FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: RECOMMENDATIONS FOR RISK-INFORMING THE REACTOR OVERSIGHT PROCESS FOR NEW REACTORS

PURPOSE:

This paper responds, in part, to the staff requirements memorandum (SRM) on SECY-12-0081, "Risk-Informed Regulatory Framework for New Reactors," dated October 22, 2012 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12296A158). Specifically, this paper addresses the Commission's request to give additional consideration to the use of relative risk metrics, or other options, that would provide a more risk-informed approach to the determination of the significance of inspection findings for new reactors, and to provide a notation vote paper as directed in the SRM.

SUMMARY:

The staff performed technical evaluations of (1) its proposal to use qualitative considerations for characterizing the significance of inspection findings, (2) the use of relative risk measures for characterizing the significance of inspection findings, and (3) the appropriateness of the existing performance indicators (PIs) and the related thresholds for new reactors. The staff actively engaged with a variety of internal and external stakeholders with interest and expertise in ROP implementation, risk applications, and new reactor designs. As a result of the staff's evaluations and stakeholder interactions, the staff recommends an integrated risk-informed approach using qualitative along with quantitative measures in a structured manner. This approach addresses the potentially significant performance issues that would not otherwise be captured solely by the quantitative risk characterization to ensure an appropriate regulatory response. The staff also concludes that the significant challenges in the development and implementation of a relative risk approach appear to significantly outweigh the benefits. Finally, the staff concludes that many of the PIs are based on regulations or standards that also apply to new reactor designs; however, some PIs in the Initiating Events and Mitigating Systems cornerstones warrant further analysis to fully develop appropriate PIs, thresholds, or guidance for new reactor applications.

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BACKGROUND:

Baseline risk estimates for most new reactor designs are lower than those for a design similar to that of the current fleet (potentially by an order of magnitude or more), when internally initiated events and externally initiated events that have been quantified are included. The lower risk values raised questions about how to apply acceptance guidelines for changes to the licensing basis and regulatory response in the ROP. Over the past several years, the staff has corresponded with the Commission, as well as the Advisory Committee on Reactor Safeguards (ACRS) and its Subcommittee on Reliability and Probabilistic Risk Assessment (PRA), to address the staff's recommendations related to risk-informed guidance for new light-water reactor applications. A summary of the background and history of correspondence is provided in Enclosure 1.

Most recently, in its SRM to SECY-12-0081, "Risk-Informed Regulatory Framework for New Reactors," dated October 22, 2012 (ADAMS Accession No. ML12296A158), the Commission disapproved the staff's recommendation (Option 3B) related to the ROP, in which the staff, after working with internal and external stakeholders, would identify appropriate changes to augment the existing risk-informed guidance with deterministic backstops to ensure an appropriate regulatory response for the new reactor designs. Specifically, the Commission directed the staff to give additional consideration to the use of relative risk metrics or other options that would provide a more risk-informed approach to the determination of the significance of inspection findings for new reactors, or, if the staff believes that this is not a viable option for new reactor oversight, the Commission directed the staff to provide a technical basis for its conclusions. The SRM further stated that the staff should provide the Commission with a notation vote paper that contains:

1. a technical basis for the staff's proposal for the use of deterministic backstops, including examples

2. a technical evaluation of the use of relative risk measures, including a reexamination of the pros and cons listed in the staff's 2009 white paper

3. a discussion of the appropriateness of the existing PIs and the related thresholds for new reactors

The SRM also requested that the staff: (1) provide an information paper to the Commission that reviews the history of the U.S. Nuclear Regulatory Commission's (NRC's) use and consideration of large release frequency, and (2) pursue an independent review of the ROP's objectives and implementation. Those two activities are outside the scope of this paper. SECY-13-0029, "History of the Use and Consideration of the Large Release Frequency Metric by the U.S. Nuclear Regulatory Commission," was issued on March 22, 2013, and the independent review will also be addressed separately.

DISCUSSION:

To address the aspects of the SRM to SECY-12-0081 related to risk-informing the ROP for new reactors, the staff actively engaged with a variety of internal and external stakeholders with interest and expertise in ROP implementation, risk applications, and new reactor designs. NRC participants included staff from the Office of Nuclear Reactor Regulation (NRR), the Office of New Reactors (NRO), the Office of Nuclear Regulatory Research (RES), and the regions. External stakeholder participants included representatives from the Nuclear Energy Institute (NEI), reactor licensees, the ACRS, and the public.

The staff conducted the first of a series of public meetings with stakeholders on February 5, 2013 (ADAMS Accession No. ML13059A054). Additional public meetings were held on March 25, 2013 (ADAMS Accession No. ML13100A226) and April 15, 2013 (ADAMS Accession No. ML13126A166). This topic was also briefly introduced, discussed, and updated during several monthly ROP Working Group meetings throughout the development of this paper since November 2012. Although these meetings were noticed and conducted as public meetings, NRC staff and industry representatives were the primary participants in the discussions. Participants in these meetings generally agreed with the conclusions and recommendations provided in this paper.

ROP Framework and Processes for Responding to Performance Issues

Some of the key tenets of the ROP and the drivers in its development were to (1) improve the objectivity of the oversight processes to minimize subjective decisionmaking, (2) improve the scrutability and predictability of NRC actions so that regulatory response has a clear tie to licensee performance, and (3) risk-inform the processes so that NRC and licensee resources are focused on performance issues with the greatest impact on safe plant operation. In ways consistent with Regulatory Guide (RG) 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” the ROP’s risk-informed processes integrate risk insights with more traditional deterministic factors (such as defense-in-depth and safety margins) to guide regulatory decisionmaking.

The regulatory framework for reactor oversight consists of three key strategic performance areas: reactor safety, radiation safety, and safeguards. Within each strategic performance area are seven cornerstones that reflect the essential safety aspects of facility operation: initiating events, mitigating systems, barrier integrity, emergency preparedness, public radiation safety, occupational radiation safety, and security. Satisfactory licensee performance in the cornerstones provides reasonable assurance that the licensee is safely operating its facility and that the NRC’s safety mission is being accomplished. Each cornerstone contains inspection procedures and PIs to verify that their objectives are being met. Both inspection findings and PIs are evaluated and given a color designation based on their safety significance, and this designation is considered in the ROP Action Matrix to determine a predictable regulatory response.

Within the ROP, the significance determination process (SDP) is used to characterize the safety and security significance of inspection findings. All inspection findings require a performance deficiency, the vast majority of which are associated with violations. SDP implementation guidance is contained in Inspection Manual Chapter (IMC) 0609, “Significance Determination Process” (ADAMS Accession No. ML101400479). IMC 0609, Appendix A, “The Significance Determination Process (SDP) for Findings At-Power” (ADAMS Accession No. ML101400574), is used to determine the safety significance of inspection findings in the cornerstones of initiating events, mitigating systems, and barrier integrity. Within these cornerstones, risk thresholds are established based on increases in core-damage frequency (ΔCDF) and large early release frequency (ΔLERF) from a plant's baseline risk. For those relatively infrequent cases in which sufficient probabilistic risk assessment (PRA) methods and tools are not available or appropriate to provide reasonable and timely estimates of safety significance, the staff uses IMC 0609, Appendix M, "Significance Determination Process Using Qualitative Criteria" (ADAMS Accession No. ML101550365), which considers factors such as defense-in-depth, safety margins, recovery, and the potential for plant-wide impacts from the performance deficiency to determine the safety significance in those cases. SDPs in the other ROP cornerstones are structured in a more deterministic fashion to determine an appropriate regulatory response (e.g., emergency preparedness, radiation safety, and security). An important over-arching goal of the SDP and ROP in general is to address safety issues in a timely manner before an unacceptable erosion of defense-in-depth and safety margin occurs.

<u>SECY-12-0081 Recommended Approach for Responding to Performance Issues</u>

As noted in SECY-12-0081 (ADAMS Accession No. ML12117A012), the tabletop results demonstrated that the existing risk-informed SDP is acceptable, and could occasionally generate an increased regulatory response based on greater-than-green results. However, the performance deficiencies would likely have to involve common-cause failures that affect multiple systems or involve long-term exposures of risk-significant components. In addition, the case study on reactor coolant system integrity demonstrated that the existing quantitative process does not produce the appropriate response for degradation of passive components and barriers.

To address the shortfalls identified by the tabletop exercises, the staff recommended in SECY-12-0081 that the SDP analyses for new reactor designs should be augmented with additional qualitative considerations, in a manner consistent with the integrated risk-informed decision-making framework in RG 1.174, to provide a "deterministic backstop" that would ensure performance issues receive an appropriate regulatory response. For example, the staff had noted that "deterministic backstops" could potentially be developed to reinforce the importance of maintaining barrier integrity, to address extended equipment outages resulting from degraded conditions, or to address repetitive equipment failures that could degrade the reliability or availability of structures, systems, and components (SSCs) in performing their intended safety functions. The staff further noted that these "deterministic backstops" should not infringe on the operational flexibility afforded by the more robust new reactor designs, but should instead be designed to identify the infrequent yet potentially significant performance issues that would not otherwise be revealed by the risk evaluations to ensure an appropriate regulatory response.

<u>Integrated Risk-Informed Approach Using Qualitative Measures</u>

In the SRM to SECY-12-0081, the Commission directed the staff to provide a more risk-informed approach to the significance determination of inspection findings for new reactors. The staff was specifically instructed to provide "a technical basis for the staff's proposal for the use of deterministic backstops, including examples." To more accurately reflect the intent of the staff's recommendation in SECY-12-0081 and its proposed approach as described in this paper, the staff has replaced the term "deterministic backstops" with the term "qualitative measures."

The technical bases for using qualitative measures is already part of an integrated risk-informed approach with its tenets taken from several sources, most notably: (1) Regulatory Guide (RG) 1.174, which states that decisions "are expected to be reached in an integrated fashion, considering traditional engineering and risk information, and may be based on qualitative factors as well as quantitative analyses and information;" (2) SECY-99-007A, "Recommendations for Reactor Oversight Process Improvements (Follow-Up to SECY-99-007)" (ADAMS Accession No. ML992740073), which established the basis for ROP implementation and notes its alignment with the RG 1.174 principles; and (3) the Commission's PRA Policy Statement from 1995, which states that "the use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy."

In the process of assessing potential qualitative measures, one of the key considerations was how to integrate these qualitative measures with the quantitative risk assessment in a reliable and predictable fashion. The staff conceived an approach that would use both quantitative methods (e.g., a plant's PRA) and qualitative (traditional deterministic) methods in an integrated risk-informed fashion. In this integrated risk-informed approach, qualitative measures, such as defense-in-depth, safety margins, condition time, and qualitative credit, would be rated based on their individual impacts on safety to determine the level of degradation that these measures would contribute to the inspection finding. The evaluation would progress through a structured methodology (e.g., a decision tree, table, and/or flowchart) to arrive at an overall qualitative rating of "not degraded," "moderately degraded," "degraded," or "significantly degraded." This overall qualitative rating would then be considered along with the quantitative risk result using a significance-determination table to arrive at the resultant significance color band in an integrated, reliable, and predictable fashion. More detail on the approach and technical basis, as well as illustrative examples, is provided in Enclosure 2.

Participants at the public meetings, including industry representatives, generally agreed that this conceptual approach was consistent with RG 1.174 and appeared to appropriately incorporate qualitative measures with quantitative results, but agreed that additional detail regarding how the approach would work would need to be developed before its efficacy could be gauged. Industry participants expressed concern that some factors may be "double-counted" in both the quantitative and qualitative evaluations; the staff noted its intent to explicitly define the qualitative measures in a manner that would exclude those that have already been accounted for in the quantitative risk evaluation. Also, members from industry noted that the qualitative evaluation seemed to only escalate the significance of a finding and did not appear to mitigate the significance. The staff noted its intent to clarify that the significance could be reduced as well as increased based on the proposed qualitative evaluation, particularly for mitigating capability that is not modeled in the quantitative PRA evaluation.

The technical basis for this approach is also consistent with recommendations from the Near-Term Task Force (NTTF) Review of Insights from the Fukushima Dai-Ichi Accident and with the Risk Management Regulatory Framework that is underway to address the recommendations of NUREG-2150, "A Proposed Risk Management Regulatory Framework." Specifically, Recommendations 1 and 12 from the NTTF state that "the task force recommends establishing a logical, systematic, and coherent regulatory framework for adequate protection that appropriately balances defense-in-depth and risk considerations," and "the task force recommends that the NRC strengthen regulatory oversight of licensee safety performance (i.e., the ROP) by focusing more on defense-in-depth requirements consistent with the defense-in-depth framework." The overarching Recommendation 2.3 of NUREG-2150 states that "A balanced approach that considers traditional and risk assessment techniques should be used to identify barriers and controls so that appropriate requirements are defined to prevent, contain, and mitigate exposures to radioactive materials." If the staff were to further pursue the integrated risk-informed approach described in this paper, those efforts would be coordinated with the efforts underway to implement the NTTF and NUREG-2150 recommendations.

The integrated risk-informed approach is also consistent with the ROP goals of being objective, risk-informed, predictable, and understandable, as well as the Principles of Good Regulation: independence, openness, efficiency, clarity, and reliability. This approach can also be considered for the current fleet of operating reactors, as well as future reactor designs that may have even lower baseline risk values, so that there would be a reliable and predictable regulatory approach for operating reactor oversight, regardless of vintage. The use of qualitative measures is also consistent with the operating reactors' SDP for the cornerstones of emergency preparedness, public radiation safety, occupational radiation safety, and security. As described in SECY-12-0081, a similar approach can also be applied to the current event response guidance as stipulated in Management Directive (MD) 8.3, "NRC Incident Investigation Program" (ADAMS Accession No. ML031250592), and IMC 0309, "Reactive Inspection Decision Basis for Reactors" (ADAMS Accession No. ML111801157), which could also be applied to all operating reactors.

<u>Relative Risk Approach</u>

In the SRM to SECY-12-0081, the Commission directed the staff to give additional consideration to the use of relative risk metrics, or, if the staff believes that this is not a viable option for new reactor oversight, to provide a technical basis for its conclusions. The SRM further requested that the staff provide a technical evaluation of the use of relative risk measures, including a reexamination of the pros and cons listed in the staff's 2009 white paper.

The relative risk approach considers the total baseline CDF (x-axis) and the ΔCDF (y-axis) for a plant to determine the significance of an inspection finding using sloped lines for the thresholds. The concept behind this approach is that the lower the baseline CDF of a plant, the lower the ΔCDF value, or the larger the fractional change, necessary for increased significance of a finding. Conversely, the higher the baseline CDF of a plant, the higher the ΔCDF value, or the smaller the fractional change, necessary for increased significance of a finding. Therefore, the significance of a finding would be relative to the baseline CDF value, instead of the current approach of absolute thresholds that do not change given a particular plant's baseline CDF.

The staff performed its technical evaluation of the use of relative risk measures and presented the results during the public meetings. The staff took the same scenarios from the 2011 tabletop and applied the relative risk approach, with and without including seismic estimates, to determine the significance of potential findings. The result was an increase in the significance, and therefore regulatory response, of findings compared to the existing approach. Baseline

CDFs for new reactors including seismic estimates were also examined, because new reactors' baseline CDFs will include internal and external events (e.g., seismic, flooding, and fires), and it is believed that the CDF values for new reactors will be dominated by external, particularly seismic, events. Increasing the baseline CDF values for the new reactors by the estimated seismic CDF resulted in an expected decrease in the significance of some scenarios' findings.

The staff also considered alternative options to the proposed purely relative risk approach: (1) a staircase thresholds approach that incorporates step drops in ΔCDF at specific baseline CDF values; and (2) a hybrid thresholds approach that includes an absolute CDF threshold at higher baseline CDF values, and transitions into a relative CDF threshold at lower baseline CDF values. As a result of the discussions at the public meetings, staff and industry agreed that the staircase thresholds approach did not appear to be a feasible option, primarily because of the cons associated with acute cliff effects. It was noted that a licensee could calculate total baseline CDF just to the right of the cliff and lessen the chance of non-green findings by increasing the thresholds. Of the relative risk approaches, the industry generally supported the hybrid thresholds approach if the <u>total</u> baseline CDFs were used and the transition point was established at or near 10^{-6}/year. Some industry participants expect the total baseline CDF values for new reactors, which include internal and external events, to exceed 10^{-6}/year and therefore will retain the same color band thresholds as that of the existing fleet. Both the staff and industry concluded that, if the baseline CDF exceeded 10^{-6}/year, the hybrid thresholds approach would yield the same results as the existing approach because the thresholds would be identical, and therefore would not resolve the shortcomings noted in the ROP tabletop exercises as discussed in SECY-12-0081.

The pros and cons of a relative risk approach, including a reexamination of those noted in the staff's and NEI's white papers from 2009, were discussed during the public meetings. Some of the more significant impediments to a relative risk approach that were discussed included:

- concerns with implementation depending on how baseline CDF is defined

- difficulty in articulating the potential differences in regulatory approach for operating and new reactors

  - if applied <u>only</u> to new reactors, operating and new reactors would have different SDP finding thresholds.

- potential to overly infringe on the operational flexibility afforded the safer and more robust new reactor designs

- complexity in developing, documenting, and implementing a relative risk approach

- potential to inadvertently focus licensee and staff attention on relatively insignificant issues as far as overall plant safety is concerned

- resource-intensive for both NRC and potentially the licensees to develop accurate, plant-specific broad-scope PRA models
    - if applied to operating reactors in addition to new reactors, the NRC would need to develop and use a broader scope PRA that addresses internal and external hazards for all plants
    - licensees are likely to also want to develop their own plant-specific broad-scope PRAs to use in discussions with the NRC regarding SDP evaluations and outcomes

Additionally, meeting participants generally acknowledged that the fidelity of risk tools is reduced at very low values. Consequently, prolonged analysis to achieve a higher degree of precision in outcomes could impede timely decision-making and regulatory responses to performance.

Participants at the meetings further noted that even if a relative risk approach were adopted, a risk-informed integrated approach that considers qualitative measures may still be needed to appropriately respond to the potentially significant performance issues that would not otherwise be considered based solely on risk calculations.

Based on its evaluation, the staff concludes that although the relative risk approach may potentially have merit, the cons of the relative risk approach outweigh its pros. Therefore, the staff does not view a relative risk approach, including the hybrid and staircase threshold variations, as a viable option. For all the aforementioned reasons, staff and other stakeholders favor an integrated risk-informed approach (using qualitative measures) over a relative risk approach. Enclosure 3 contains a more detailed technical evaluation of the use of relative risk measures, including a reexamination of the pros and cons listed in the staff's and NEI's 2009 white papers.

<u>Appropriateness of Existing Performance Indicators and Thresholds</u>

As discussed in SECY-12-0081, the case studies developed for the Mitigating System Performance Index (MSPI) tabletops showed that the existing MSPI is not adequate and would be largely ineffective in determining an appropriate regulatory response for new reactor designs. Furthermore, a meaningful MSPI may not even be possible for passive systems using the current formulation of the indicator. The staff noted that the existing performance limit approach, which is effectively a backstop, potentially could be modified and emphasized for new reactor designs. The staff concluded in SECY-12-0081 that (1) alternate PIs in the Mitigating Systems cornerstone could be developed, and (2) additional inspection could be used for the new reactors to supplement insights currently gained through MSPI for the current fleet.

In response to the SRM on SECY-12-0081, the staff reviewed the basis and related thresholds for the remaining PIs to determine if these PIs and thresholds could be appropriately applied to the operation of plants for new reactor designs. The staff concludes that many of the PIs are based on regulations or standards that would also apply to new reactor designs and that many of the thresholds are deterministic. The staff notes that for the Unplanned Scrams with

Complications indicator in the Initiating Events cornerstone, a complicated scram for new reactor designs would need to be defined. As noted in SECY-12-0081, a risk-informed alternative to the MSPI indicators in the Mitigating Systems cornerstone would need to be developed for new reactor applications. The staff concludes that the remaining PIs and associated thresholds could apply to new reactors. A more detailed discussion is provided in Enclosure 4.

CONCLUSIONS AND RECOMMENDATIONS:

As a result of the staff's evaluations and stakeholder interactions, the staff concludes that the conceptual integrated risk-informed approach using qualitative measures is an appropriate means to identify the potentially significant performance issues that would not otherwise be revealed by the risk calculations to ensure an appropriate regulatory response. Further, the staff concludes that the significant challenges in the development and implementation of a relative risk approach appear to significantly outweigh the benefits and does not consider this approach a viable option. Additionally, if the staff were to develop and implement a relative risk approach, the structured integrated risk-informed approach would likely still be needed to address shortcomings that the relative risk approach would not solve, such as considering defense-in-depth (particularly barrier integrity) and degradation of passive components. The staff believes that the proposed integrated risk-informed approach would provide a clear and efficient way of ensuring reliable and predictable regulatory responses within the existing ROP framework, consistent with the principles of good regulation. Lastly, the staff concludes that many of the PIs are based on regulations and standards that also apply to new reactor designs, but some PIs in the Initiating Events and Mitigating Systems cornerstones warrant further analysis to fully develop appropriate PIs, thresholds, or guidance for new reactor applications. The staff is requesting Commission direction before it invests resources to further develop and eventually implement these recommendations:

Recommendation 1: Commission approves the staff's plans to further develop the qualitative measures used to supplement the risk evaluations and the integrated risk-informed approach for evaluating the safety significance of inspection findings to ensure an appropriate regulatory response to performance issues for new reactor designs.

Recommendation 2: Commission approves the staff's plans to further analyze the current PIs and thresholds and develop appropriate PIs and thresholds for new reactor applications, particularly for those PIs noted in the Initiating Events and Mitigating Systems cornerstones, or develop additional inspection guidance to address any shortfalls to ensure that all cornerstone objectives are adequately met.

RESOURCES:

Implementation of Recommendations 1 and 2 would require staff resources to engage stakeholders, evaluate proposed changes, and draft updates to guidance documents. Based on recent experience with the development of risk-informed regulatory guidance and performance-indicator guidance, each of these efforts is estimated to require no more than 1.0 full-time equivalent during fiscal year (FY) 2014 and FY 2015. Although these activities are not specifically included in the FY 2014 and FY 2015 budgets, resources for oversight support are available within the operating reactor business line to complete this work, and appropriate adjustments could be made through the planning, budgeting, and performance-management process.

COORDINATION:

This paper has been coordinated with the Office of the General Counsel, which has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. A copy of this paper has been provided to the ACRS.

R. W. Borchardt
Executive Director
for Operations

Enclosures:
1. Background and History of Correspondence
2. Technical Basis and Examples of Integrated Risk-Informed Approach Using Qualitative Measures
3. Technical Evaluation of Relative Risk Measures, Including Reexamination of Pros and Cons
4. Appropriateness of Existing Performance Indicators and Thresholds