions may have on a rulemaking will be discussed again during the public meeting on implementation held during the final rule stage.

At this time, while the staff does not routinely apply the CER process to other regulatory actions such as orders, generic communications, and inspections, it does apply the overall concepts of CER (e.g. providing early communication of guidance, conducting meetings with stakeholders, and coordinating schedule implementation). After some experience with CER in the rulemaking process, the staff could reevaluate CER for applications other than the rulemaking process. The staff received the following feedback on the use of CER for other regulatory actions from external stakeholders during the May 2012 public meeting:

- Preparing responses to 10 CFR 50.54(f) letters is often more resource-intensive than rulemakings.
- Generic communications can change the licensing basis of plants.
- The regulatory issue resolution protocol may be a useful tool to define the regulatory problem and associated success criteria (to ensure that such actions effectively address the defined problems with minimum burden).

Quantifying the Cumulative Impacts of Regulation

The Commission directed the staff to consider the need to quantify the cumulative impacts of regulation and provide the Commission with its views on how the agency might develop a measurement and evaluation approach that would inform both future and current regulatory activities.

The staff discussed this question with members of the public during the May 2012 public meeting. One attendee noted during the public meeting that quantifying the cumulative impacts of regulation is challenging, and stated that qualitative assessments should not be overlooked.

Though the CER template described earlier in this paper has not been developed, the staff expects any CER template to be a qualitative, rather than a quantitative, tool. Furthermore, if a CER template were to provide quantitative data, which could include industry-wide, fleet-wide, or site-specific schedule, cost, or staff-hour burdens, staff is uncertain how it would use that data to quantitatively evaluate CER. Also, considerations at “fleet level” and below could be complicated and resource-intensive. The NRC has an accepted method for performing a regulatory analysis where regulatory burdens are converted into cost. However, there is no current analytical method for converting, combining, and assessing CER data to compute CER burden and an appropriate implementation period for a rulemaking. Therefore, the staff does not recommend at this time using a quantitative approach for evaluating CER. Rather, the staff believes that the NRC should qualitatively evaluate CER by considering, in part, currently-identified, pending and planned regulatory actions and their implementation dates.

RECOMMENDATIONS:

The staff recommends that the Commission:

1. Approve the staff's proposed actions to implement the CER process enhancements, as described in the "Discussion" section of this paper.
2. Note that the staff is revising rulemaking schedules, as appropriate, to consider CER as described in this paper and it will plan future rulemakings accordingly.

RESOURCES:

The lead rulemaking offices (the Office of Nuclear Reactor Regulation, the Office of New Reactors, and the Office of Federal and State Materials and Environmental Management Programs) have revised their rulemaking resources in the FY 2013 President's Budget and the FY 2014 Performance Budget to include those resources associated with the CER Process.

COORDINATION:

This paper has been coordinated with the NRC's Rulemaking Coordinating Committee and all rulemaking lead and partner offices. 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.

/RA/

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