

POLICY ISSUE
(Notation Vote)

April 1, 2015

SECY-15-0050

FOR: The Commissioners

FROM: Mark A. Satorius
Executive Director for Operations

SUBJECT: CUMULATIVE EFFECTS OF REGULATION PROCESS ENHANCEMENTS AND
RISK PRIORITIZATION INITIATIVE

PURPOSE:

This paper responds to the Commission's direction in Staff Requirements Memorandum (SRM)-COMSECY-14-0014, "Cumulative Effects of Regulation and Risk Prioritization Initiative: Update on Recent Activities and Recommendations for Path Forward," dated July 18, 2014 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14199A187). This paper provides the Commission with options for addressing the cumulative effects of regulation (CER) and the risk prioritization initiative (RPI) for operating power reactors. The options and the Nuclear Regulatory Commission (NRC) staff's recommendation are based on recent CER and RPI activities and lessons learned, including CER case studies, RPI demonstration pilots, and stakeholder feedback. This paper does not contain any new commitments.

SUMMARY:

This paper provides four options for addressing CER and RPI. The first option maintains the status quo, which includes the current CER enhancements. The next three options augment current regulatory processes or propose changes to regulatory processes by incorporating risk insights to prioritize initial compliance and implementation dates for regulations and orders on a plant-specific basis for operating power reactors.

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The staff recommends the Commission approve Option 2. This augments existing regulatory processes with a risk-informed prioritization method. In addition, the staff will explore using an internal expert panel to use risk information to enhance regulatory decision-making at the beginning stages of development of regulatory action as part of CER. The staff also recommends the Commission approve the pilot for Option 3, which would provide a voluntary opportunity for operating power reactor licensees to submit a plant-specific plan for initial compliance and implementation when the NRC develops a regulation. After obtaining feedback and lessons-learned from Option 2 and results of the pilot of Option 3, the staff would provide the Commission a paper on the results, and seek further direction if the staff believes it would be warranted.

This paper was developed using feedback obtained from the public and with experience gained during tabletop and pilot exercises. The experience and feedback led to the four options described herein. This SECY also offers an update on staff efforts to address CER effects in the areas of operating power reactors, fuel-cycle facilities, Agreement State programs, and material licensees.

BACKGROUND:

Consistent with Executive Order 13563, "Improving Regulation and Regulatory Review," issued on January 18, 2011, and guidance provided by the Office of Management and Budget (OMB) memorandum, titled "Cumulative Effects of Regulation," issued on March 20, 2012, the NRC staff's CER efforts examine ways in which the agency may be able to enhance the efficiency with which it carries out regulatory actions, while mitigating the cumulative effect of regulatory activities on both the NRC and licensees. RPI would be intended to complement other CER processes. If put into place, it could be a tool to reduce CER for operating reactor licensees. The goal is to enable NRC staff and licensees to focus resources on issues that are most significant to public safety using risk information. In addition, RPI could incentivize the further use and development of probabilistic risk assessment (PRA).

In COMSECY-14-0014, "Cumulative Effects of Regulation and Risk Prioritization Initiative: Update on Recent Activities and Recommendations for Path Forward," April 9, 2014 (ADAMS Accession No. ML14069A061), NRC staff recommended that the deliverables for the following be merged:

- SRM-SECY-12-0137, "Implementation of the Cumulative Effects of Regulation Process Changes," dated March 12, 2013 (ADAMS Accession No. ML13071A635)
- SRM-COMGEA-12-0001/COMWDM-12-0002, "Proposed Initiative to Improve Nuclear Safety and Regulatory Efficiency," dated February 6, 2013 (ADAMS Accession No. ML13037A541)

Under the proposal, the staff would provide one notation vote paper, a summary of the results of case studies to review the accuracy of cost and schedule estimates used in the NRC's regulatory analyses and a plan to sunset the development of a CER template. In SRM-COMSECY-14-0014, the Commission approved the NRC staff's plan to merge the CER and RPI deliverables. The Commission also directed NRC staff to provide a notation vote paper that addresses consideration of the regulatory process changes required to support reliable,

efficient, and effective implementation of RPI in the long-term. The Commission directed NRC staff to provide a discussion on how corrective actions for findings, violations, and degraded or nonconforming conditions adverse to quality will be treated as part of RPI. This SECY paper addresses these Commission directives.

External Stakeholder Feedback on CER and RPI

The NRC staff held multiple public meetings to discuss the CER and RPI efforts for operating power reactors. (Public meetings before April 2014 are discussed in COMSECY-14-0014.) The NRC held its most recent public meeting on CER on October 9, 2014. That public meeting summary is available in ADAMS under Accession No. ML14316A022.

The NRC staff received significant stakeholder input on RPI through the observation of generic and plant-specific tabletop exercises and the NRC staff's participation in demonstration pilots of the Nuclear Energy Institute's (NEI) draft prioritization process, which is discussed in Enclosure 2. Overall, the nuclear power industry expressed significant interest in using existing available risk information to prioritize regulatory activities. Industry evaluated a large number of issues during these exercises to demonstrate how risk insights can be used to prioritize both plant-initiated and regulatory issues. The nuclear power industry indicated that further development of PRA capabilities as described in the SRM-COMGEA-12-0001/COMWDM-12-0002 would not be a prudent use of licensee resources at this time, given the large number of current regulatory activities facing the nuclear power industry, since the currently available risk information and tools are sufficient to support this effort.

RPI: NEI Draft Guidance Development and Demonstration Pilot Exercises

In October 2013, NEI began to develop a draft process as a potential way to address RPI for operating power reactors. NRC staff provided comments on NEI draft guidance at various stages using insights gained from tabletop exercises, demonstration pilots, and discussions with stakeholders during public meetings. NRC staff will continue to work with nuclear power industry and other stakeholders to evaluate possible endorsement of NEI guidance with appropriate clarifications and exceptions, if this initiative is approved by the Commission. The latest version of that guidance was submitted to the NRC by letter dated November 14, 2014 (ADAMS Accession No. ML14325A681).

NEI's draft process consists of three main elements: (1) generic prioritization by an industry generic assessment expert team (GAET) (Note: the GAET is the only component in the generic process; in addition some licensees may choose to use only the information obtained from the GAET or may choose not to participate in the RPI process at all), (2) plant-specific prioritization and scheduling by an integrated decision-making panel (IDP) of licensee experts, and (3) "issue aggregation." The panel performing these elements would have expertise in PRA as well as other key areas, such as radiation protection, emergency preparedness, and nuclear security. The GAET's conclusions from the generic prioritization component of the process would be passed on to operating power reactor licensees, which, in turn, would use that information during the plant-specific prioritization process to make the plant-specific determinations on the safety and security effect of each issue or activity. The IDP would then evaluate the issues as an integrated set and rank them relative to each other as part of issue aggregation, prioritizing items of higher safety significance over those of lower safety significance.

In COMSECY-14-0014, NRC staff described its observation of tabletop exercises of the draft process. Six operating power reactor licensees participated in the demonstration pilots: Palisades, H.B. Robinson, E.I. Hatch, Davis-Besse, Prairie Island, and V.C. Summer. The demonstration pilots were conducted between May and September of 2014. These licensees used the process described above. Each licensee prioritized 10 plant initiatives, such as: modifications and equipment replacement, regulatory obligations (e.g., National Fire Protection Association (NFPA) 805 implementation schedules), and docketed commitments associated with inspection findings. NRC staff observed all the activities at Palisades and H.B. Robinson. In addition, NRC staff observed a sample of issues from the remaining licensees. In September 2014, NRC staff held a public meeting to discuss the processes used by licensees to prioritize issues in security, emergency preparedness, and radiation protection. The risk significance of those issues is not easily amenable to quantification, and a small number of these issues were prioritized during the demonstration pilots. Enclosure 2 contains more details and insights obtained from the NRC staff's participation in the demonstration pilots.

NRC staff also explored whether greater flexibility (including proposing alternatives or elimination) could be afforded if high quality, Level 1 and Level 2 PRAs were available. The amount of flexibility provided would be commensurate with the quality of risk information used to justify the request. If a licensee chose to develop greater PRA capability that was peer reviewed and consistent with Regulatory Guide 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities" (ADAMS Accession No. ML090410014), then the licensee could propose an alternative or perhaps eliminate the issue altogether if the risk fell below established risk significance thresholds. However, based on stakeholder feedback, industry may not be prepared to conduct and maintain PRAs of the scope and quality that would be needed for NRC staff to allow a licensee to propose an alternative or to eliminate an issue. Furthermore, NRC staff would need to consider the effect of this option on legal, inspection, and enforcement issues. Consequently, the staff notes that, given the lack of experience in applying an RPI-type process and the substantial legal uncertainties, none of the options described in this paper include an elimination element.

DISCUSSION:

This paper provides the Commission with options and recommendations for CER and RPI for operating power reactors. The paper also provides an update of NRC staff efforts to address CER effects in the areas of operating power reactors, fuel-cycle facilities, Agreement State programs, and material licensees. These efforts are discussed in Enclosure 1.

The staff continues to make steady improvements in activities related to implementing CER. The rulemaking process enhancements to address CER (e.g., increased public interaction in all phases of the rulemaking process, publishing guidance with rules) have received positive feedback and are requirements per office rulemaking procedures. The NRC staff is encouraged by the increased public involvement in setting generic implementation schedules and feedback on at least one draft regulatory analysis. These activities will continue to be enhanced as part of Option 1.

Regulatory Analysis Improvements

In SRM-SECY-12-0137, the Commission directed the staff to engage in case studies to evaluate the accuracy of cost and schedule estimates within regulatory analyses. The nuclear power industry completed those case studies and provided three recommendations related to: the scope of the regulatory action, the early release of regulatory analysis and detailed implementation guidance, and cost estimates made in the regulatory analysis. NRC staff evaluated the industry's recommendations, and has implemented additional regulatory analysis process enhancements as described in Enclosure 3. In addition, Enclosure 3 describes planned regulatory analysis updates, efforts made to improve cost estimating within regulatory analyses, and ways in which the risk insights gained from the generic prioritization component of the RPI process could be used to improve regulatory analyses.

CER Expansion to Generic Communications Program

In SRM-SECY-12-0137, the Commission directed that any expansion of the consideration of the CER should be considered in the broader context of RPI (e.g., guidance and generic communications). During CER public meetings in 2013, the nuclear power industry said there could be value in expanding the CER process enhancements to the generic communications program. In reviewing the processes for generic communications, NRC staff concluded that those processes already reflect elements of CER process enhancements. Those enhancements include providing opportunities for public interaction in the beginning stages of development and opportunities for public comment on some draft generic communications. As a pilot, NRC staff incorporated six CER questions in the *Federal Register* notices (FRNs) for two draft generic letters. NRC staff did not receive feedback that identified significant effects on the licensee's ability to carry out other NRC regulatory requirements. However, as part of the pilot for an expert panel, discussed in Option 2 of this paper, the inclusion of generic communications could be considered as part of the regulatory actions evaluated under that option.

NRC staff plans to continue using the six CER questions in the FRNs for generic letters seeking information under Title 10 of the *Code of Federal Regulations* (10 CFR) 50.54(f), "Conditions of Licenses." The six CER questions, findings and other considerations are discussed further in Enclosure 4.

Considerations for Implementing a Risk Prioritization Initiative

The SRM-COMGEA-12-0001/COMWDM-12-0002 directed the NRC staff to develop options for operating power reactors on "allowing licensees to propose to the NRC a prioritization of the implementation of regulatory actions as an integrated set and in a way that reflects their risk significance on a plant-specific basis." That SRM also directed NRC staff to explore how such a process could enhance the use and development of PRA information. In this paper, NRC staff proposes four options for carrying out RPI in a manner that further addresses CER. Options 2 and 3, if put in place would promote PRA by allowing operating power reactor licensees to use a risk-informed prioritization method to schedule regulatory actions using existing NRC regulatory processes based on currently available qualitative and quantitative PRA information and new PRA information emerging from other regulatory initiatives, such as industry implementation of the risk-informed fire protection standard, NFPA 805, and Fukushima-related initiatives. A fourth option (Option 4) explores a potential rulemaking that would promote the use of existing

PRA information and may incentivize operating power reactor licensees to develop new PRA information by enhancing their site-specific PRA models.

SRM-COMSECY-14-0014 directed NRC staff to consider “how corrective actions for findings, violations, and degraded or nonconforming conditions adverse to quality will be treated as part of the risk prioritization initiative.” NRC staff, including regional NRC staff members who are experts in the reactor oversight process (ROP) area, evaluated this issue and sought stakeholder perspectives during public meetings. The nuclear power industry prefers that all issues, including those that are in response to items entered into their site-specific corrective action programs based on an NRC inspection finding, be part of the scope of RPI. Industry is of the view that such issues should be included under RPI because that would provide them with the ability to evaluate all issues when allocating resources, whether they are driven by inspections or otherwise. The NRC staff disagrees with the nuclear power industry on this aspect. RPI is generally intended to prioritize changes associated with the implementation of new or current requirements. The staff believes that licensees must restore compliance issues identified during inspections using existing processes associated with dispositioning inspection findings. As a result of the staff feedback to NEI, NEI revised its guidance to limit the proposed scope of RPI to docketed commitments resulting from inspection findings.

Discussion of CER and RPI Options for Operating Power Reactors

This discussion offers the options and recommendations for CER and RPI for operating power reactors. Each of these options builds upon the previous option(s), such that Option 2 includes the Option 1 CER process enhancements; Option 3 includes Options 1 and 2 CER and RPI enhancements; and Option 4 includes the CER and RPI enhancements in Options 1 through 3. The staff notes the NRC employs two approaches to address initial compliance and implementation schedule concerns: (1) “effective date” in the FRN (consistent with Office of the Federal Register limitations), or (2) implementation language in a paragraph of the specific rule, establishing the date for compliance with the rule. The NRC generally offers an opportunity for early stakeholder input on implementation schedule concerns. The NRC’s proposal, reflecting consideration of the early stakeholder input, would be reflected in the proposed rule (as approved by the Commission or the EDO, as applicable). Opportunity for stakeholder input on the NRC proposal in the proposed rule must ordinarily be provided as part of the proposed rule’s publication in the *Federal Register*. Final rule reflects the NRC decision-maker’s choice to use either effective date or implementation language.

Options 2 through 4 employ a risk-informed prioritization method guidance document. The guidance could be used two ways:

- The licensee could use the guidance to support processes that the NRC’s current regulatory framework allows. In those cases, the NRC would ultimately approve (through existing processes (i.e., exemptions or requests submitted during the proposed rule phase of prospective rulemakings) the plant-specific initial compliance and implementation schedules for regulations and orders.
- The process described in the guidance could be codified in the final rule language of prospective rules to allow licensees to establish plant-specific initial compliance and implementation schedules after final rule issuance OR a facilitating regulation could be issued to allow such a process for all future and existing regulations.

In this Commission paper, the staff organizes the options in a step-wise manner per regulatory vehicle to gain experience with the guidance and gather lessons learned before moving on to the next step, as follows:

- Option 2 pertains to exemptions and enhances the current exemption process by providing guidance to support each scheduler request.
- Option 3 pertains to prospective rules. It would allow a licensee to use the guidance during the proposed rule phase to develop plant-specific initial compliance and implementation schedules to be included in the text of the applicable regulation.

Option 4 involves rulemaking to develop a regulation that would allow licensees to develop plant-specific initial compliance and implementation schedules for existing or future regulations (with the possibility of expanding this to orders). The regulation effectively would include (codify) the key elements of the guidance.

Option 1: Maintain the Status Quo

The NRC would maintain the existing regulatory processes. NRC staff would continue to carry out or pursue those CER and regulatory analysis improvements that the Commission already has approved for implementation.

Option 1: Implementation Considerations

Option 1 has no unresolved implementation issues. Maintaining the status quo would continue the current CER approach without the need for any new NRC staff resources. It would continue the current approach to regulation that is well-understood. The observed benefit of the CER process enhancements (e.g., increased stakeholder interaction in developing implementation schedules and draft regulatory analyses) would continue. However, Option 1 may not ensure that NRC and reactor licensee resources and activities are focused on the items of highest risk significance on a plant-specific basis. It may not resolve some industry CER concerns with existing or future requirements. It will not motivate reactor licensees to develop new PRA models.

Option 2: Augment Regulatory Processes with RPI Method and Expert Panel Addressing CER

Under Option 2, the NRC would augment existing regulatory processes based on CER and RPI lessons-learned, best practices, and stakeholder feedback. This option consists of two parts. The first part proposes to augment current regulatory processes by allowing licensees to use a risk-informed prioritization method as the basis to request schedule changes for initial compliance and implementation dates for regulations and orders. These changes would be accomplished through existing processes (e.g., exemptions, docketed commitment changes, license amendments, and order modifications for operating power reactors). This augmented process would address changes to the implementation dates only. One NRC method to perform the prioritization would be through endorsement, in a regulatory guide, of an industry-developed risk-informed prioritization method (with appropriate clarifications and exceptions). The augmented regulatory process would facilitate the submittal, review, and regulatory determination of schedule change submittals, using risk information as a basis. NRC

staff would develop guidance to support the NRC's review of these licensee submittals that use this risk-informed process.

If a licensee chooses to adopt this augmented process, the licensee would use risk information and processes established in the regulatory guide to prioritize and rank regulatory actions to support its request for individual schedule changes based on the safety significance. This risk information as discussed earlier could be obtained from the GAET (as part of the generic assessment) or from the IDP (as part of the plant-specific assessment). Using the NRC's current regulatory processes (i.e., 10 CFR 50.12, "Specific Exemptions," or 10 CFR 50.90, "Application for Amendment of License, Construction Permit, or Early Site Permit," license amendments), a licensee may request exemptions or license amendments for scheduler purposes. However, there is no guidance available to ensure that these submittals are prepared and reviewed in a consistent manner. Documentation of a risk-informed prioritization method for schedule changes would clarify NRC staff expectations and streamline the NRC staff's reviews of exemptions or license amendment requests.

In the second part of this option, NRC staff would pilot an expert panel that would use risk insights and other relevant technical information as part of NRC's generic process. The panel consisting of NRC's senior managers and subject matter experts would consider proposed rules, orders and generic communications early in the development stages consistent with CER process enhancements. The panel could make recommendations to prioritize, schedule, or eliminate when appropriate, proposed rules, orders and generic communications across the Operating Reactor business line. The staff could use this information to ensure that the NRC's resources and activities are focused on the items of highest risk significance.

As discussed in both the regulatory analysis improvements section and RPI Demonstration Pilot Exercises section above, insights gained during various public interactions on CER and RPI prompted NRC staff to propose exploring an expert panel. Specifically, during tabletops, the industry GAET deliberated to provide generic prioritization of issues using risk insights. These panels consisted of various industry subject matter experts from different utilities at various levels of their respective organizations.

Option 2: Implementation Considerations

For the first part of Option 2 the implementation considerations are as follows:

This option would support the agency's efforts in CER and further the use of PRA risk insights. However, the implementation of a risk-informed prioritization process would require the NRC to develop a regulatory guide, supporting templates, and a standard review plan. This option would be voluntary. It could encourage licensees to use available risk insights to focus resources on issues that are most safety significant.

For the first part of Option 2, NRC would issue guidance addressing how individual licensees could request a plant-specific initial compliance and implementation date for any regulation, order, docketed commitment and license condition. The request would be in the form of an exemption, docketed commitment changes, license amendments, and order modifications for operating power reactors and contain information developed to follow NRC guidance.

Should the Commission direct NRC staff to put Option 2 in place, submittals (and consequently NRC staff reviews) could increase because some licensees may choose to adopt the RPI process. Because all future schedule requests would be submitted and reviewed on a case-by-case basis, NRC staff would have the opportunity to prevent the perpetual deferral where the safety benefit of the requirement is nullified by the delay, obviating the need for a pre-determined backstop. If the Commission approves this option, the staff would develop principles or criteria, for Commission approval, governing the staff's approach for addressing potential perpetual deferral situations. Alternatively, the Commission could consider whether a pre-determined backstop is preferable. NRC staff would review the schedule requests and make a regulatory decision based on the merits of that request and any previous requests related to the same issue. Initially, more time may be needed to review these regulatory actions and adapt to the new process. However, as the licensees and NRC staff become more familiar with these types of reviews and the guidance, the resources to review these actions could be lessened. Option 2 offers only an interim solution for addressing current CER concerns because it would not ensure consideration of CER in the establishment of schedules for initial compliance and implementation of regulations.

The NRC staff evaluated the potential effect of putting Option 2 in place on inspection and enforcement functions and estimates that this impact would be low because only a subset of the plants will likely use this option. Therefore, the efforts to manage resources for inspection and enforcement will not likely increase significantly.

The resources for this part of Option 2 are unbudgeted. The time required to develop this process and develop regulatory guidance would be less than two years.

For the second part of Option 2 the implementation considerations are as follows:

If the Commission approves this part of Option 2, this would require added resources. The establishment of the panel would require the development of the infrastructure to support the panel. The inclusion of the panel in the regulatory process likely would extend the overall development schedule of rules, orders and generic communications. NRC staff notes that several panels exist within the NRC, including the Generic Issues Program, the Committee for Review of Generic Requirements and the Common Prioritization of Rulemaking. The NRC staff would need to ensure that such a panel would complement, and not conflict, with the functions of these existing panels. The pilot would consider whether such a panel could have the unintended consequence of creating unnecessary burdens or inefficiencies.

Option 3: Establish Voluntary Plant-Specific Implementation Schedules in Prospective New Rules (Operating Power Reactors Only)

In addition to augmenting the existing regulatory processes to include piloting an expert panel and inclusion of the risk-informed prioritization process described above, Option 3 addresses RPI by building on the first part of Option 2 in two approaches. In the first approach, licensees could submit, during the comment period of a proposed NRC regulation, a proposed plant-specific schedule to be codified in the text of the final regulation (analogous to the "implementation" language in the proposed rulemaking for 10 CFR 50.46c, "Emergency Core Cooling System Performance during Loss-Of-Coolant Accidents."). The information in the licensee's comment submission would be based upon NRC guidance developed in Part 1 of Option 2. NRC inclusion of plant-specific compliance date in the language of the final regulation

would prevent the need for the NRC to issue an exemption to give the plant-specific compliance and implementation schedule for initial compliance.

A second approach under Option 3, the NRC would codify the key attributes of NRC guidance on plant-specific schedule relief for initial compliance and implementation dates for regulations (developed in part 1 of Option 2) in the language of each NRC regulation which the NRC wishes to offer schedule relief. As with the first approach of Option 3, the second approach would prevent the need for the NRC to issue an exemption to offer the plant-specific compliance and implementation schedule for that regulation.

Based on insights gleaned through observing RPI tabletops and participating in pilot exercises, NRC staff concludes that flexible implementation schedules would allow licensees to use site- or unit-specific risk information to commit resources to matters of higher safety significance before those of less significance. In cases where the regulation permits licensee-determined implementation schedules, a generically applicable implementation or compliance date would also be set forth in the regulation for those licensees that do not wish to establish a site- or unit-specific implementation date. This would be similar to the NRC's issuance of the 10 CFR 50.63, "Loss of All Alternating Current Power" (53 FR 23215, June 21, 1988), Station Blackout Rule that allowed licensees to submit to the NRR Office Director a date for completing the implementation of coping strategies to address a station blackout event.

Option 3: Implementation Considerations

Flexible implementation schedules could offer benefits with respect to reducing cumulative burden associated with regulations and are consistent with Executive Order 13563 and the OMB Memorandum discussed in the Background section. Using risk information, if available and applicable, to determine the flexible dates would enable NRC staff to reflect the safety significance of the prospective requirement in the requested schedules. Furthermore, this would allow licensees to focus resources on items of greatest safety significance sooner than those of lesser safety significance. This could motivate industry to use PRA and risk insights. This could result in a reduction of 10 CFR 50.12 exemptions requested given that the licensees would be allowed to submit voluntarily a plant-specific implementation plan when the NRC adopts a final rule. NRC staff would use guidance developed under Option 2 to describe how the risk insights could be used to support the risk-informed prioritization process. NRC staff does not believe that a backstop is required for this option for schedule requirements generated for future rules. Because all future schedule requests would be submitted and reviewed on a case-by-case basis, NRC staff would have the opportunity to prevent the perpetual deferral where the safety benefit of the requirement is nullified by the delay, obviating the need for a pre-determined backstop. If the Commission approves this option, the staff would develop principles or criteria, for Commission approval, governing the staff's approach for addressing potential perpetual deferral situations. Alternatively, the Commission could consider whether a pre-determined backstop is preferable.

Added NRC staff resources and time could be required to develop and issue rules that contain opportunities for flexible implementation. Similar to Option 2, this option would be voluntary and would not require licensees to use a risk-informed prioritization process and might not further encourage PRA development.

Option 3 would have several other effects on resource and resource management in support of inspections and enforcement. Because Option 3 could result in varying implementation schedules, inspection planning could be more challenging. Extra resources might be needed to track and determine applicable implementation dates. Enforcement actions might become more varied and require added time and resources to close. However, enforcement and inspection resource disruptions could be managed, assuming sufficient communication and coordination of the proposed schedules and changes exist. Extra resources also would be required during the early stages of individual rulemakings. These would involve the staff's solicitation of stakeholder input for specific schedules for implementation dates and the resolution of accommodative rule language. Tailored implementation dates could result in complex rule language, but the benefit could be increased focus of plant-specific resources on issues of higher safety significance. Any future changes to the implementation schedules would be managed under current regulatory processes for exemptions and would not require additional resources resulting from the implementation of Option 3.

Option 4: Initiate RPI Rulemaking to Allow Scheduling Flexibility for initial compliance and implementation of Regulations (Operating Power Reactors Only)

The SRM-COMGEA-2-0001/COMWDM-12-0002 directed NRC staff to evaluate a process that could obviate the need for exemptions and allow the licensees to prioritize the initial compliance and implementation dates for regulations with plant-specific risk information and in an integrated set.

Option 4 would address this direction in a limited fashion, by the NRC issuing a standalone "RPI Rule." Such a rule, which would be voluntary, would establish a prioritization process enabling each licensee to make site-specific schedule changes to the initial compliance and implementation date for regulations in accordance with the process established in the rule without requesting an exemption.

The regulation whose initial compliance and implementation date could be changed under the RPI rule could be either:

- technical regulations specified (listed) in the RPI rule
- all technical regulations—existing and future

NRC staff considered the applicability of a backstop as part of Option 4, and is aware that the industry has proposed a backstop of three operating cycles. If the Commission selects this option, then NRC staff would evaluate the length of the backstop and whether that backstop should be commensurate with the risk-significance of the regulation whose compliance and implementation date is being deferred.

To put the RPI rule in place, the NRC would endorse one method for implementing a risk prioritization process (i.e., the regulatory guide described in Options 2 and 3), officially pilot the process, audit the risk prioritization programs at licensees, and then incorporate NRC inspection and enforcement of the process under the ROP baseline inspection program and the enforcement manual. The licensee would carry out the prioritization process, and manage the

integrated compliance and implementation schedule of the regulations, which the licensee voluntarily chooses to be re-prioritized under the RPI rule. The bases of the schedule results would be subject to NRC inspection.

If NRC staff considers expanding the RPI rule to orders, the staff would evaluate expanding the scope and provide the Commission a paper with a recommendation.

Option 4: Implementation Considerations

This option could promote risk insights and potential development of PRA capability. This option would delineate the level of PRA development and regulatory flexibility available to the licensees. Furthermore, it would be analogous to other regulatory processes such as 10 CFR 50.59, “Changes, Tests and Experiments,” and 10 CFR 50.65, “Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants,” and allow the NRC staff the ability to inspect and enforce deviations from the proposed risk prioritization process. It would give operating power reactor licensees the flexibility in scheduling the initial compliance and implementation date for regulations falling within the scope of the RPI rule.

Pursuit of this option would require additional time and resources, beginning with the development of a new rule, including a “backstop” provision. The typical rulemaking process is approximately three years from the development of the regulatory basis to issuance of the final rule. Additional guidance would be needed to support the rule, which, while developed in parallel with the rulemaking, would require additional resources. Because this would be a shift in the NRC’s current regulatory processes, training would be required to make the NRC staff aware of the new process. This option would be adopted by licensees on a voluntary basis; hence, it would not incentivize the further development of PRA for licensees that do not choose to adopt it. Those licensees would still benefit from the current CER process enhancements of Option 1 and the added use of risk information if they elect to pursue the process outlined in Options 2 or 3. Future RPI rulemaking would not address immediate industry concerns with the CER effect of existing regulatory requirements—including matters such as orders and licensee non-compliances. Because issues in the areas of emergency preparedness, radiation protection, and in some cases security are not easily amenable to risk quantification, the staff would have to rely on qualitative risk insights as well as other attributes of the risk-informed framework (e.g., defense in depth, safety margins) to develop clear objective criteria in these areas.

The implementation, inspection, and enforcement could be modeled after other risk-informed initiatives such as the 10 CFR 50.65 rule (64 FR 38551, July 19, 1999). NRC staff would need to prevent adverse effects to the ROP because of this rule. Enforcement actions may be more varied and may require additional time and resources to disposition. This option may require the development of new baseline inspection procedures and additional training for inspectors. It could also result in potential impact to regional inspection planning and create unforeseen resource challenges.

Regulatory Process Change Required to Support RPI and Obviate the Need for Exemptions

The SRM-COMSECY-14-0014 directed NRC staff to “include consideration of the regulatory process changes required to support reliable, efficient, and effective implementation of the RPI in the long term (e.g., modification of the language of 10 CFR 50.12 to obviate the need for

exemptions, provided that the risk prioritization is based on an appropriate PRA).” NRC staff reviewed 10 CFR 50.12 and its statement of considerations and concluded that 10 CFR 50.12 exemptions should be used infrequently. As a result, NRC staff identified three possible approaches that, if carried out, would obviate a licensee’s need to request one or more exemptions to implement the RPI concept (as applied to initial implementation of new or amended regulations).

The first approach would be for the NRC to include, in future rulemakings, detailed “implementation” language that specifies the NRC-approved method and acceptance criteria for carrying out the RPI concept as applied to that new or revised regulation’s initial implementation. This approach is reflected in the “second approach” of Option 3. A second approach would be to amend 10 CFR 50.12 (and any necessary conforming changes throughout 10 CFR Chapter I) to specify the NRC-approved method and acceptance criteria for carrying out the RPI concept as applied to that new or revised regulation’s initial implementation. A third approach would be to adopt a new standalone rule (and make conforming changes throughout 10 CFR Chapter I including 10 CFR 50.12), which would specify the NRC-approved method and acceptance criteria for carrying out the RPI concept as applied to that new or revised regulation’s initial implementation. NRC staff notes that the first approach (i.e., implementation language in all future rulemakings) is incorporated into Option 3, described in this paper.

NRC staff considered the second and third approaches (rulemaking to amend 10 CFR 50.12 and new standalone rule, respectively) in developing Option 4. NRC staff concluded that amending the existing 10 CFR 50.12 requirements would not be ideal for a dynamic process that could result in frequent schedule change requests. In addition, a rulemaking to add a new section in 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” would be transparent and clear in communicating the intent of the new process. Therefore, NRC staff determined that a new rulemaking would be preferred over amending the existing 10 CFR 50.12 requirements. From a resource perspective, resources required to amend an existing rule or to develop a new rule would be comparable.

NRC staff notes that added regulatory and practical issues would have to be addressed with respect to applying RPI principles to combined licenses (and possibly early site permits) issued under 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.” At this time, the RPI process does not appear to be relevant to either design certification applications or to final design certification rules issued under 10 CFR Part 52 (and currently codified in various appendices to 10 CFR Part 52). However, stakeholder input would be useful on this subject before the NRC staff presents a final recommendation for applying RPI principles to design certification rulemaking.

RECOMMENDATION:

The NRC staff recommends that the Commission:

1. Approve Option 2. Part 1 augments existing regulatory processes with a risk-informed prioritization method. Part 2 permits the staff to explore using an internal expert panel to use risk information to further enhance regulatory decision-making.

2. Approve the pilot for Option 3, which would offer a voluntary opportunity for power reactor licensees to submit a plant-specific implementation plan when NRC develops a rule.

If 1 and 2 above are approved, the staff would obtain lessons-learned and stakeholder feedback from implementing Option 1 and 2 and the pilot of Option 3. The staff would then provide a paper to the Commission with the results and a recommendation on whether to proceed with implementation of Option 3.

RESOURCE IMPLICATIONS:

The resources for CER activities are included as part of the current fiscal year (FY) President's Budget (PB) and the FY 2016 Congressional Budget Justification (CBJ) under the Operating Reactors Business Line/Rulemaking Product Line/Rulemaking Support. If the Commission chooses the staff's recommendation, the RPI activities would require resources in FY 2015 and FY 2016. There are no resources budgeted in FY 2015 and FY 2016 for this effort, and a resource reallocation would be required. Any resources for FY 2017 will be addressed in accordance with the Planning, Budgeting, and Performance Management Process. A more detailed breakdown of estimated resources for current and future years by Business Line/Product Line/Product and Office by FY are in Enclosure 5, "Resource Estimates."

COORDINATION:

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

Interactions with the Advisory Committee on Reactor Safeguards

NRC staff presented a draft of this Commission paper to the Advisory Committee on Reactor Safeguards Reliability and PRA subcommittee on February 20, 2015, and to the full committee on March 6, 2015. The full committee documented its views and recommendations in a letter dated March 11, 2015 (ADAMS Accession No. ML15070A282).

/RA/

Mark A. Satorius
Executive Director
for Operations

Enclosures:

1. Update on Staff Efforts to Address CER
Effects on Fuel Cycle Facilities, Agreement State
Programs and Radioactive Material Licensees
2. NRC Staff Observations from Risk
Prioritization Initiative Demonstration Pilots
3. Regulatory Analysis Improvements
4. Cumulative Effects of Regulation Expansion
to Generic Communications Program
5. Resource Estimates

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**Update on Staff Efforts to Address CER Effects on Fuel-Cycle Facilities,
Agreement State Programs and Radioactive Material Licensees**

The Office of Nuclear Material Safety and Safeguards (NMSS) has put in place initiatives to address the cumulative effects of regulation (CER) consistent with Commission direction in the SRM to SECY-11-0032, dated October 1, 2011, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML112840466) and the SRM to SECY-12-0137, dated March 12, 2013 (ADAMS Accession No. ML13071A635). NMSS, in coordination with the Office of Nuclear Security and Incident Response, and Region II, created a fuel-cycle integrated schedule Gantt chart (integrated schedule) to list the major regulatory activities under development that affect fuel-cycle facilities. This integrated schedule facilitates discussions and seeks feedback from stakeholders (both internal and external) on the CER.

The integrated schedule contains a condensed overview of the significant NRC fuel-cycle regulatory activities. It offers a one-page graphical representation of the major rulemakings and guidance development milestones, scheduled public interactions, and links to related documents. This tool is used by the U.S. Nuclear Regulatory Commission (NRC) to:

- Supply an overview of significant regulatory activities for the next four years.
- Facilitate communications and interactions with stakeholders.
- Coordinate multiple regulatory activities and sequence the timing of milestones to reduce burden and improve efficiency.
- Focus efforts on activities with the most strategic plan benefit while managing existing resources.
- Evaluate the need to add, shed, or adjust assignments.

In addition to the integrated schedule, a supplement has been developed that offers the purpose, key information, related documents, and meeting information for each topic in the list.

NMSS also meets quarterly with industry and stakeholders to discuss the status of items on the integrated schedule. Feedback from these meetings updates the integrated schedule, adjusts milestones, and informs industry of progress on the various regulatory initiatives. The discussions also improve mutual understanding of the NRC's drivers and metrics, and of the industry's priorities for the items listed. Feedback has resulted in modifying milestones, adjusting comment periods, or rescheduling public meetings, as needed.

The CER quarterly meetings have resulted in improvements in communication with the internal and external fuel cycle stakeholders. NMSS has added CER to the fuel cycle public Web site, see <http://www.nrc.gov/materials/fuel-cycle-fac/regs-guides-comm.html#cumeffects>.

Agreement State Programs and Radioactive Material Licensees CER Efforts

NMSS has put in place initiatives to address CER effects relative to Agreement State Programs and radioactive material licensees as directed in SRM-SECY-12-0137.

ENCLOSURE 1

For non-reactor and non-fuel-cycle licensees that the NRC shares regulatory authority with its Agreement State partners, the CER effects on radioactive material licensees are lessened because NRC's regulatory actions, and their resulting effects are spread over a broad spectrum of different types of licensees (e.g., medical, industrial, academic, and low-level waste), as opposed to only one type of licensee.

In accordance with SRM-SECY-12-0137, NRC staff regularly engages with the Organization of Agreement States, Inc. (OAS) to understand the effects of CER on Agreement States and determine how best to address this issue. These activities include:

- An Agreement State representative actively participates on the NRC CER working group.
- NRC staff supplies reports on NRC rulemakings with CER issues, as needed, in monthly calls to State agency representatives of the OAS and Conference of Radiation Control Program Directors.
- NRC staff annually meets with the OAS board to prioritize upcoming regulatory products affecting the Agreement States.
- NRC staff has supplied the fiscal year (FY) 2016/2017 Common Prioritization of Rulemaking rankings to Agreement States for their review and comment on the annual list of planned rulemaking activities.

In addition, to promote better outreach with our Agreement State partners, NMSS has revised its rulemaking procedures to ensure that when Agreement States are notified of any impending *Federal Register* publication of a Commission-approved proposed rule affecting their programs, the States are encouraged to notify their affected licensees.

With regard to future activities, NRC staff and the Agreement States have proposed: (1) integrate CER-related issues during compatibility category determinations of proposed rules, and (2) review and revise NRC management directives and NRC policy statements that affect Agreement State programs to ensure that products consider Agreement State CER effects. In addition, the staff plans to address all future Agreement State CER and radioactive material licensees CER issues as a part of NMSS's overall responsibilities for providing oversight of materials safety and security programs in the Agreement States and nationwide through the National Materials Program.

NRC Staff Observations from Risk Prioritization Initiative Demonstration Pilots

The purpose of the demonstration pilots of Nuclear Energy Institute’s (NEI) draft prioritization and scheduling implementation guidance was to evaluate how licensees can use an industry process to prioritize regulatory issues on a generic and plant-specific basis.

COMSECY-2014-0014, “Cumulative Effects of Regulation and Risk Prioritization Initiative: Update on Recent Activities and Recommendations for Path Forward,” April 9, 2014 ((Agencywide Documents Access and Management System (ADAMS) Accession No. ML14069A061) and the follow-on staff requirements memorandum (SRM) (ADAMS Accession No. ML14199A187) informed the Commission on the NRC staff’s planned participation in the pilots and offered added direction to the NRC staff, respectively. COMSECY-2014-0014 specifically discussed details on (1) the pilot objectives and scope, (2) the number and names of pilot plants for NRC participation, (3) the approach to prioritization, and (4) the regulatory methods used to disposition changes identified during the prioritization.

The table below illustrates NRC staff participation in the pilots. NRC staff included individuals supporting the risk prioritization initiative (RPI) working group as well as subject matter experts from various offices and regions.

NRC Staff Participation in Demonstration Pilots Activities (May - September 2014)		
	Generic Assessment and Characterization (ML14297A530)	
	<i>NRC Participants</i>	
NEI Headquarters	NRR (DRA, DPR) NSIR	
	Plant-specific Prioritization and Aggregation	
	Integrated Decision-Making Panel	Issue Aggregation Panel
	<i>NRC Participants</i>	
Palisades	NRR (DRA, DE, DORL, DIRS) NSIR (DSP) Region III	NRR (DRA, DORL) Region III
H.B. Robinson	NRR (DRA, DE, DSS)	NRR (DRA, DPR)
E.I. Hatch	NRR (DRA)	NRR (DRA)
Davis-Besse	NRR (DRA) NSIR (DSP)	NRR (DRA)
Prairie Island	NRR (DRA, JLD) Region III	NRR (DRA, DPR)
V.C. Summer	NRR (DRA, DPR) NSIR (DPR)	NRR (DRA, DPR) NSIR (DPR)
	Security, EP, and RP (ML14231B034)	
	Integrated Decision-Making Panel	Issue Aggregation Panel
	<i>NRC Participants</i>	
NRC Headquarters	NRR (DRA, DPR), NSIR (DSP, DPR), Region III	

Overall, the pilots illustrated that the process developed by NEI was effective in applying objective decision-making attributes to prioritize both regulatory activities and licensee initiatives on a generic and plant-specific basis. The integrated decision-making panel (IDP) used rational methods that were articulated clearly in draft NEI guidance. The staff observed that pilots simulated how an actual panel would work in a plant environment. The IDP participants shared their different areas of expertise and asked challenging questions. They considered both the positive and adverse effects of the proposed issues in their deliberations. Using available risk information when included in the IDP discussion, such as insights from the site-specific probabilistic risk assessment (PRA) models, facilitated risk-informing the process.

Some topics considered key factors contributing to public safety, such as emergency preparedness, radiation protection, security, and reliability (as it pertains to reliability of systems, structures, and components used to generate electricity and the stewardship of the plant site because failure of such systems could cause plant transients), might not be appropriately assessed using readily available quantitative risk information. Consequently, the NEI guidance proposed other steps that relied on qualitative risk insights to the extent practical and flow charts to determine their overall priority. This draft process emulated some characteristics found in previous successful risk-informed activities, such as the NRC reactor oversight process, maintenance rule, and the severe accident mitigation alternatives approach for license renewal.

NRC staff noted that NEI should continue to refine its draft guidance to determine the relative importance of regulatory actions and licensee activities involving radiation protection, security, and emergency preparedness. Specifically, using qualitative risk information needed to navigate the assessments has the potential to be more subjective and very dependent on how an issue is characterized. NRC staff notes that improvements have been made on the characterization of issues related to security, emergency preparedness, and radiation protection in the revised NEI guidance. However, more work is still necessary to ensure those issues are being characterized correctly and consistently.

Other information about the NRC staff's observations can be found in "Summary of Staffs Observation of Industry Demonstration Pilot Activities of NEI Draft Guidance for Prioritization and Scheduling Implementation" (ADAMS Accession No, ML14302A269). In addition, NEI supplied its summary and observations of the demonstration pilots in the "Nuclear Energy Institute, Report on Prioritization and Scheduling Pilot" (ADAMS Accession No. ML14349A378).

Regulatory Analysis Improvements

In the staff requirements memorandum to SECY-12-0137 (“Implementation of the Cumulative Effects of Regulation Process Changes,” dated March 12, 2013, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13071A635), the Commission directed the U.S. Nuclear Regulatory Commission (NRC) staff to “perform ‘case studies’ to review the accuracy of cost and schedule estimates used in NRC’s regulatory analysis.”

To address the SRM’s direction, in 2013 the staff engaged industry to seek volunteer facilities to perform case studies to review the accuracy of cost and schedule estimates used in NRC’s regulatory analyses. The Nuclear Energy Institute (NEI) working on the industry’s behalf interacted with the staff to select three regulations that affect the power reactor community to investigate the cost and schedule differences between the ex-ante NRC estimates and the ex-post industry results. As discussed in Enclosure 1 to COMSECY-14-0014, “Cumulative Effects of Regulation and Risk Prioritization Initiative: Update on Recent Activities and Recommendations for Path Forward,” April 9, 2014 (ADAMS Accession No. ML14069A061), NEI engaged the industry on case studies in the areas of fatigue management, fire protection, and physical security. During a public meeting on January 28, 2014 (ADAMS Accession No. ML14031A204), NEI presented an overview of the case studies (ADAMS Accession No. ML14028A452), which included their calculated high-level differences between estimated cost and actual implementation cost of each of the three regulations. Schedule differences between actual and estimated schedules and their effect on costs were not addressed. NEI supplied a handout with its final case study results and recommendations (ADAMS Accession No. ML14028A455). NEI recommended:

- Clearly define the scope, closure criteria, and characteristics so that realistic resources can be estimated for compliance with the new action or position.
- Before the regulation is first published for comment, the scope, regulatory analysis, and guidance of the regulation should receive early public input to help accurately estimate the costs and benefits of the regulation. This should be done before the public comment period for the proposed rule so that the basis for the proposed rule is as accurate as possible.
- Regulatory analyses should include information on the basic assumptions and sources that drive the high-level estimates. Furthermore, the regulatory analyses should offer a range of estimates based on various sensitivities instead of single point estimates.

After reviewing the results of the case studies, NRC staff identified that, to improve the regulatory analysis process, the staff should:

- Develop and establish a clear understanding of the following during development of the regulatory basis for a prospective rule: (1) background, (2) regulatory issue, (3) objectives, (4) scope, and (5) affected entities.
- Consider performing, on a case-by-case basis and as part of the regulatory basis stage, a preliminary high-level cost assessment. The regulatory basis should also discuss how the backfit rule would apply to the proposed rulemaking. When practical, NRC staff

should permit public input on methods and alternatives for resolving the regulatory issue, including any cost and backfit assessments, before publishing the proposed rule.

- Continue to incorporate recent regulatory analysis improvements and receive input from external stakeholders during the development of regulatory analyses.

These improvements also have been discussed in the cost-benefit update activities described in SECY-14-0002, "Plan for Updating the U.S. Nuclear Regulatory Commission's Cost-Benefit Guidance" (ADAMS Accession No. ML13274A495), which is a two-phase process for updating the NRC's cost estimating procedures. The first phase (i.e., administrative changes such as the consolidation of guidance documents), is expected to culminate with the release of draft guidance for public comment in the summer of 2015. The second phase will focus on addressing potential changes in policy and method, and will be a multiyear effort. Updating the guidance and improving the accuracy of the agency's quantitative estimate is a priority for NRC staff. NRC staff notes that, as part of its plans to improve cost estimation, it is in the process of establishing contracts to obtain the necessary skill set that could perform independent cost estimates. Once the contract is in place, NRC staff expects to pilot this independent cost estimate process with a power reactor regulation.

Notwithstanding these planned improvements, NRC staff notes that the regulatory analyses studied were completed before the agency's CER efforts. NRC staff believes that many of the CER improvements put in place in 2011 would have resulted in more accurate regulatory analyses estimates. For example, in publishing draft guidance for comment concurrent with proposed rules, the industry, public, and the NRC could have identified other cost and schedule implications in the lower-level implementation details in the guidance. The NRC now includes a specific request for detailed input on regulatory analyses. The industry and public have not routinely offered comments on draft regulatory analyses. Without this input, the NRC had difficulty refining its estimates between the proposed and final rule phases.

NRC staff determined that information obtained during those discussions and documented in the subsequent report could further inform the agency's regulatory analyses. During demonstrated pilots, NRC staff observed the generic characterization process described in the guidance and done by the generic assessment expert team (GAET). The GAET reviews regulatory actions and prepares a report on its deliberations, which would be supplied to NRC staff. As part of the deliberations, the GAET often discussed how a prospective regulatory action could affect different groups of entities (e.g., boiling-water reactors versus pressurized-water reactors).

From these observations, NRC staff determined that the information garnered from the generic characterization activities described in NEI's draft guidance and documented in its report could be used to improve and refine the NRC's regulatory analysis work. Examples include specific cost and benefit breakdowns, differing implementation timelines, and differing requirements. The GAET discussions on risk insight could inform the consideration of potential benefits to public safety that is contained in the regulatory analysis. This information could identify individual cost elements that could be used to estimate the future costs of carrying out the prospective regulatory action offered during early interactions on a proposed rule.

Cumulative Effects of Regulation Expansion to Generic Communications Program

In the staff requirements memorandum (SRM) to SECY-12-0137, "Implementation of the Cumulative Effects of Regulation Process Changes," dated March 12, 2013, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13071A635), the Commission directed that "any expansion of the consideration of CER should be considered in the broader context of actions directed from COMGEA-12-0001/COMWDM-12-0002."

Through public meetings in calendar year 2013, the industry said there could be value in expanding the cumulative effects of regulation (CER) process enhancements to the generic communications program. In reviewing the processes for generic communications, the U.S. Nuclear Regulatory Commission (NRC) staff concluded that those processes already reflect the goals of CER by allowing for public interaction in the beginning stages of development, including opportunities for public comment on draft generic communications. However, as part of the pilot for an expert panel, discussed in Option 2, the inclusion of generic communications could be considered as part of the regulatory actions evaluated under that option.

In the *Federal Register* notices (FRNs) of two generic letters, the NRC staff included six CER questions:

1. In light of any current or projected cumulative effects, does this generic letter request provide sufficient time for licensees to respond with the information requested, including any need to develop this information through supporting engineering calculation or analyses?
2. If a current or projected cumulative effect poses a significant challenge, what should be done to address it? For example, if more time is required to develop and provide information, what period of time is sufficient? Are there equally effective alternatives to providing the requested information to the NRC that reduce the cumulative effect?
3. Do other (NRC or other regulatory agency) regulatory actions (e.g., orders, rules, generic letter, bulletins, and 50.54(f) requests) influence licensee responses to this draft generic letter? If so what are they and do you have a suggested approach to reduce the cumulative effects in light of these other regulatory actions?
4. Are there other projects that licensees are undertaking, plan to undertake, or should be undertaking that provide greater safety benefit, that might be displaced or delayed because of the expenditure of effort and resources to respond to this generic letter?
5. Are there unintended consequences associated with responding to this generic letter at this time?
6. Please comment on the NRC's supporting justification for this generic letter.

Generic Letters

- NRC Generic Letter 20xx-xx: "Treatment of Natural Phenomena Hazards in Fuel Cycle Facilities" (ADAMS Accession No. ML13157A158). On November 6, 2014

ENCLOSURE 4

(ADAMS Accession No. ML14316A411), the NRC received industry feedback to the CER questions. In summary, the industry response did not identify any significant effect on a licensee's ability to carry out other significant NRC regulatory requirements or respond to the generic letter. However, because NRC staff previously stated its intent to issue NRC staff guidance in the form of an interim staff guidance (ISG) on the topic of natural phenomenon hazards, industry recommended that the draft ISG be issued before the release of the final generic letter. This industry recommendation is being carried out by the Office of Nuclear Material Safety and Safeguards (NMSS).

- NRC Generic Letter 201X-XX: "Monitoring of Neutron-Absorbing Materials in Spent Fuel Pools" (ADAMS Accession No. ML13100A086). The NRC did not receive any industry responses to the six CER questions.

NRC staff plans to continue using the six CER questions in the FRNs for generic letters seeking information under Title 10 of the *Code of Federal Regulations* (10 CFR) 50.54(f), "Conditions of Licenses."

Other Generic Communications

The staff did not identify the need to include the six CER questions in other forms of generic communications such as bulletins (BL), regulatory issue summaries (RIS), information notices (IN), security advisories (SA), or information assessment team advisories (IATA). The issuance of a BL communicates an urgent NRC safety, environmental, or security concern; therefore bulletins are not issued for public comment. For RIS, the generic communications program already emphasizes that staff interact early with external stakeholders before the development of the RIS. The issues communicated to industry in a RIS are typically long-standing issues that have been thoroughly vetted with external stakeholders. In addition, a RIS does not require the collection of information from licensees, so no licensee response is required following its issuance. IN inform licensees of operational experience and do not request a response. SA supply information on potential security events or recently identified vulnerabilities, do not require responses, and are usually not publicly available. IATA are time-sensitive information about potential security threats, do not require responses, and are not publicly available.