

**POLICY ISSUE
NOTATION VOTE**

December 17, 2013

SECY-13-0137

FOR: The Commissioners

FROM: Mark A. Satorius
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 (1) developed a technical basis for its proposal to use qualitative considerations for characterizing the significance of inspection findings, (2) performed a technical evaluation of the use of relative risk measures for characterizing the significance of inspection findings, and (3) evaluated the appropriateness of the existing performance indicators (PIs) and the related thresholds for new reactors. To accomplish these three items, the staff engaged with internal and external stakeholders that have interest and expertise in Reactor Oversight Process (ROP) implementation, risk applications, and new reactor designs. Based on its evaluations and interactions with stakeholders, the staff has adopted new terminology to explain its recommended approach. The staff recommends the development of an integrated risk-informed approach using qualitative measures (formerly referred to as deterministic backstops) along with quantitative risk insights to inform regulatory decisions in a structured

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manner. This approach is intended to address the potentially significant performance issues that warrant a regulatory response but would not be characterized as significant using only quantitative risk methods. The technical basis for the recommended approach is supported by the underlying risk-informed policy of the ROP. The staff is recommending only the conceptual approach described in this paper; the illustrative example was developed merely to demonstrate how such an approach could work and is not intended as a recommendation. If the Commission approves the staff's recommendation, the staff would work with stakeholders to translate the concept into a structured process that is understandable, maximizes use of objective measures, and produces predictable regulatory outcomes. The process would be developed over time, tested and refined before it is implemented, and enhanced through experience, consistent with the continuous improvement features of the ROP. The staff also concludes that although the relative risk approach has some merit, the shortcomings of the relative risk approach outweigh its 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.

BACKGROUND:

Baseline risk estimates for most new reactor designs, including estimates of the risk of both internally and externally initiated events, are expected to be lower than those for a design similar to that of the current fleet, potentially by an order of magnitude or more. 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 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; and

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. These 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), the regions, and the ACRS. External stakeholder participants included representatives from the Nuclear Energy Institute (NEI), reactor licensees, industry consultants, 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 notices were posted about these meetings and they were conducted as public meetings, NRC staff and industry representatives were the primary participants in the discussions. Based on discussions and feedback from the public meetings conducted during the development of the draft paper, participants generally agreed with the evaluations, conclusions, and recommendations provided in this paper.

The staff forwarded a draft of this Commission paper to the ACRS on June 24, 2013, and made it publicly available (ADAMS Accession No. ML13169A406). The staff presented and discussed the draft Commission paper with the ACRS Subcommittee on Reliability and PRA and the full ACRS on July 22, 2013, and September 5, 2013, respectively. The ACRS provided its conclusions and recommendations based on the June 24 draft in a letter to the Executive Director for Operations (EDO) on September 19, 2013 (ADAMS Accession No. ML13252A282). The staff is developing its response to the recommendations in the ACRS letter. The ACRS letter and staff response are summarized in the recommendations portion of this paper. The staff also presented and discussed the draft Commission paper with external stakeholders during a public meeting on August 5, 2013 (ADAMS Accession No. ML13234A358). In addition to these discussions, NEI provided formal comments in a letter dated August 15, 2013 (ADAMS Accession No. ML13234A502). Based on feedback from the ACRS and external stakeholders on the draft paper, the staff revised the draft to clarify and better support its conclusions and recommendations.

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 decision-making, (2) improve the transparency 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 decision-making. The ROP was designed and is continuously assessed to ensure that it meets its intended goals of being objective, risk-informed, predictable, and understandable. The ROP and other NRC processes are also intended to meet the NRC's Principles of Good Regulation: independence, openness, efficiency, clarity, and reliability.

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 its objectives are being met. Both inspection findings and PIs are evaluated and given a color designation based on their safety significance. The color designations for the inspection findings and PIs are considered equally 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 (Δ CDF) and large early release frequency (Δ LERF) from a plant's baseline risk.

For those relatively infrequent cases in which sufficient 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. The current Appendix M process consists of a bounding evaluation and several decision attributes derived from some of the elements of RG 1.174. 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). In addition, the current event response guidance, as stated 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), uses an integrated risk-informed approach using deterministic criteria for initial event screening, and risk thresholds are subsequently applied to determine if a reactive inspection will be launched. 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. In addition to determining regulatory response, SDP results are used to inform other program evaluations, such as the Accident Sequence Precursor Program (ASP) and the Industry Trends Program (ITP).

In addition, several current regulatory and programmatic controls exist and can be leveraged as necessary, to help inform and ensure appropriate response and oversight of new reactors, including: (1) the ROP self-assessment process as described in IMC 0307, "Reactor Oversight Process Self-Assessment Program," could be used to evaluate and potentially adjust the ROP for new reactors in the future as a result of additional experience and lessons learned; (2) all inspection findings (including those characterized as very low safety significance) are entered in the licensee's corrective-action program, receive attention by licensees and the NRC, and would also be considered for cross-cutting aspects in accordance with the current process; and (3) deviations from the ROP Action Matrix as described in IMC 0305, "Operating Reactor Assessment Program," could also be used to adjust the staff's actions in providing an appropriate regulatory response, if deemed necessary, and then each deviation would be evaluated for potential program improvements. In addition, performance and condition of structures, systems, and components (SSCs) would be monitored in accordance with Title 10 of the *Code of Federal Regulations* Section 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants." Once the ROP for new reactors has been established, adjustments and refinements to the ROP for new reactors would evolve over time based on experience through the continuous improvement features of the ROP.

During the August 5, 2013, public meeting and in the subsequent submittal of formal comments, NEI proposed that the staff provide and recommend a "status quo" approach to the Commission for consideration. This approach would postpone any changes to the ROP for new reactors and use existing ROP tools until experience has been gained in its application during plant operations. The staff would use the existing SDP processes for determining the safety significance of inspection findings, with a greater reliance on the use of Appendix M to IMC 0609, as well as the Action Matrix deviation process to ensure an appropriate regulatory response to performance issues. After careful consideration, the staff did not accept this proposal for a number of reasons. The Action Matrix deviation process is intended to be infrequently used for unanticipated instances in which the prescribed process and regulatory actions dictated by the Action Matrix do not provide the most appropriate response. Similarly, the current Appendix M to IMC 0609 is intended to be used infrequently and only when existing quantitative methods and tools are unable to appropriately characterize the safety significance of the finding. NEI's proposed approach for new reactor oversight would routinely use two processes that were intended to be used infrequently. Because of this reliance on the more subjective and less predictable aspects of the ROP, NEI's proposed approach as applied to new reactors would not align with several of the NRC's Principles of Good Regulation (e.g., the approach would be less clear and reliable) and the goals of the ROP (e.g., the approach would be less predictable, objective, and understandable), and would provide a less risk-informed

approach to the determination of the significance of inspection findings and regulatory response for new reactors.

SECY-12-0081 Recommended Approach for Responding to Performance Issues

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 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 that 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 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.

Integrated Risk-Informed Approach Using Qualitative Measures

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.” As discussed below and in [Enclosure 2](#), the staff developed a conceptual approach (complete with technical basis and an illustrative example) that integrates risk information with qualitative measures to characterize the significance of ROP inspection findings.

The staff is recommending only the conceptual approach described in this paper; the illustrative example was developed merely to demonstrate how such an approach could work and is not intended as a recommendation. If the Commission approves the staff’s recommendation, the details and framework of a methodology would need to be developed over time with significant stakeholder involvement. Furthermore, the resulting product may not resemble the illustrative example; it also would need to be tested and refined to ensure it produces reliable and predictable regulatory outcomes. In short, the concept must evolve into a fully conceived and vetted methodology before it is ready for implementation in the ROP.

The conceptual approach is consistent with the current ROP framework, which applies deterministic criteria and risk insights to inform regulatory decisions. The technical and policy

bases for using qualitative measures are already part of an integrated risk-informed approach with its tenets taken from several sources, most notably: (1) 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; (3) the SRM for SECY-98-144 (Revision 1), “White Paper on Risk-Informed, Performance Based Regulation” (ADAMS Accession No. ML003753593), which states that a risk-informed approach should consider “other” factors; and (4) the Commission’s PRA Policy Statement from 1995 (60 FR 42622, “Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement”), which declares 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 addition, a key tenet of the ROP is to risk-inform the processes so that NRC and licensee resources are focused on performance issues with the greatest impact on safe plant operation. The current SDP and event response processes use qualitative measures in an integrated risk-informed fashion, and these processes could be modified to incorporate a more transparent and predictable structure to provide for a reliable and appropriate regulatory response.

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 and qualitative methods in an integrated risk-informed fashion. In this integrated risk-informed approach, qualitative measures, such as, but not limited to, 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. 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 conceptual approach and technical basis, as well as illustrative examples, is provided in [Enclosure 2](#). The approach described in [Enclosure 2](#) is an illustration of how an integrated risk-informed approach could be applied. The staff is not proposing a specific methodology at this time; the details and framework would need to be developed over time with significant stakeholder involvement.

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, NUREG-2150, "A Proposed Risk Management Regulatory Framework" (ADAMS Accession No. ML12109A277). Specifically, Recommendations 1 and 12 from the NTTF report 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: being independent, open, efficient, clear, and reliable. 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 current SDP and event response guidance. The conceptual methodology described in this paper is presented to demonstrate how an approach using qualitative measures could be used. The specific details and framework of an integrated risk-informed approach would need to be developed over time with significant stakeholder involvement, including determining the elements of the qualitative measures, defining the impact rating thresholds, establishing the framework to determine the combined qualitative ratings, and developing an implementation plan.

Relative Risk Approach

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 also directed the staff to 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 (ADAMS Accession No. ML090160004).

The relative risk approach considers the total baseline CDF (x-axis) and the Δ CDF (y-axis) for a plant to determine the significance of an inspection finding using sloped lines for the thresholds, as shown in Figure 1 on the following page. The concept behind this approach is that the lower the baseline CDF of a plant, the lower the Δ CDF 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 Δ CDF 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 thresholds that do not change given a particular plant's baseline CDF.

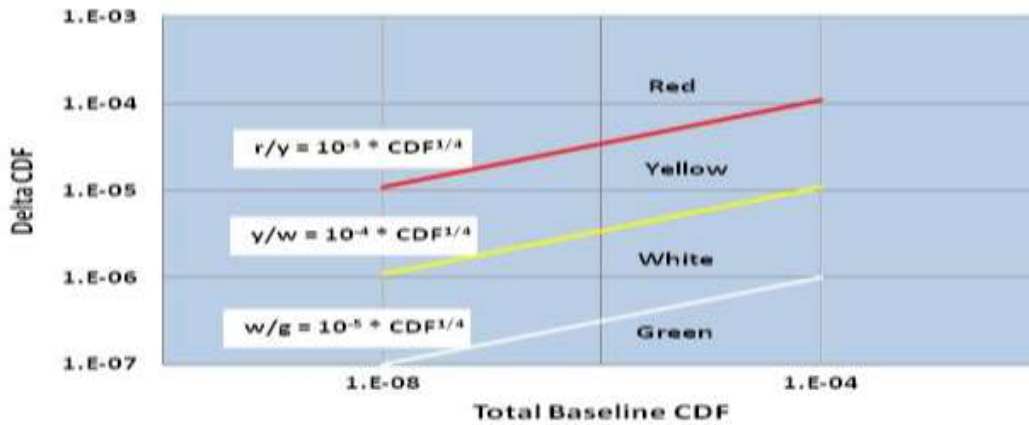


Figure 1: Relative Risk Approach

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 ACRS' conceptual relative risk approach to determine the significance of potential findings. The result was an increase in the significance, and therefore regulatory response, of most findings compared to the existing approach. Baseline CDFs for new reactors will include internal and external events (e.g., seismic, flooding, and fires), and for new reactor designs with low internal-event CDF values, the PRA results will likely be dominated by external events, particularly seismic events. Staff expects that in most cases, once external events are quantified and factored into a plant's baseline CDF, it will likely result in an increase in the baseline CDF values for the new reactor designs. If a relative risk approach was applied that takes into account external events, the likely result would be a decrease in the significance of some findings. This is a consequence of the concept behind a relative risk approach that the higher the baseline CDF of a plant, the higher the Δ CDF value necessary for increased significance of a finding.

The staff also considered alternative options to the conceptual ACRS relative risk approach: (1) a staircase thresholds approach that incorporates step drops in Δ CDF 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 does not offer an additional advantage over a relative risk approach, primarily because of the cons associated with acute cliff effects. Of the alternative options considered, the industry generally supported the hybrid thresholds approach if the total baseline CDFs were used and the transition point was established at or near 10^{-6} /year. However, the staff believes that the hybrid thresholds approach does not offer an additional advantage over the relative risk approach.

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 evaluated and discussed during the public meetings. The primary advantage, or pro, of a relative risk approach is that it could be

developed and applied in a manner that is consistent with the Commission's stated expectation to maintain the enhanced safety margins for new reactors, while providing greater operational flexibility than is possible with current reactors. Some of the more significant impediments, or cons, to a relative risk approach that were evaluated and discussed included: (1) the potential to inadvertently focus licensee and staff attention on less significant safety issues; (2) concerns with public perception issues in communicating the safety significance of findings; and (3) concerns with creating less incentive for licensees to enhance safety margin.

Based on the staff's evaluation, the relative risk approach has some merit, but the shortcomings of the relative risk approach outweigh its benefits. [Enclosure 3](#) contains a more detailed technical evaluation of the use of relative risk measures, including additional discussion of the reexamination of the pros and cons listed in the staff's and NEI's 2009 white papers.

Appropriateness of Existing Performance Indicators and Thresholds

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 for new reactor designs and would be largely ineffective in determining an appropriate regulatory response. 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 serves as 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 whether 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 reactors. The staff concludes that the remaining PIs and associated thresholds could apply to new reactors. A more detailed discussion is provided in [Enclosure 4](#).

RECOMMENDATIONS:

As a result of the staff's evaluations and stakeholder interactions, the staff concludes that an integrated risk-informed approach using both qualitative and quantitative measures in a structured manner is an effective means to achieve an appropriate regulatory response. The intent of this approach would not be to increase the number of inspection findings that result in an escalated response or to place an increased reliance on qualitative assessments, but the approach should instead be designed to identify the infrequent yet potentially significant performance issues that would not otherwise be revealed solely by quantitative risk evaluations. Further, the staff concludes that although the relative risk approach has some merit, the staff believes that the shortcomings of this approach outweigh its benefits. Although the staff is not recommending the relative risk approach, the staff will continue to be open to additional ideas as it develops the recommended integrated risk-informed approach with stakeholder input. The staff believes that an integrated risk-informed approach would provide a clear and efficient way

of ensuring reliable and predictable regulatory outcomes within the existing ROP framework, which would be consistent with the NRC's Principles of Good Regulation.

The staff is recommending the conceptual approach described in this paper; the example is simply illustrative to demonstrate how an integrated risk-informed approach could work and is not fully conceived or recommended. If the Commission approves the recommendation, the staff would work with stakeholders to develop the approach over the next few years, ahead of projected dates for operation of new reactors, which would factor in qualitative considerations in a structured manner to arrive at a risk-informed decision. The staff would test the approach via methods such as tabletop exercises or some form of pilot program with stakeholder involvement to verify that the methodology produces reliable regulatory outcomes and is predictable and understandable. The staff could present its recommendations to the Commission prior to implementation. The staff would also need to consider if SDP outcomes could be applied to other programs, such as ASP and ITP, when developing any future changes to the SDP. Lastly, the staff concludes that many of the PIs are based on regulations or 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 reactors.

The staff is requesting Commission direction before it invests resources to develop and eventually implement these recommendations:

Recommendation 1: Develop an integrated risk-informed approach for evaluating the safety significance of inspection findings for new reactor designs. The integrated risk-informed approach would use qualitative measures to supplement the risk evaluations in a structured manner to ensure an appropriate regulatory response to performance issues.

Recommendation 2: Develop appropriate PIs and thresholds for new reactor applications, specifically those PIs in the Initiating Events and Mitigating Systems cornerstones, or develop additional inspection guidance to address identified shortfalls to ensure that all cornerstone objectives are adequately met.

The staff expects that the proposed process enhancements for Recommendations 1 and 2 could be developed over the next few years, using existing resources, well in advance of their potential implementation in the oversight of new reactor operations. These process enhancements, if approved and implemented, would be refined based on experience and lessons learned in ways consistent with existing provisions for ROP continuous improvement. The staff would work with internal and external stakeholders to formulate the process changes and develop the guidance necessary to implement the noted recommendations and provide an appropriate regulatory response for new reactors. The staff would also ensure that the approach is properly vetted and tested to confirm that it meets the goals of the ROP by producing predictable, understandable, and objective regulatory responses. The staff would provide a paper to the Commission with its proposed approach for using qualitative factors at least 1 year before its scheduled implementation.

The staff forwarded a draft of this Commission paper and discussed it with the ACRS. By its letter dated September 19, 2013, the ACRS agreed that the staff should develop guidance for a structured evaluation of qualitative measures, regardless of whether absolute or relative measures are used for the quantitative assessment of risk significance. They further

recommended that the staff develop an integrated SDP that places primary reliance on the quantitative measures, supplemented as necessary by qualitative assessments of conditions that are not evaluated fully in the supporting plant risk models. The staff believes that its recommended approach would appropriately balance the quantitative and qualitative measures in a structured, integrated, and risk-informed fashion, without detracting from the benefits of the risk evaluations. The letter further noted that the ACRS encourages the staff to continue exploration of the use of relative risk measures, but the staff continues to believe that although the relative risk approach has some merit, the shortcomings of the relative risk approach outweigh its benefits. In addition, the staff believes that the proposed integrated risk-informed approach is a simpler approach for ensuring appropriate and predictable regulatory responses within the existing ROP framework that would be consistent with the principles of good regulation and the ROP program goals of being objective, risk-informed, understandable, and predictable. Finally, the ACRS concurred with the staff's recommendation to develop additional indicators, thresholds, and guidance as appropriate for monitoring the cornerstone performance objectives for new reactors. It should also be noted that the ACRS reviewed and commented on the June 24, 2013, draft version of this paper. Based on feedback from the ACRS and external stakeholders, the staff revised the paper to clarify and better support its conclusions and recommendations.

RESOURCES:

The resource implications associated with the staff's recommendations are addressed in Enclosure 5, which is non-public.

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 draft copy of this paper was provided and presented to the ACRS. The ACRS issued a letter dated September 19, 2013 (ADAMS Accession No. ML13252A282), about its conclusions and recommendations on the draft paper. The staff is developing its response to the recommendations in the ACRS letter.

/RA/

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Enclosures:

1. [Background and History](#)
2. [Technical Basis and Examples of Integrated Risk-Informed Approach Using Qualitative Measures](#)
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Background and History

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 Reactor Oversight Process (ROP). The staff developed a white paper in February 2009 that identified the issues posed by the lower risk estimates for new reactor designs in risk-informed applications and potential options for implementation (Agencywide Documents Access and Management System (ADAMS) Accession No. ML090160004).¹ The Nuclear Energy Institute developed an additional white paper in March 2009 to discuss these issues and recommended no change to the current risk metrics (ADAMS Accession No. ML090900674). Staff and industry representatives briefed the Advisory Committee on Reactor Safeguards (ACRS) and held public meetings, including one that focused on the potential issues associated with the ROP (ADAMS Accession No. ML092780211).

Based on these interactions, the staff developed a draft Commission paper (ADAMS Accession No. ML101090355) to describe the staff's plans to identify appropriate changes to the risk-informed guidance for new reactors. The staff held another public meeting and an ACRS briefing in June 2010 to review the draft paper and discuss the path forward. In a letter to the Commission dated July 27, 2010 (ADAMS Accession No. ML102000422), ACRS agreed with the staff's position on the proposed framework as described in Option 2 of that draft paper. The staff reviewed the ACRS letter and responded on August 25, 2010 (ADAMS Accession No. ML102210553). The final Commission paper, SECY-10-0121, "Modifying the Risk-Informed Regulatory Guidance for New Reactors," was issued on September 14, 2010 (ADAMS Accession No. ML102430197). The two white papers and the ACRS correspondence were included as enclosures to that paper. A Commission briefing on the topic was held on October 14, 2010.

Subsequently, the Commission issued a staff requirements memorandum (SRM) on March 2, 2011, directing the staff to continue to use the existing risk-informed framework, including current regulatory guidance, for licensing and oversight activities for new plants, pending additional analysis (ADAMS Accession No. ML110610166). In the SRM, the Commission stated that it "reaffirms that the existing safety goals, safety performance expectations, subsidiary risk goals and associated risk guidance (such as the Commission's 2008 Advanced Reactor Policy Statement and Regulatory Guide 1.174), key principles and quantitative metrics for implementing risk-informed decision making, are sufficient for new plants."

The Commission further stated that "new reactors with these enhanced margins and safety features should have greater operational flexibility than current reactors. This flexibility will provide for a more efficient use of U.S. Nuclear Regulatory Commission (NRC) resources and allow a fuller focus on issues of true safety significance." The Commission also directed the staff to engage with external stakeholders in a series of tabletop exercises to test various realistic performance deficiencies, events, modifications, and licensing-bases changes against

current NRC policy, regulations, guidance, and all other requirements (e.g., technical specifications, license conditions, and code requirements) that are or will be relevant to the licensing bases of new reactors. The purpose of the tabletop exercises was to either confirm the adequacy of those regulatory tools (and make the NRC aware of these potential scenarios so that commensurate regulatory oversight can be applied) or identify areas for improvement, such as potential adjustments to the ROP.

In response to the SRM on SECY-10-0121, the staff conducted a series of public workshops and meetings with stakeholders in 2011 and provided a status briefing to the ACRS Subcommittee on Reliability and PRA on September 20, 2011. Based on these interactions, the staff developed a draft Commission paper (ADAMS Accession No. ML12011A191) describing the results of the tabletop exercises, including key observations and conclusions regarding regulatory and programmatic controls that strengthen the various programs and tend to limit the decrease in the enhanced safety margin of the new reactor designs. The staff held another public meeting on February 28, 2012, and briefed the ACRS Subcommittee on Reliability and PRA on March 7, 2012, to review the draft paper and discuss the path forward. A briefing of the full ACRS was held on April 12, 2012. The ACRS provided its conclusions and recommendations to the Commission in letter dated April 26, 2012 (ADAMS Accession No. ML12107A199). The staff provided a response to each of the recommendations in the ACRS letter dated May 30, 2012 (ADAMS Accession No. ML12123A695). The final Commission paper, SECY-12-0081, "Risk-Informed Regulatory Framework for New Reactors," was issued on June 6, 2012 (ADAMS Accession No. ML12117A012).

As noted in SECY-12-0081, the ROP tabletops tested various realistic scenarios that are or will be relevant to the licensing bases for new reactors to confirm the adequacy of the current ROP risk-informed processes for regulatory decisionmaking or identify areas for improvement. In preparation for the ROP tabletops, the staff developed a broad cross-section of well-vetted cases from actual greater-than-green significance determination process (SDP) findings, mitigating systems performance index (MSPI) data, and event response (in the risk-informed reactor-safety cornerstones of initiating events, mitigating systems, and barrier integrity) from the current fleet of reactors. For each case study, the staff applied similar situations to the new reactor designs, filling in any gaps with realistic hypothetical situations and reasonable assumptions, and then compared the risk values and resultant regulatory responses from the new reactor scenarios to those derived from the current fleet. A complete summary of the ROP tabletop examples and results was made publicly available (ADAMS Accession No. ML11308A354). In summary, the ROP tabletops demonstrated that current risk thresholds were appropriate for ROP applications; however, a few changes to the ROP might be warranted to implement the existing risk-informed concepts of Regulatory Guide (RG) 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," for new reactors, and the staff presented three options for consideration by the Commission. The staff recommended an option (Option 3B) 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. Under this recommended option, the staff would:

- (1) Develop deterministic backstops or other qualitative considerations for characterizing the significance of inspection findings in the reactor safety cornerstones to compensate for

shortfalls noted during the tabletop exercises and allow for a transparent and predictable process for determining the appropriate regulatory response to address performance issues.

- (2) Modify the contribution of existing deterministic criteria or develop new deterministic criteria for initiating a reactive inspection for events or degraded conditions at new reactor facilities, to provide a transparent and predictable process for determining the appropriate regulatory response to plant events.
- (3) For active new reactor designs, develop a risk-informed alternative to MSPI (new performance indicators (PIs) or risk-informed inspection) or augment the existing MSPI guidance to place more emphasis on the performance limit (backstop) or revise the performance limit (backstop); also, for passive new reactor designs, increase inspection of passive mitigating systems as necessary to supplement insights that will not be afforded with MSPI.

Additionally, as noted in SECY-12-0081, several current regulatory and programmatic controls exist, and can be leveraged as necessary, to help inform and ensure appropriate response and oversight: (1) the ROP self-assessment process would be used to evaluate and potentially adjust the ROP for new reactors in the future as a result of additional experience and lessons learned; (2) all inspection findings (including those characterized as having very low safety significance) would be entered in the licensee's corrective-action program, would receive attention by licensees and the NRC, and would also be considered for cross-cutting aspects in accordance with the current process; and (3) deviations from the ROP Action Matrix could also be used to adjust the staff's actions to provide for an appropriate regulatory response, if deemed necessary, and then each deviation would be evaluated for potential program improvements.

The staff also acknowledged in SECY-12-0081 that the ACRS recommended that the staff consider a relative risk option for the ROP in their letter dated April 26, 2012. The staff noted its belief that an approach involving relative risk was previously considered but was not pursued for various reasons. In addition, the staff's proposed approach of using deterministic backstops to supplement the risk insights is a simpler approach to achieving the desired outcome while remaining consistent with the existing ROP framework and program goals of being objective, risk-informed, understandable, and predictable. In the February 2009 white paper, the staff considered the merits of a relative risk metric, but impediments to this approach were identified by both internal and external stakeholders. Therefore, the staff did not consider this option further or include it in SECY-10-0121. In its SRM to SECY-10-0121, the Commission did not approve the development of lower numeric thresholds for new reactors in which the ACRS recommendation would effectively result. In addition, the staff's proposed approach is consistent with the existing ROP framework, which provides for deterministic considerations in regulatory decision-making in accordance with RG 1.174; deterministic backstops for new reactors would provide a clear, efficient, and reliable way of ensuring appropriate and predictable regulatory responses within the existing ROP framework, in ways consistent with the principles of good regulation.

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. Specifically, 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, 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 performance indicators 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 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 (ADAMS Accession No. ML13022A207), and the independent review will also be addressed separately.

Technical Basis and Examples of Integrated Risk-Informed Approach Using Qualitative Measures

Technical Lead: Jeff Circle, NRR/DRA

Background

In SRM-SECY-12-0081, "Risk-Informed Regulatory Framework for New Reactors" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12296A158), the staff was given the task of providing a more risk-informed approach to determining the significance 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." This enclosure provides details on the technical basis for the staff's proposal for the use of deterministic backstops with 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." In providing examples, a method was developed using these principles which represents one possible way in which such a process can be developed to assess Reactor Oversight Process (ROP) Significance Determination Process (SDP) findings. Therefore, it is conceptual in nature and would require additional refinement from the staff with stakeholder involvement before such a concept can be realized in a regulatory environment.

Technical Basis

The technical bases for using qualitative measures are already part of an integrated risk-informed approach with its tenets taken from several sources. The staff initially reviewed the SRM for SECY-98-144 (Revision 1), "White Paper on Risk-Informed, Performance-Based Regulation." SECY-98-144 and Attachment 3, "Significance Determination Process Basis Document," to Inspection Manual Chapter (IMC) 0308, "Reactor Oversight Process (ROP) Basis Document" (ADAMS Accession No. ML071860181), note that a risk-informed approach should consider "other" factors. In the SDP, these other factors have included those which are cited as part of an integrated risk-informed decision-making approach following the tenets of Regulatory Guide (RG) 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis". In addition, the staff followed the contents of SECY-99-007A, "Recommendations for Reactor Oversight Process Improvements (Follow-Up to SECY-99-007)," as a technical basis for the proposed concept of incorporating qualitative measures. In keeping with prior staff requirements memoranda, the proposed program approach for new reactor licensees is intended to maintain compatibility with the existing risk-informed processes currently used in assessing ROP findings for the operating fleet.

The Integrated Risk-Informed Program

In the integrated ROP, the results of two approaches, quantitative risk-based and qualitative traditional deterministic, are blended together to arrive at a risk-informed decision. As with the existing ROP SDP, under the new staff proposal the resultant numerical increases in core damage frequency (Δ CDF) and large early release frequency (Δ LERF) of a finding will be computed to form the quantitative risk result. Analysts will continue to use the most realistic analysis techniques available, engage licensees when necessary, and estimate the Δ CDF and

ΔLERF largely through quantification of the Standardized Plant Analysis Risk (SPAR) models. This quantitative analysis will be augmented with a deterministically based structured qualitative-analysis methodology which can be assessed using simple tools, such as a decision tree or table of element ratings. The tools will be derived from the principles of risk-informed decisionmaking in RG 1.174 and will maintain consistency with regulatory requirements and limits.

The proposed use of a structured and traceable approach follows specific principles of good regulation, e.g., independence, openness, efficiency, clarity, and reliability. The output is a qualitative rating based on levels of degradation or credit given toward the traditional deterministic elements of defense-in-depth, safety margins, condition time, and uncertainty. Uncertainty is captured implicitly by the existence of multiple layers of defense-in-depth and safety margins whose licensing limits are defined below their absolute engineering limits. In choosing guidance for a rating of each element for this illustration, the intent was to minimize overlap of the qualitative assessment with the quantitative one to avoid “double-counting” the degradation or amount of credit toward the final result of a finding. In moving forward with development of this approach, the staff would explicitly define the qualitative factors in a manner that would exclude those elements that have already been accounted for in the risk calculations. For the purpose of this paper, only four outcomes of possible overall qualitative rating were developed to illustrate the feasibility of this methodology. They are “decreased impact,” “neutral impact,” “increased impact,” and “significantly increased impact.” For an overall qualitative rating of “neutral impact”, the color-band thresholds will be identical to the ones currently employed in the ROP for the operating fleet. The combined aggregate of quantitative risk and the total qualitative rating will be applied to a table which will take both into account in determining the SDP finding’s color band.

Elements of Qualitative Measures

The elements of defense-in-depth and safety margins were chosen for qualitative measures after evaluating existing criteria contained in the PRA Policy Statement (60 FR 42622) ; RG 1.174; SECY-97-287, “Final Regulatory Guidance on Risk-Informed Regulation: Policy Issues”; and SECY-99-007A as those that meet the specific qualitative aspects of the ROP and SDP. In addition, elements of technical-specification-related condition time and qualitative credit were added and will be described in the next few sections of this document.

Description and Guidance for Using Qualitative Measures

The details for each element along with conceptual guidance are provided in the following paragraphs. For each element of risk-informed qualitative measure, an individual impact rating will be assessed based on the analyst’s judgment using the tables below as a guide. The criteria and definitions for individual impact ratings are as defined below and might not be identical to those of the overall qualitative ratings. To simplify the decision process, the staff limited the number of possible impact ratings while maintaining meaningful differences. An impact rating of “negligibly degraded” would represent a condition that would result in little or no regulatory concern.

Defense-in-Depth

For the purposes of this paper, the staff relies on various existing guidance documents to interpret defense-in-depth. Definitions might be further addressed and refined to be in alignment with the outcome of Fukushima lessons learned activities. The defense-in-depth design philosophy is based on providing successive levels of protection so that health and safety will not wholly depend on any single element of the design, construction, maintenance, or operation of the plant. These levels of protection can be viewed as barriers of potential accident mitigation. The goal in incorporating defense-in-depth practices is that a plant will have greater tolerance to failures and external challenges. As noted in RG 1.174, when a comprehensive risk analysis is not done (or cannot be done), traditional defense-in-depth considerations should be used or maintained to account for uncertainties. The evaluation should consider the intent of the general design criteria, national standards, and engineering principles such as the single-failure criterion. Some elements defined as being part of defense-in-depth include the barriers of the fuel cladding, reactor vessel, reactor coolant, and containment. For fire-protection findings, Title 10 of the *Code of Federal Regulations* (10 CFR) 50.48, "Fire Protection," defines defense-in-depth elements to include fire detection, fire suppression, fire prevention, mitigation, and post-fire safe shutdown. For security concerns, 10 CFR Part 73, "Physical Protection of Plants and Materials," defines defense-in-depth elements to include physical barriers, the alarm system, locks, area access, armaments, surveillance, and communication systems. For shutdown findings, defense-in-depth elements include the key safety functions of decay-heat removal, containment control, inventory control, spent-fuel cooling, reactivity control, and power availability. In assessing any degradation in defense-in-depth, this table for possible rating outcomes should be used:

| Number of Defense-in-Depth Barriers Lost or Impacted by the Finding | Impact Rating |
|---|------------------------|
| None | Negligibly degraded |
| Impact on any barrier without a complete loss of that barrier | Moderately degraded |
| Complete loss of only one barrier | Degraded |
| A loss of more than one barrier | Significantly degraded |

Note that in the case of a negligibly degraded defense-in-depth impact rating, it was assumed that the overall qualitative rating would be the baseline rating of *neutral impact*.

Safety Margins

RG 1.174 considers safety margins to be those factors applied to system engineering design parameters in order to account for uncertainty in calculations to fulfill requirements for licensing or design bases. As pointed out in NUREG-1860, "Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing," often these margins are used for licensing purposes and the limit falls below the ultimate capacity of a system, structure, or component. In the context of this conceptual approach, the consideration of safety margins would be limited to the maximum value for licensing purposes. To avoid double-counting of the combined impacts of safety margins and defense-in-depth, only safety margins for nonfailed barriers of defense-in-depth will be evaluated for any additional impact. Any further erosion of safety margins for these intact barriers, as well as for systems used to mitigate the loss of these

barriers, is qualitatively considered. The choices were limited to allow a simpler staff determination of the degree of erosion of safety margins without the need to perform detailed calculations. For findings that erode safety margins to be at the limit of the defense-in-depth barrier's licensed operability, an impact rating of **SIGNIFICANTLY DEGRADED** is applied. For cases in which there is an impact but some margin remains, an impact rating of **DEGRADED** is applied.

| Impact of Safety Margin to Remaining D-I-D Barriers | Impact Rating |
|---|------------------------|
| No lost margin | Negligibly degraded |
| Some margin lost | Degraded |
| At the licensed threshold | Significantly degraded |

Condition Time

In the quantitative risk assessment, the staff factors the impact of the amount of time that a performance deficiency has existed using the parameter of exposure time. Staff guidance for crediting and calculating specific exposure times for different performance-deficiency categories is contained in the Risk Assessment Standardization Project (RASP) Handbook (ADAMS Accession No. ML081790322), Volume 1, "Internal Events." Exposure time is related to, but not necessarily identical to, the time that a performance deficiency has existed with consideration given to discovery and repair. Likewise, for the deterministic assessment, the length of time for which the performance deficiency has existed is uniquely addressed here as Condition Time. It is evaluated in comparison with the plant's technical specification outage time. This time is typically from the start of the performance deficiency to the time of discovery of the nonconformance; this time might overlap the exposure time accounted for in the quantitative analysis because of both methods being used to evaluate the impact of a single performance deficiency. It is assessed against the licensing bases contained in the technical specifications:

| Condition Time | Impact Rating |
|---|------------------------|
| Less than the maximum outage time allowed in the technical specifications | Negligibly degraded |
| From the maximum outage time to twice the maximum outage time allowed in the technical specifications | Degraded |
| More than twice the outage time allowed in the technical specifications | Significantly degraded |

Qualitative Credit

There might be circumstances in which the U.S. Nuclear Regulatory Commission's existing procedures and practices do not avail themselves to providing credit to equipment or operator actions that are capable of reducing the risk significance of performance deficiencies. "Qualitative credit" is included as a risk-informed qualitative measure to accommodate that situation.

During the quantitative evaluation of performance deficiencies, analysts will consider additional equipment or procedures that could mitigate consequences arising from the performance deficiency. A prerequisite for consideration of operator actions, or any other recovery, is that procedures should be in place and properly tested equipment staged to perform the action. However, for qualitative credit, equipment and activities can be assessed as skill-of-the-craft where some limited qualitative credit for performance can be given beyond that which was accounted for in the quantitative analysis. Possible examples include the use of tested and operable equipment with guidance provided by the Technical Support Center or other experienced personnel on its use. Equipment and guidance originally intended for use in events described in Section B.5.b. of the February 25, 2002, Interim Compensatory Measures (ICM) Order (EA-02-026) can also be considered if they are applicable to mitigating the conditions from the particular assessed performance deficiency. To avoid double-counting, application of qualitative credit should only be considered for those cases for which it wasn't previously factored into the quantitative analysis and it cannot be used as a whole substitute for a complete loss of more than one defense-in-depth barrier. The restriction in scope of credit is inherent because of the high degree of uncertainty involved in crediting this kind of recovery.

| Qualitative Credit | Impact Rating |
|---|---------------|
| Staged and tested equipment with sufficient guidance for operation which hasn't been credited in the quantitative analysis. | Credit |
| Otherwise | No credit |

Use of the Qualitative Methodology and Aggregation of the Final Result

The qualitative measure results for each element can be applied either to a decision tree or a table format as shown in Table 1 of this enclosure. The result will be the qualitative rating which is applied with the quantitative rating shown in Table 2 of this enclosure to yield the color band of the SDP finding.

New Reactor Examples of Integrated Risk-Informed Approach Using Qualitative Measures

The examples in this section involve new reactor designs and are not findings at actual plants. These postulated performance deficiencies are drawn from accumulated experience gained with the ROP for the existing operating fleet and some of the results of the tabletop exercises which were done for SRM-SECY-10-0121, "Modifying the Risk-Informed Regulatory Guidance for New Reactors" (ADAMS Accession No. ML110610166), and described in SECY-12-0081. The purpose of these examples is to show how both the quantitative and qualitative programs will work together in producing color findings for new reactor designs.

1. Loss of One Turbine-Driven EFW Pump for the United States Advanced Pressurized Water Reactor (USAPWR) Design

a) Description

The emergency feed water system (EFWS) is designed to remove reactor core decay heat and reactor coolant system sensible heat through the steam generators after transient conditions or postulated accidents such as a reactor trip, a loss of main feedwater, a main steam-line break, a feedwater-line break, a loss of offsite power (LOOP), a small-break loss-of-coolant accident (LOCA), a station blackout (SBO), an anticipated transient without scram (ATWS), or a steam-generator tube rupture (SGTR). The EFWS is not normally used during normal plant startups and cooldowns. The EFWS consists of two motor-driven pumps, two steam-turbine-driven pumps, two emergency feedwater pits, piping, valves, and associated instrumentation.

b) Postulated Performance Deficiency and Exposure Time

A performance deficiency caused by improper testing and maintenance by the licensee results in the undetected unavailability of turbine-driven EFW pump A (RPP-001A) for a period of 3 months leading up to the discovery of failure. An extent-of-condition evaluation concluded that a degraded condition might have existed on the other turbine-driven pump RPP-001D, but the pump had tested satisfactorily. All other pumps were available during that 3-month period.

c) Quantitative Risk Analysis

The USAPWR SPAR model was quantified with basic events EFW-TDP-FR-001A, EFW-TDP-FS-001A, and EFW-TDP-TM-001A set to logical TRUE with consideration of potential common-cause failure. The resultant annualized Δ CDF for the three month exposure time is estimated to be 7.7×10^{-6} per year, a numeric **WHITE** finding.

d) Qualitative Measures

(1) Defense-in-Depth

For the USAPWR, the loss of a single EFWS pump would impact decay-heat removal but would not result in the complete loss of a single barrier of defense-in-depth. This would result in a defense-in-depth impact rating of **MODERATELY DEGRADED**.

(2) Safety Margins

For this example, a potential extent-of-condition degradation existed for the other pump, which would degrade safety margins, but not at the regulatory limit. Therefore, safety margins would have an impact rating of **DEGRADED**.

(3) Condition Time

Because the condition time is more than twice the maximum allowable outage time in technical specifications, the impact rating is **SIGNIFICANTLY DEGRADED**.

(4) Qualitative Credit

For the purpose of this example, two illustrative cases will be considered:

- a. The licensee did not present any additional recoveries that can be credited, which would produce an impact rating of **NO CREDIT**.
- b. The licensee presented an alternate source pump which, although it was staged and maintained, was not credited in the risk analysis. This will result in a rating of **CREDIT**.

e) Conclusion

(1) No qualitative credit

Using Table 1, the qualitative rating is **INCREASED IMPACT**. Applying this qualitative rating with the estimated Δ CDF of 7.7×10^{-6} per year to Table 2 yields an overall determination for this performance deficiency of **YELLOW**.

(2) Qualitative credit

Using Table 1, the qualitative rating is **NEUTRAL IMPACT**. Applying this qualitative rating with the estimated Δ CDF of 7.7×10^{-6} per year to Table 2 yields an overall determination for this performance deficiency of **WHITE**.

2. Failure of Valves to the Passive Residual Heat Removal (PRHR) Heat Exchanger in the AP1000 Design

a) Description

The operating PRHR heat exchanger is designed to remove sufficient heat, in conjunction with available inventory in the steam generators, to cool the reactor coolant system. The PRHR heat exchanger also prevents water relief through the pressurizer safety valves during loss of main feedwater or a main feed-line break. The passive heat exchanger is mounted inside the in-containment refueling water storage tank (IRWST) and is isolated by one normally open motor-operated valve from the hot leg and two normally shut (fail-open) air-operated valves (AOVs) in parallel to the cold leg.

b) Postulated Performance Deficiency and Exposure Time

A performance deficiency by a licensee causes air-operated valves V108A and V108B not to be able to open during a postulated transient. This will render the cold-leg outlet of the PRHR heat exchanger inoperable. It is assumed that this performance deficiency was not detected by the licensee for an entire operating cycle, which limits the SDP exposure time to 1 year. For this example, the performance deficiency might be programmatic and impact valves in other systems.

c) Quantitative Risk Analysis

The AP1000 SPAR model was quantified with basic events PRH-AOV-CC-V108A and PRH-AOV-CC-V108B set to logical TRUE. The resultant Δ CDF is estimated to be 2.84×10^{-6} per year, a numeric **WHITE** finding.

d) Qualitative Measures

(1) Defense-in-Depth

For the AP1000, the PRHR heat exchanger itself is a single barrier of defense-in-depth. Therefore the defense-in-depth impact rating is **DEGRADED**.

(2) Safety Margins

For this example, the performance deficiency was initially discovered in AOV V108A/B. There is an impact to the safety margins of the remaining barriers to defense-in-depth, but it is less than the licensed safety margin, which will result in an impact rating of **DEGRADED**.

(3) Condition Time

It is assumed that this exposure period will exceed Section 3.5 of the Technical Specifications by more than double. The maximum 1-year condition time would produce a rating of **SIGNIFICANTLY DEGRADED**.

(4) Qualitative Credit

It is assumed for this example that the licensee has a separate means of remotely opening the valves. However, there is no procedure to carry this out and it is directed only by the Technical Support Center after its activation. It was not modeled in the quantitative analysis. This would produce a rating of **CREDIT**.

e) Conclusion

Applying these impact ratings to Table 1, the combined qualitative rating is **INCREASED IMPACT**. Applying the result to Table 2 with a Δ CDF of 2.84×10^{-6} per year yields a color determination of **YELLOW**. This finding is driven by the 1-year condition time. If the Condition Time were reduced to 1 month, the impact rating of Condition Time would be **DEGRADED**, which will result in a qualitative rating of **NEUTRAL IMPACT** and a **WHITE** color determination.

3. **Failure of the RCIC Train for the Advanced Boiling Water Reactor (ABWR)**

a) Description

The reactor-core isolation cooling (RCIC) System has the dual function of providing (1) high-pressure emergency core-cooling system (ECCS) flow following a postulated LOCA and (2) reactor-coolant inventory control for reactor isolation transients. The RCIC System consists of a single steam-turbine-driven pump which provides a diverse makeup source during loss of all alternating current (ac) power.

b) Postulated Performance Deficiency and Exposure Time

A performance deficiency by a licensee causes loss of the RCIC train, which goes unnoticed for one quarter, assuming a 3-month surveillance interval. Because of the nature of the performance deficiency, a great deal of uncertainty exists about operator recovery. Despite no extent of condition being found, there still exists a potential for this performance deficiency to manifest itself in interactions with other components in both remaining trains of the high-pressure core flood (HPCF) system.

c) Quantitative Risk Analysis

The ABWR SPAR model was quantified with basic events RCI-TDP-FR-TRAIN, RCI-TDP-FS-RSTRT, RCI-TDP-FS-TRAIN, and RCI-TDP-TM-TRAIN set to logical TRUE. The resultant Conditional Core Damage Probability (CCDP) for the 3-month period is annualized to a Δ CDF of 5.3×10^{-8} per year, a numeric **GREEN** finding.

d) Qualitative Risk Analysis

(1) Defense-in-Depth

Because there is impact to one element of defense-in-depth, an impact rating of **MODERATELY DEGRADED** was applied.

(2) Safety Margins

Because none of the safety margins of the other intact elements of defense-in-depth are affected, an impact rating of **NEGLIGIBLY DEGRADED** was applied.

(3) Condition Time

It is assumed that a 1-month condition time for RCIC is more than twice the outage time allowed by the technical specifications. Therefore an impact rating of **SIGNIFICANTLY DEGRADED** was applied.

(4) Qualitative Credit

Qualitative Credit was not considered for this case, which has a rating of **NO CREDIT**.

e) Conclusion

The quantitative result for Δ CDF is estimated to be 5.3×10^{-8} per year. For this case, the qualitative result is **NEUTRAL IMPACT**. From Table 2, the overall determination for this type of performance deficiency remains from the quantitative result of **GREEN**.

Conclusions on Methodology and Implementation Issues

The methodology that is outlined in this paper is presented as a concept to demonstrate how an approach using qualitative measures can be used to illustrate practical examples. The overall approach the staff proposes is to consider using a structured rating system for those qualitative elements which normally constitute the deterministic part of the integrated risk-informed SDP to arrive at a threshold color. This maintains the SDP fundamental attributes of objectivity and scrutability (openness) in that it is intended to provide a clear framework for decision logic that remains consistent across applicable findings. In considering this approach for integration into the framework, the staff notes that specific details of this structured rating system need to be developed and addressed in the following areas.

Selecting elements of qualitative measures

The list of elements of qualitative measures presented in this paper is conceptual and is intended to be used in developing the prior examples. In order to implement a program using qualitative measures, the staff will need to define and establish a comprehensive list of qualitative-measure elements which are compatible with the SDP.

Defining impact rating thresholds

Once the list of qualitative measures elements is established, a series of resulting impact ratings, rules on application guidance, and thresholds need to be developed for use. The staff would take into account areas of differences within the reactor types as well as the thresholds for parameters.

Establishing levels of combined qualitative ratings

A more detailed decision logic framework needs to be developed to arrive at a combined qualitative rating. At this point, the staff needs to balance the impact with potential quantitative results to ensure consistency.

Implementation

If directed to develop qualitative measures, the staff will develop a detailed plan that incorporates stakeholder participation and comments. The rationale for making the combined assessment using an approach similar to Table 2 will also be considered.

Table 1 Qualitative Measures and Qualitative Rating

| Defense-in-Depth | Safety Margins | Condition Time | Qualitative Credit | Qualitative Rating |
|-------------------------|------------------------|------------------------|---------------------------|---------------------------|
| Negligibly Degraded | | | | Neutral Impact |
| Moderately Degraded | Negligibly Degraded | Negligibly Degraded | Credit | Reduced Impact |
| | | | No Credit | Reduced Impact |
| | | Degraded | Credit | Reduced Impact |
| | | | No Credit | Neutral Impact |
| | | Significantly Degraded | Credit | Reduced Impact |
| | | | No Credit | Neutral Impact |
| | Degraded | Negligibly Degraded | Credit | Reduced Impact |
| | | | No Credit | Neutral Impact |
| | | Degraded | Credit | Neutral Impact |
| | | | No Credit | Neutral Impact |
| | | Significantly Degraded | Credit | Neutral Impact |
| | | | No Credit | Increased Impact |
| | Significantly Degraded | Negligibly Degraded | Credit | Neutral Impact |
| | | | No Credit | Neutral Impact |
| | | Degraded | Credit | Neutral Impact |
| | | | No Credit | Increased Impact |
| Significantly Degraded | | Credit | Increased Impact | |
| | | No Credit | Increased Impact | |

Table 1 Qualitative Measures and Qualitative Rating (continued)

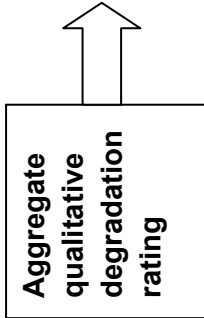
| Defense-in-Depth | Safety Margins | Condition Time | Qualitative Credit | Qualitative Rating | |
|-------------------------|------------------------|------------------------|---------------------------|--------------------------------|------------------|
| Degraded | Negligibly Degraded | Negligibly Degraded | Credit | Reduced Impact | |
| | | | No Credit | Neutral Impact | |
| | | Degraded | Degraded | Credit | Neutral Impact |
| | | | | No Credit | Neutral Impact |
| | | | Significantly Degraded | Credit | Neutral Impact |
| | | | | No Credit | Neutral Impact |
| | Degraded | Degraded | Negligibly Degraded | Credit | Neutral Impact |
| | | | | No Credit | Neutral Impact |
| | | | Degraded | Credit | Neutral Impact |
| | | | | No Credit | Increased Impact |
| | | | Significantly Degraded | Credit | Increased Impact |
| | | | | No Credit | Increased Impact |
| | Significantly Degraded | Negligibly Degraded | Negligibly Degraded | Credit | Neutral Impact |
| | | | | No Credit | Increased Impact |
| | | | Degraded | Credit | Increased Impact |
| | | | | No Credit | Increased Impact |
| Significantly Degraded | | Significantly Degraded | Credit | Increased Impact | |
| | | | No Credit | Significantly Increased Impact | |

Table 1 Qualitative Measures and Qualitative Rating (continued)

| Defense-in-Depth | Safety Margins | Condition Time | Qualitative Credit | Qualitative Rating |
|-------------------------|------------------------|-----------------------|--------------------------------|--------------------------------|
| Significantly Degraded | Negligibly Degraded | Negligibly Degraded | Credit | Neutral Impact |
| | | | No Credit | Neutral Impact |
| | | Degraded | Credit | Neutral Impact |
| | | | | Increased Impact |
| | | | No Credit | Increased Impact |
| | | | | Increased Impact |
| | Degraded | Negligibly Degraded | Credit | Increased Impact |
| | | | No Credit | Increased Impact |
| | | Degraded | Credit | Increased Impact |
| | | | | Increased Impact |
| | | | No Credit | Increased Impact |
| | | | | Significantly Increased Impact |
| | Significantly Degraded | Negligibly Degraded | Credit | Increased Impact |
| | | | No Credit | Increased Impact |
| | | Degraded | Credit | Increased Impact |
| | | | | Significantly Increased Impact |
| No Credit | | | Significantly Increased Impact | |
| | | | Significantly Increased Impact | |

Table 2 Integrated Quantitative and Qualitative Rating

| ΔCDF (CCDP normalized to 1 year) | $\Delta CDF < 10^{-6}$ | $10^{-6} \leq \Delta CDF < 10^{-5}$ | $10^{-5} \leq \Delta CDF < 10^{-4}$ | $\Delta CDF \geq 10^{-4}$ |
|--|-------------------------|--------------------------------------|--------------------------------------|----------------------------|
| $\Delta LERF$ (CLERP normalized to 1 year) | $\Delta LERF < 10^{-7}$ | $10^{-7} \leq \Delta LERF < 10^{-6}$ | $10^{-6} \leq \Delta LERF < 10^{-5}$ | $\Delta LERF \geq 10^{-5}$ |
| Qualitative Rating | | | | |
| Reduced Impact | Green | Green | White | Yellow |
| Neutral Impact | | White | Yellow | Red |
| Increased Impact | White | Yellow | Red | Red |
| Significantly Increased Impact | Yellow | Red | Red | Red |



Technical Evaluation of Relative Risk Measures, Including Reexamination of Pros and Cons

Technical Lead: Eric Powell, NRO/DSRA

Background

The Commission directed the U.S. Nuclear Regulatory Commission (NRC) staff in SRM-SECY-12-0081, "Risk-Informed Regulatory Framework for New Reactors" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12296A158), 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. Specifically, the Commission directed the staff to perform 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.

As shown in Figure 1, the current significance determination process (SDP) of the Reactor Oversight Process (ROP) has quantitative thresholds for an increase in core damage frequency (CDF) at $10^{-6}/\text{yr}$, $10^{-5}/\text{yr}$, and $10^{-4}/\text{yr}$ for the green-white, white-yellow, and yellow-red thresholds, respectively. Also, the current SDP has quantitative thresholds for an increase in large early release frequency (LERF) at $10^{-7}/\text{yr}$, $10^{-6}/\text{yr}$, and $10^{-5}/\text{yr}$, for the green-white, white-yellow, and yellow-red thresholds, respectively. These thresholds are independent of the baseline CDF of the plants to which they are being applied, and each threshold denotes an increase in the safety significance of a finding.

Relative Risk Approach

At a public meeting on March 25, 2013, the staff presented the conceptual relative risk approach as proposed by the Advisory Committee on Reactor Safeguards (ACRS) (Figure 2). Also, the staff presented a slightly different relative risk approach with change in core damage frequency (ΔCDF) on the y-axis (Figure 3) instead of fractional change in CDF on the y-axis which the ACRS proposed. These two graphs have the same finding thresholds, but portray the information differently (i.e., ΔCDF vs. fractional change in CDF). The staff used ΔCDF instead of fractional change in CDF, because ΔCDF is used in the SDP and is consistent with RG 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis." The change from fractional change in CDF to ΔCDF is not a substantive change, but one that the staff believed would be useful in discussions moving forward with the technical evaluation of a relative risk approach.

The relative risk approach uses the total baseline CDF (x-axis) and the ΔCDF (y-axis) for a plant to determine the significance of an inspection finding using the sloped lines shown on the graph (Figure 3). The concept behind this approach is that the lower the baseline CDF of a plant, the lower the ΔCDF value, or larger 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 thresholds which do not change given a particular plant's baseline CDF.

Technical Evaluation of Applying Relative Risk Approach

The staff conducted a series of tabletop exercises in 2011 in response to SRM-SECY-10-0121, "Modifying the Risk-Informed Regulatory Guidance for New Reactors" (ADAMS Accession No. ML102230076). As part of those tabletops, the staff looked at the application of the ROP to new reactors. The ROP tabletops tested various scenarios that are or will be relevant to the licensing basis for new reactors to confirm the adequacy of the current ROP risk-informed processes for regulatory decisionmaking or to identify areas for improvement. For each scenario, the staff applied similar situations to the new reactor designs, and then compared the risk values and resulting regulatory responses from the new reactor scenarios to those derived from the current fleet. In order to exercise the SDP for the new reactor designs, the staff assumed long exposure times and common-cause failure (CCF) of multiple trains of equipment. Also, the Standardized Plant Analysis Risk (SPAR) models used to evaluate some of the scenarios were only internal events at-power and did not include external events.

The staff presented the results of its technical evaluation at the public meeting on March 25, 2013. The staff took the same scenarios from the 2011 tabletop and applied the conceptual ACRS relative risk approach to determine the significance of potential findings. The cases in 2011 were evaluated using the existing SDP thresholds. The results of applying relative risk are shown in Table 1 and are compared to the existing SDP for the same scenario. The results in Table 1 show that applying the relative risk approach will increase the significance, and therefore the regulatory response, of most findings compared to the existing approach. Applying the relative risk approach to the 19 cases from 2011, 13 of the findings moved up one color (i.e., green to white, white to yellow, or yellow to red). This is an increase in the significance of the finding and represents an increase in regulatory response accordingly. It should be noted that 3 of the 19 cases had a significance of red already based on the current SDP, so no increase was possible.

Baseline CDFs for new reactors will include internal and external events (e.g., seismic, flooding, and fires), and for new reactor designs with low internal event CDF values the PRA results will likely be dominated by external events, particularly seismic events. Staff expects that in most cases, once external events are quantified and factored into a plant's baseline CDF, it will likely result in an increase in the baseline CDF values for the new reactor designs. If a relative risk approach was applied that takes into account external events, the likely result would be a decrease in the significance of some findings. This is a consequence of the concept behind a relative risk approach that the higher the baseline CDF of a plant, the higher the Δ CDF value necessary for increased significance of a finding.

Other Options Considered

The staff considered other options than the proposed relative risk approach, such as a staircase thresholds approach and hybrid thresholds approach. Both of these alternative approaches are discussed below:

Staircase Thresholds Approach

At the public meeting on March 25, 2013, the staff presented a conceptual staircase thresholds approach (Figure 4). The staircase thresholds approach uses a step function with a plant's total

baseline CDF (x-axis) and Δ CDF (y-axis) to determine the significance of an inspection finding using the staircase lines on the graph. A staircase function is a concept that simplifies the selection of thresholds by not having to use an algorithm, like the relative approach, to calculate the threshold as a function of baseline CDF.

The staircase thresholds approach has very acute cliff effects that have negative implications. It is possible 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. Therefore, this approach does not offer an additional advantage over a relative risk approach.

Hybrid Thresholds Approach

At the public meeting on March 25, 2013, the staff also presented a conceptual hybrid thresholds approach (Figure 5). The hybrid thresholds approach uses a plant's total baseline CDF (x-axis) and Δ CDF (y-axis) to determine the significance of an inspection finding using the sloped and flat lines on the graph. This approach combines relative risk thresholds with the existing thresholds, with the transition happening at a baseline CDF of $10^{-6}/\text{yr}$ on the x-axis. The staff's idea behind this hybrid approach, and for selecting the transition point at $10^{-6}/\text{yr}$, was that it would enable the application of a relative approach to the new reactors, and the operating reactors would continue to use the existing thresholds.

Industry representatives discussed with the staff pros and cons of the hybrid approach at a public meeting on April 15, 2013. In summary, many of the industry's "problems with establishing alternate risk metrics and/or thresholds" from the 2009 NEI white paper would not arise if total baseline CDF values were used and the transition point was established at or near $10^{-6}/\text{yr}$. Industry expects the total baseline CDF values for new reactors, which include internal and external events, to exceed $10^{-6}/\text{yr}$ and therefore will retain the same color band thresholds as those of the existing fleet. Therefore, this approach would yield the same result as using the existing SDP thresholds.

Whether or not new reactor designs will have total baseline CDF values greater than or less than $10^{-6}/\text{yr}$ is debatable. However, if not now, eventually a design will likely have a CDF value below $10^{-6}/\text{yr}$ and the same concerns identified by NEI in 2009 will apply. Therefore, the staff views this approach as a short-term solution. If the new reactors' total baseline CDF values are greater than $10^{-6}/\text{yr}$, there would be no benefit to implementing the hybrid thresholds approach, because it would yield the same results as the existing approach given that the thresholds would be identical. Accordingly, this approach does not offer an additional advantage over a relative risk approach.

Reexamination of the Pros and Cons

The staff developed a white paper (ADAMS Accession No. ML090160004) in 2009 that identified the issues posed by the lower risk estimates for new reactor designs in risk-informed applications and potential options for implementation. The staff specifically addressed the pros and cons of converting to a relative risk approach for the ROP thresholds and RG 1.174. The Nuclear Energy Institute (NEI) developed an additional white paper in 2009 (ADAMS Accession No. ML090900674) to discuss these issues and recommended no change to the current risk metrics.

The staff reexamined the pros and cons from both the staff and NEI white papers. An additional advantage, or pro, of the relative risk approach that was evaluated and discussed during the public meetings is that it could be developed and applied in a manner that is consistent with the Commission's stated expectation to maintain the enhanced safety margins for new reactors, while providing greater operational flexibility than for current reactors. This was the main benefit described in the ACRS letter dated April 26, 2012 (ADAMS Accession No. ML12107A199). The example that was used by the ACRS, based on the conceptual thresholds (Figure 2), was that a plant with a baseline CDF of $10^{-4}/\text{yr}$ would trigger a White finding with a CDF increase of 1 percent (i.e., a CDF increase of $10^{-6}/\text{yr}$). However, a plant with a baseline CDF of $10^{-8}/\text{yr}$ would trigger a White finding with a CDF increase of a factor of 10 (i.e., a CDF increase of $10^{-7}/\text{yr}$). The staff understands the ACRS's recommendation, and an approach involving relative risk was previously considered, but was not pursued because the staff did not view it as consistent with the Commission decision to not approve the development of lower numerical thresholds for new reactors (in SRM-SECY-10-0121).

Some of the more significant impediments, or cons, to a relative risk approach for new reactors that were evaluated and discussed during the public meetings included:

- potential to inadvertently focus licensee and staff attention on less significant safety issues;
- concerns with public perception issues in communicating the safety significance of findings; and
- concerns with creating less incentive for licensees to enhance safety margin.

Participants at the public meeting discussed the potential for the relative risk approach to inadvertently focus licensee and NRC staff attention on less significant safety issues for two reasons. For example, using the conceptual relative risk thresholds in Figure 3, a plant with a baseline CDF of $10^{-7}/\text{yr}$ would receive a White finding for a finding with a ΔCDF value of $2 \times 10^{-7}/\text{yr}$, while a plant with a baseline CDF of $10^{-4}/\text{yr}$ would receive a Green finding for a finding with a ΔCDF value of $9 \times 10^{-7}/\text{yr}$. Under the current ROP, more attention, by both licensees and NRC staff, would be spent on a White finding that has a lower safety significance than a Green finding that has a higher safety significance (e.g., $2 \times 10^{-7}/\text{yr}$ (White finding) compared to $9 \times 10^{-7}/\text{yr}$ (Green finding)). Likewise, using the conceptual relative risk thresholds, a plant with a baseline CDF of $10^{-6}/\text{yr}$ would receive a White finding if they had a finding with a ΔCDF value greater than approximately $3 \times 10^{-7}/\text{yr}$. However, the current SDP threshold is at $10^{-6}/\text{yr}$ for a White finding. More attention, by both licensees and NRC staff, would be spent on a White finding that was greater than approximately $3 \times 10^{-7}/\text{yr}$ using the relative risk approach, compared to a Green finding that was greater than $10^{-6}/\text{yr}$ using the current SDP.

A relative risk approach creates potential public perception issues in communicating the safety significance of a finding for two reasons. First, the current SDP thresholds are used to communicate both performance deficiencies and the safety significance of a finding. Changing to a relative risk approach would no longer communicate a consistent safety significance of findings. The thresholds for Green, White, Yellow, and Red would no longer be directly comparable to the ROP-defined safety significance (i.e., very low safety significance, low to

moderate safety significance, substantial safety significance, and high safety significance) of a finding for a new reactor ROP that used relative risk thresholds. Second, applying a relative risk approach to new reactors but not operating reactors would create public perception issues as pointed out in NEI's 2009 white paper. When using two sets of SDP thresholds, the possibility exists for two findings with the same quantitative value to be different colors. This communicates to the public that the findings have a different safety significance, when in fact they have the same safety significance based on the quantitative PRA assessment.

The current SDP creates an incentive for licensees to enhance safety margin through plant improvements. Under the current SDP approach, if a licensee made an improvement that decreased their baseline CDF value, that would increase the Δ CDF value that would be necessary to receive a greater than GREEN finding. However, under a relative risk approach, if a licensee made an improvement that decreased their baseline CDF value, that would decrease the Δ CDF value that would be necessary to receive a greater than GREEN finding. The enhancement in safety margin would effectively result in a stricter SDP threshold when applying a relative risk approach.

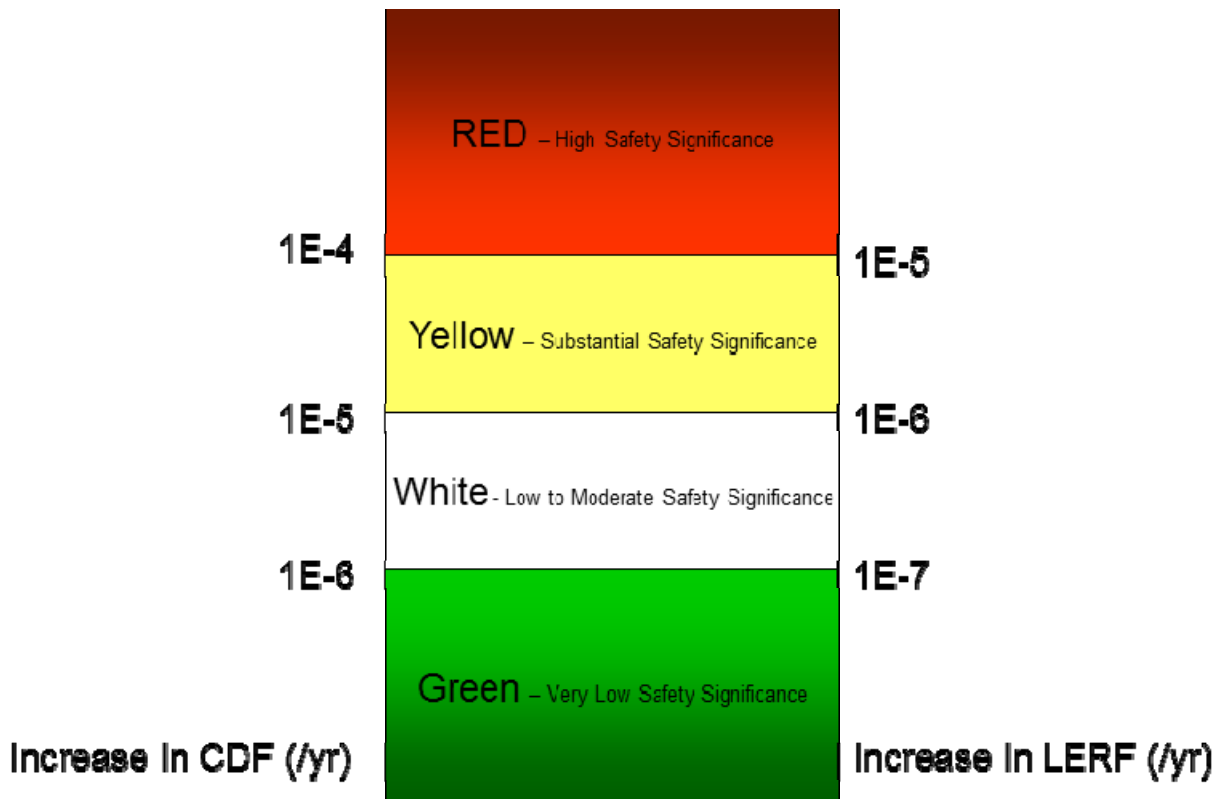


Figure 1 Quantitative thresholds for the significance of findings for the current SDP

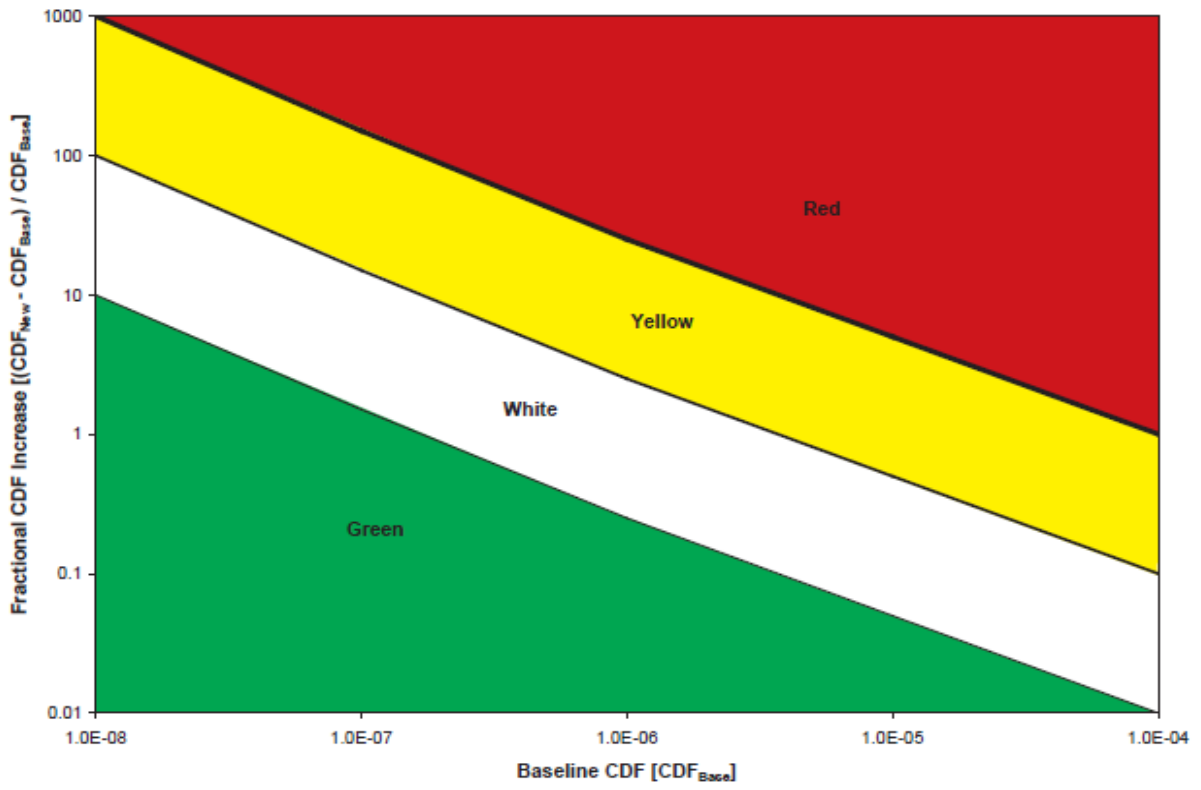


Figure 2 Relative risk approach—ACRS

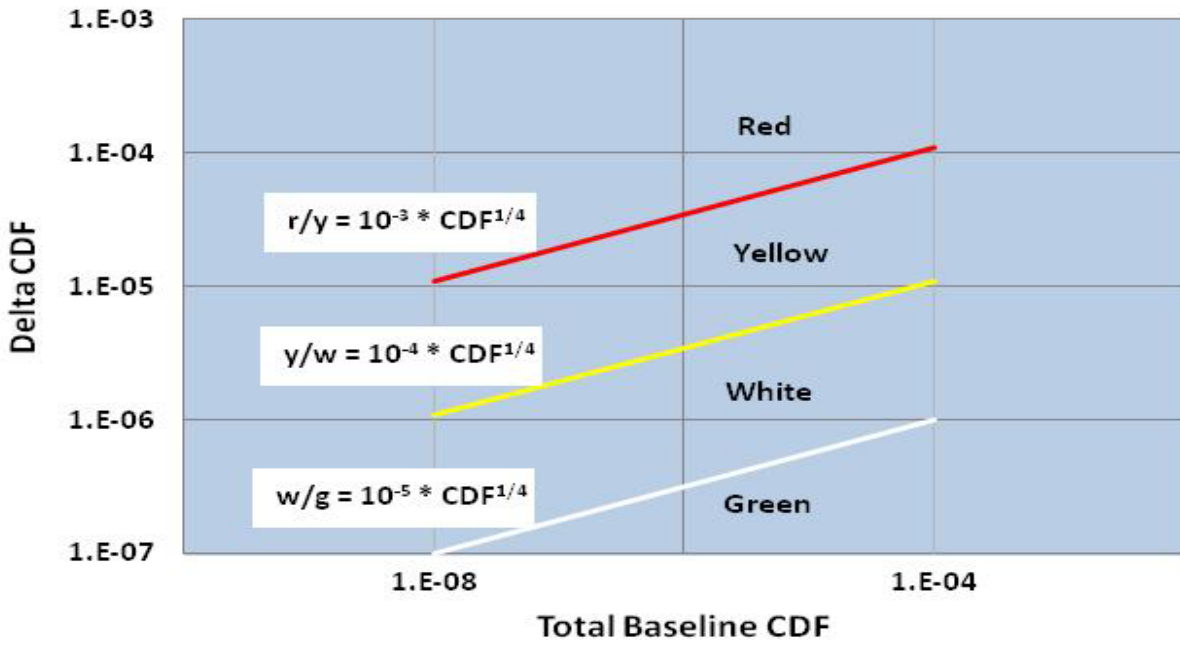


Figure 3 Relative risk approach—staff

Table 1 Application of Relative Risk to the 2011 Tabletop Cases

| Design | Example | Exposure Period | Δ CDF (/yr) | Model | 2011 Tabletop Outcome | Applying Relative Risk Approach |
|---|--|-----------------|--------------------|--------------------------------------|-----------------------|---------------------------------|
| Advanced Boiling Water Reactor (ABWR) | HPCF pump fails | 23 days | 1.4E-8 | SPAR | | |
| | | 1 year | 2.2E-7 | | | |
| | Both HPCF pumps fail with common cause | 23 days | 4.8E-8 | SPAR | | |
| | | 1 year | 7.7E-7 | | | |
| United States Advanced Pressurized Water Reactor (US-APWR) | One TDEFW pump fails | 1 year | 2.2E-5 | SPAR | | |
| | | 1 year | 3.4E-6 | PRA importances (internal events) | | |
| | | 1 year | 3.4E-6 | MHI PRA (internal fire and flooding) | | |
| | Both TDEFW pumps fail with common cause | 1 year | 4.4E-4 | SPAR | | |
| | | 1 year | 3.4E-5 | PRA importances (internal events) | | |
| | | 1 year | 8.8E-6 | MHI PRA (internal fire and flooding) | | |
| ABWR | RCIC pump unavailable | 1 year | 4.1E-7 | SPAR | | |
| | RCIC pump and both HPCF pumps unavailable | 1 year | 1.6E-6 | SPAR | | |
| US-APWR | One MDEFW pump and one TDEFW pump unavailable because of lost suction source | 1 year | 1.3E-4 | SPAR | | |
| | | 1 year | 7.7E-5 | MHI PRA (internal fire and flooding) | | |
| United States EPR Design (U.S. EPR) | One train of EFW unavailable because of lost suction source | 1 year | 7.7E-7 | Areva PRA | | |
| AP1000 | PXS-V121A fails to remain open because of disk-stem separation | 295 days | 9E-5 | SPAR | | |
| | | 1 year | 1.1E-4 | SPAR | | |
| US-APWR | RV head corrosion (increases medium and large LOCA frequencies) | 1 year | 1.4E-7 | SPAR | | |
| AP1000 | | 1 year | 1.2E-6 | SPAR | | |

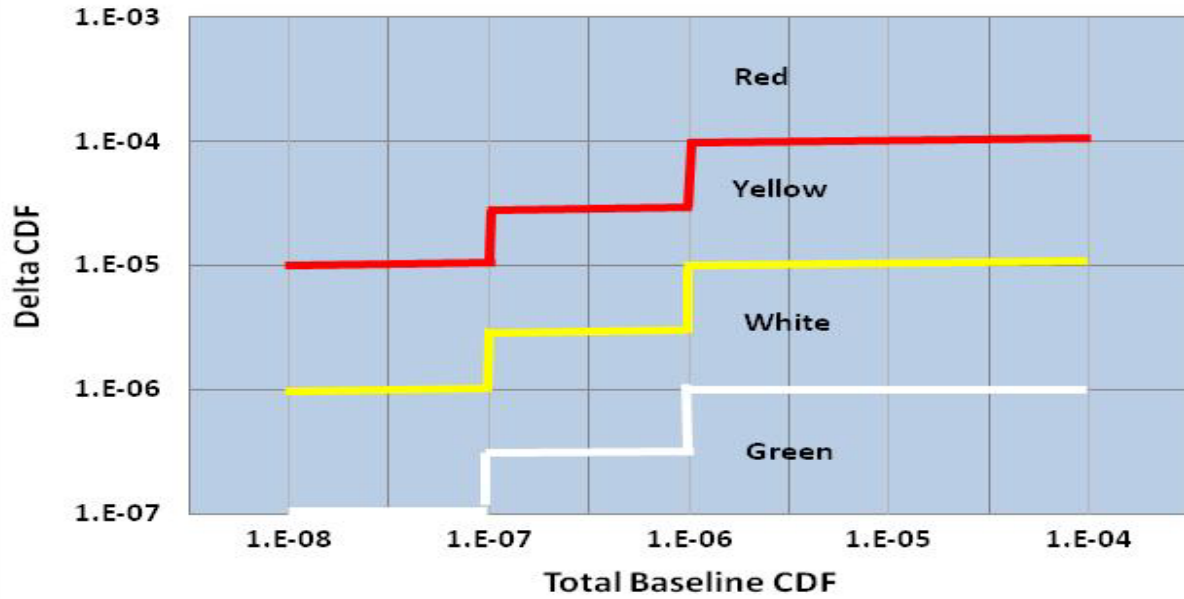


Figure 4 Staircase thresholds approach

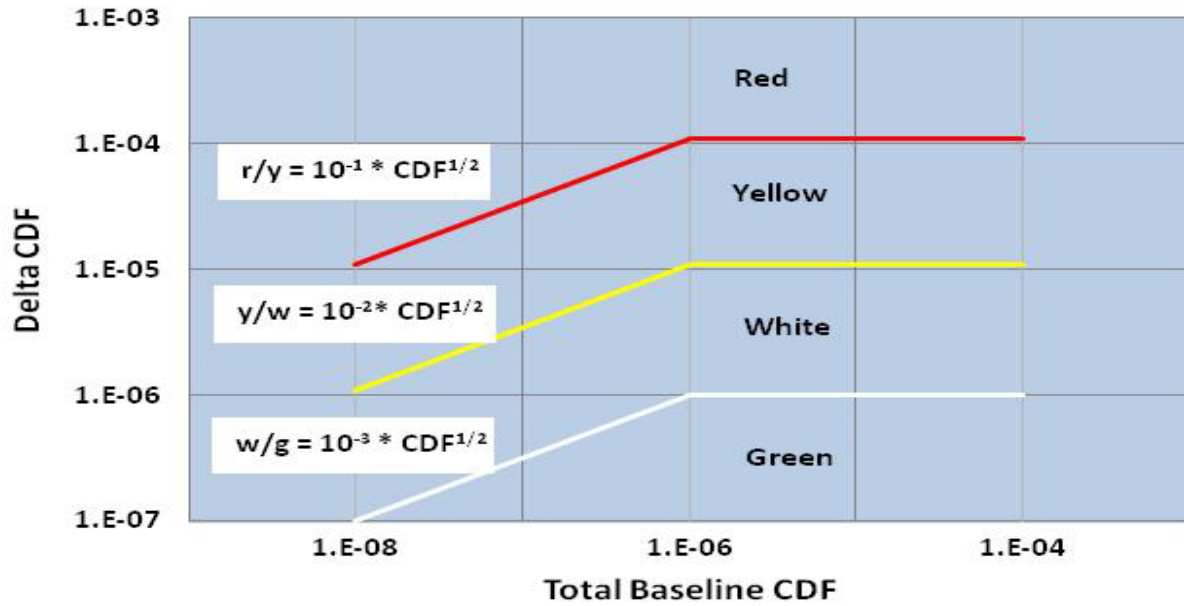


Figure 5 Hybrid thresholds approach

Appropriateness of Existing Performance Indicators and Thresholds

Technical Lead: Michael Balazik, NRR/DIRS

Background

As discussed in SECY-12-0081, "Risk-Informed Regulatory Framework for New Reactors," the case studies developed for the Mitigating System Performance Index (MSPI) tabletops showed that the existing MSPI is not adequate for new reactor designs and would be largely ineffective in determining an appropriate regulatory response. 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 incorporates a backstop that indicates when the performance of a monitored component in an MSPI system is significantly lower than expected industry performance, potentially could be modified and emphasized for active new reactor designs. The staff concluded in SECY-12-0081 that alternate performance indicators (PIs) in the Mitigating Systems cornerstone could be developed or additional inspection could be used for the new reactors to supplement insights currently gained through MSPI for the current fleet.

In response to the Staff Requirements Memorandum (SRM) on SECY-12-0081 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12296A158), the staff reviewed the basis and related thresholds for the remaining PIs to determine whether they could be appropriately applied to the operation of new reactor design plants. A more detailed discussion on the appropriateness of existing PIs and their thresholds for new reactors is provided in the sections that follow.

Performance Indicator Review

PIs, together with risk-informed baseline inspections, are intended to provide a broad sample of data to assess licensee performance in the risk-significant areas of each cornerstone. Objective performance evaluation thresholds are intended to help determine the level of regulatory engagement appropriate to licensee performance in each cornerstone area. Implementation guidance for the PI program is contained in U.S. Nuclear Regulatory Commission (NRC) Inspection Manual Chapter (IMC) 0608, "Performance Indication Program" (ADAMS Accession No. ML043560102). More detailed guidance on the data collection and PI calculations are contained in IMC 0308, Attachment 1, "Technical Basis for Performance Indicators" (ADAMS Accession No. ML071860516), and in Nuclear Energy Institute (NEI) 99-02, "Regulatory Assessment Performance Indicator Guideline" (ADAMS Accession No. ML092931123), which is jointly produced and maintained by the NEI and the NRC. In response to the SRM on SECY-12-0081, the staff reviewed the basis and related thresholds for the PIs in each cornerstone to determine whether they can be appropriately applied to plant operation for new reactor designs.

Initiating Events

The objective of the initiating events cornerstone is to limit the frequency of those events that upset plant stability and challenge critical safety functions, during shutdown as well as power operations. Three PIs are associated with this cornerstone.

The Unplanned Scrams per 7,000 Critical Hours indicator is used to monitor the number of unplanned scrams, both automatic and manual, assessed over a 4-quarter period. This PI measures the rate of scrams per year of operation at power (7,000 hours) and provides an indication of initiating event frequency. As documented in SECY-99-007, "Recommendations for Reactor Oversight Process Improvements," dated January 8, 1999 (ADAMS Accession No. ML992740073), probabilistic risk assessment (PRA) models were used to provide a risk perspective on the current thresholds for this PI. This was done by performing sensitivity studies to investigate how the core damage frequency (CDF) of plants varies as the values of the PI change. Three thresholds were established as described in Appendix H of SECY-99-007. The green–white threshold corresponds to licensee performance outside of a generically achievable level of performance. The white–yellow threshold corresponds to substantially declining licensee performance and was determined by identifying the PI values that would correspond to increases in CDF of 1×10^{-5} . The yellow–red threshold corresponds to unacceptable licensee performance and corresponds to an increase in CDF of 1×10^{-4} . As a result of the sensitivity studies, the thresholds were set to 6.0 scrams per 7,000 critical hours for the white–yellow threshold and 25.0 scrams per 7,000 critical hours for the yellow–red threshold for the existing reactor designs. The thresholds are set at or below those which PRA data would recommend. The current green-white threshold was set to 3.0 scrams per 7,000 critical hours, incorporating both performance and risk data to be commensurate with a generally achievable level of performance that takes into account the statistical variability across the current plant designs. Because the risk estimates for the new reactor designs are expected to be approximately one or two orders of magnitude lower than those for operating reactor designs, the staff concludes that Unplanned Scrams per 7,000 Critical Hours PI and existing thresholds can appropriately be applied to plant operation for new reactor designs to determine a regulatory response.

The Unplanned Scrams with Complications indicator is used to monitor a subset of unplanned automatic and manual scrams that occur while the reactor is critical and require additional operator actions as determined by the guidance in NEI 99-02 that are more risk-significant than uncomplicated scrams. The PI monitors these six actions or conditions that have the potential to complicate the post-trip recovery: reactivity control, pressure control (for boiling water reactors) or turbine trip (for pressurized water reactors), availability of power to emergency buses, actuation of emergency injection sources, availability of main feedwater, and the use of emergency operating procedures to address complicated scrams. The staff notes that the NEI 99-02 guidance will need to be supplemented with additional guidance to account for passive systems because complicating conditions may not be the same for new reactor designs. The current threshold is established to identify industry performance outliers over a 4-quarter period. The staff concludes that because the PI and corresponding thresholds are not linked directly to PRA data, the Unplanned Scrams with Complications indicator can appropriately be applied to the operation of plants with new reactor designs. However, additional NEI 99-02 guidance would need to be developed to reflect the constitution of a complicated scram associated with the new designs.

The Unplanned Power Changes per 7,000 Critical Hours indicator is used to monitor the number of unplanned power changes that could have, under other plants' conditions, challenged safety functions. This PI measures the number of plant power changes for a typical year of operation at power and is not a direct measure of risk. The current threshold was determined using the industry mean plus one standard deviation based on data over a 2-year

period. Because the PI and threshold are not directly linked to PRA data, the staff concludes that the Unplanned Power Changes per 7,000 Critical Hours indicator and corresponding thresholds can appropriately be applied to plant operation for new reactor designs to determine a regulatory response.

Mitigating Systems

The objective of the mitigating systems cornerstone is to ensure the availability, reliability, and capability of systems that mitigate plant transients and reactor accidents. Six PIs are associated with this cornerstone.

The Safety System Functional Failure (SSFF) indicator is used to monitor events or conditions that could have prevented the fulfillment of the safety function of structures or systems that are needed to:

- shut down the reactor and keep it in a safe shutdown condition
- remove residual heat
- control the release of radioactive material
- mitigate the consequences of an accident

The PI is not directly linked to PRA data, but to the reporting requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 50.73, "Licensee Event Report System." The thresholds were determined using the industry mean plus one standard deviation based on data over a 2-year period. Because the SSFF PI has a regulatory basis and the thresholds are not directly linked to PRA data, the staff concludes that the SSFF PI and corresponding thresholds can appropriately be applied to plant operation for new reactor designs to determine a regulatory response.

The other five PIs within the cornerstone are the MSPI. The MSPI is calculated and reported separately for five risk-significant systems. MSPI is addressed in SECY-12-0081, "Risk-Informed Regulatory Framework for New Reactors," dated June 6, 2012 (ADAMS Accession No. ML12117A012). The staff concluded that the existing MSPI would not be adequate and would be largely ineffective in providing meaningful input to the risk-informed regulatory decisionmaking process. Numerous case studies demonstrated this shortfall. The case studies demonstrated that it would be extremely rare to cross greater-than-green MSPI thresholds that would result in an increased regulatory response for active new reactor designs, and a meaningful MSPI might not even be possible for passive systems using the current formulation of the indicator. As noted in SECY-12-0081, the staff determined that alternate PIs in the mitigating systems cornerstone, specifically MSPI, could be developed and additional inspection could be used for the new reactors to supplement insights currently gained through MSPI for the current fleet.

Barrier Integrity

The objective of the barrier integrity cornerstone is to ensure that physical barriers protect the public from radionuclide releases caused by accidents. This cornerstone contains the Reactor Coolant System Specific Activity and the Reactor Coolant Leakage indicators. These indicators

are used to monitor the integrity of the fuel cladding and reactor coolant system's pressure boundary. The thresholds are a percentage of the Technical Specification limits and therefore have a regulatory basis as opposed to a PRA basis. The staff concludes that because these PIs are linked to a regulatory standard, both the PIs and the corresponding thresholds can appropriately be applied to plant operation for new reactor designs to determine a regulatory response.

Emergency Preparedness

The objective of the emergency preparedness cornerstone is to ensure that actions taken as part of the emergency plan would protect the public health and safety during a radiological emergency. Three PIs are associated with this cornerstone.

The Drill/Exercise Performance indicator is used to monitor timely and accurate licensee performance in drills and exercises when the licensee is presented with opportunities for classification of emergencies, notification of offsite authorities, and development of protective-action recommendations. The Emergency Response Organization Drill Participation indicator measures the percentage of key Emergency Response Organization members who have participated recently in drills and exercises or in an actual event. The Alert and Notification System Reliability indicator is used to monitor the reliability of the offsite Alert and Notification System, a critical link for alerting and notifying the public of the need to take protective actions. It indicates the percentage of the sirens that are capable of performing their safety function as measured by the testing program.

The thresholds associated with these PIs are not specifically tied to PRA data, but to regulatory requirements or the professional judgment of the staff and industry. The staff concludes that because the PIs are linked to regulatory requirements or professional judgment, the Emergency Preparedness PIs and the corresponding thresholds can appropriately be applied to plant operation for new reactor designs to determine a regulatory response.

Occupational Radiation Safety

The objective of the occupational radiation safety cornerstone is to ensure adequate protection of worker health and safety by preventing workers' exposure to radiation from radioactive material during routine civilian nuclear-reactor operation. One PI is associated with this cornerstone. The Occupational Exposure Control Effectiveness PI is used to monitor the control of access to, and work activities within, radiologically significant areas of the plant and occurrences involving the degradation or failure of radiation-safety barriers that result in readily identifiable unintended doses. The PI is the sum of the number of instances of nonconformance with the Technical Specifications (or comparable procedures) controlling access to, and work within, a high-radiation area (with dose rates greater than 1 rem per hour); instances of nonconformance with controls for a very-high-radiation area; and the number of unintended-exposure occurrences. The PI thresholds are based on review and analysis of quarterly occupational radiological occurrence data provided by numerous licensee sites over a 2-year period. The PI thresholds were agreed on by an expert panel composed of NRC and industry representatives. The staff concludes that because the Occupational Exposure Control Effectiveness PI is based on regulatory requirements (in 10 CFR 20.1101, "Radiation protection programs"; 10 CFR 20.1602, "Control of access to high radiation areas"; and 10 CFR 20.1602,

“Control of Access to Very High Radiation Areas”) and plant technical specifications with no specific link to PRA data, the PI and the corresponding thresholds can appropriately be applied to plant operation for new reactor designs to determine a regulatory response.

Public Radiation Safety

The objective of the public radiation safety cornerstone is to ensure adequate protection of public health and safety by preventing exposure to radioactive material released into the public environment as a result of routine civilian nuclear-reactor operations. One PI is associated with this cornerstone. The radiological effluent technical specifications (RETS) and Offsite Dose Calculation Manual (ODCM) Effluent Occurrence PI are used to monitor the performance of the radiological effluent control program. The associated thresholds of this PI are a percentage of the values derived from the RETS and ODCM and, therefore, have a regulatory basis as opposed to a probabilistic risk basis. The current thresholds were based on a review and graphical analysis of data from Licensee Event Reports associated with process radiation monitoring system activities provided by all operating nuclear power-plant sites over a 2-year period.

As documented in SRM-SECY-08-0197, “Options to Revise Radiation Protection Regulations and Guidance with Respect to the 2007 Recommendations of the International Commission on Radiological Protection,” dated April 2, 2009 (ADAMS Accession No. ML090920103), the staff is currently participating in technical committees and evaluating the recommendation in the International Commission on Radiological Protection’s Publication 103 to determine whether changes to current regulations are merited. One potential result of this effort might result in amending the effluent limits in 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” Appendix I, “Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion ‘As Low As Is Reasonably Achievable’ for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents.” This would lead to a change in the PI thresholds for both existing and new reactor designs. The staff concludes that because the current RETS and ODCM Effluent Occurrence PI is based on regulatory requirements (from 10 CFR Part 50, Appendix I) and is not specifically linked to PRA data, the PI and the corresponding thresholds can appropriately be applied to plant operation for new reactor designs to determine a regulatory response.

Security

The objective of the Security cornerstone is to provide assurance that the licensees’ security systems and material control and accounting programs use a defense in-depth approach and can protect against (1) the design-basis threat of radiological sabotage from external and internal threats and (2) the theft or loss of radiological materials. One PI is associated with this cornerstone. The Protected Area Security Equipment Performance Index is used to monitor the unavailability of the protected area’s intrusion-detection systems and alarm-assessment systems to perform their intended function of ensuring the operability of the protected area. The PI serves as a measure of the plant’s ability to keep equipment available to perform its intended function as well as to repair degraded and out-of-service intrusion-detection equipment in a timely manner. Similar intrusion-detection systems will be required for new reactors. The Security PI is not specifically tied to probabilistic risk data. The current thresholds were developed and agreed to by an expert panel composed of NRC and industry representatives

based on historical industry data. The staff concludes that because the Security PI is not specifically tied to PRA data, the PI and corresponding thresholds can appropriately be applied to plant operation for new reactor designs to determine a regulatory response.

Conclusions

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 related thresholds could apply to new reactors. Pending Commission approval, the staff plans to further analyze the current PIs and thresholds and will attempt to develop appropriate PIs and thresholds for new reactor applications, particularly in the Mitigating Systems cornerstone. If the staff determines that appropriate PIs and thresholds are not feasible for new reactor applications, the staff plans to develop additional inspection guidance to address any shortfalls to ensure that all cornerstone objectives are adequately assessed.