February 3, 2012

MEMORANDUM TO: Edwin M. Hackett, Executive Director
Advisory Committee on Reactor Safeguards

FROM: Charles E. Ader, Director **/RA/**
Division of Safety Systems and Risk Assessment
Office of New Reactors

SUBJECT: TRANSMITTAL OF DRAFT COMMISSION PAPER ON RISK-INFORMED REGULATORY FRAMEWORK FOR NEW REACTORS

In 2009 and 2010, the staff met with the Advisory Committee on Reactor Safeguards (ACRS) and its Subcommittee on Reliability and Probabilistic Risk Assessment to discuss the staff's recommendations related to risk-informed guidance for new light-water reactor risk-informed applications. These recommendations were documented in SECY-10-0121.

In the associated Staff Requirements Memorandum, the Commission directed the staff to continue to use the existing risk-informed framework, including regulatory guidance, for licensing and oversight activities for new plants. The Commission re-affirmed that the existing safety goals, safety performance expectations, subsidiary risk goals, and associated risk guidance are sufficient for new plants. In addition, the Commission directed the staff to engage with external stakeholders in a series of tabletop exercises to test various scenarios to confirm that current regulatory tools can be applied or identify areas for improvement.

The staff has completed this series of tabletop exercises and has developed a draft Commission paper with options and recommendations for enhancements to agency guidance. The staff plans to discuss this draft paper with the Subcommittee on Reliability and Probabilistic Risk Assessment on March 7, 2012, and with the full ACRS during the April 2012 meeting.

The staff requests that the enclosed draft paper, which has been concurred on by the affected offices, be shared with the ACRS in advance of the March 7, 2012, meeting.

Enclosure: As stated

CONTACTS: Donald A. Dube, NRO/DSRA
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FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: RISK-INFORMED REGULATORY FRAMEWORK FOR NEW REACTORS

PURPOSE:

This paper responds to the staff requirements memorandum (SRM) on SECY-10-0121, “Modifying the Risk-Informed Regulatory Guidance for New Reactors,” dated March 2, 2011 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML110610166).

SUMMARY:

The SRM on SECY-10-0121 directed 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. Specifically, the SRM 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 (TS), license conditions, code requirements) that are or will be relevant to the licensing bases of new reactors. The tabletop exercises are to either confirm the adequacy of those regulatory tools (and make the NRC aware of these potential scenarios such that commensurate regulatory oversight can be applied) or identify areas for improvement, such as potential adjustments to the Reactor Oversight Process (ROP).

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In response to the SRM on SECY-10-0121, the staff conducted a series of public workshops and meetings with stakeholders from May 4, 2011, through October 26, 2011. Based on the staff's observations of the tabletop exercises for licensing applications, and considering the Commission's decision reaffirming the existing safety goals, the staff could not conclude that the enhanced safety margins for new plants will significantly decrease without regulatory policy changes for risk-informed licensing activities. Thus, the staff has no specific list of options with regard to changes to existing guidance in this category to propose to the Commission.

The staff did identify a potential gap in the Tier 2 change process regarding severe accident features that are not related to ex-vessel severe accident prevention and mitigation. The staff proposes two options for Commission consideration. Furthermore, the staff proposes three options for Commission consideration to address the different risk metrics used during new reactor licensing and the risk-informed framework for currently operating reactors.

With regard to the application of the ROP to new reactors, the tabletops demonstrated that current risk thresholds are appropriate; however, a few changes to the ROP may 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 presents three options for consideration by the Commission. The staff recommends an option in which the staff, after working with internal and external stakeholders, identifies appropriate changes to augment the existing risk-informed guidance with deterministic backstops to ensure an appropriate regulatory response for the new reactor designs.

BACKGROUND:

Risk estimates for new reactor designs are one or more orders of magnitude lower than those for operating reactor designs when internally initiated events and externally initiated events that have been quantified are included. The lower risk values raised questions regarding how to apply acceptance guidelines for changes to the licensing basis and regulatory response in the ROP.

The staff developed a white paper that identifies the issues posed by the lower risk estimates for new reactor designs in risk-informed applications and potential options for implementation. The white paper was provided to the Commission (ML090160004) and discussed with stakeholders at a public meeting on February 18, 2009. The white paper includes consideration of the Commission established goals for new reactor designs of a core damage frequency (CDF) of less than 10^{-4} per year (/yr); a conditional containment failure probability (CCFP) of less than 0.1, and a large release frequency (LRF) of less than 10^{-6}/yr.

The Nuclear Energy Institute (NEI) developed an additional white paper to discuss these issues and recommended no change to the current risk metrics. NEI submitted their paper on March 27, 2009 (ML090900674). Staff and industry representatives briefed the Advisory Committee on Reactor Safeguards (ACRS) on April 3, 2009, followed by a more detailed presentation to the ACRS Subcommittee on Reliability and Probabilistic Risk Assessment (PRA) on June 2, 2009. The staff held a second public meeting on September 29, 2009, that focused on the potential issues associated with the ROP (ML092780211).

Based on these interactions, the staff developed a draft Commission paper (ML101090355) describing the staff's plans to identify appropriate changes to the risk-informed guidance for new reactors. The staff held a public meeting on June 3, 2010, and an ACRS briefing on June 10, 2010, to discuss the path forward. In a letter to the Commission dated July 27, 2010 (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 (ML102210553). The final Commission paper was issued on September 14, 2010 (SECY-10-0121, ML102430197). A Commission briefing on the topic was held on October 14, 2010.

Subsequently, the Commission issued an 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. 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 NRC resources and allow a fuller focus on issues of true safety significance." The Commission also directed the staff to undertake the following:

- The staff should articulate, in a single document, a coherent overview of the Commission's policies and decisions regarding new reactor safety performance for the purposes of public communication and NRC staff knowledge management.

- The staff should 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., TS, license conditions, code requirements) that are or will be relevant to the licensing bases of new reactors. The tabletop exercises should either confirm the adequacy of those regulatory tools (and make the NRC aware of these potential scenarios such that commensurate regulatory oversight can be applied) or identify areas for improvement, such as potential adjustments to the Reactor Oversight Process. Specific programs and processes highlighted in the SRM include:

    - Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.59, "Changes, Tests and Experiments," during the construction and operational phases of new nuclear power plants

    - The change control process addressing severe accident design features under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants"

    - Risk-managed TS

  - o 10 CFR 50.69, "Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors"
  - o ROP

- Progress reports are to be provided to the Commission every six months.
- A notation vote paper with options and recommendations is to be provided to the Commission by June 4, 2012.

DISCUSSION:

In response to the SRM on SECY-10-0121, the staff conducted a series of public workshops and meetings with stakeholders from May 4, 2011, through October 26, 2011. 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 enhanced safety margin of the new reactor designs are summarized below and discussed in greater detail in Appendices A and B. These controls include such features as deterministic backstops, defense-in-depth measures, integrated decision-making panels, and performance monitoring. The staff also completed the summary-level public communication brochure entitled "New Reactors: Striving for Enhanced Safety" in November 2011 (NUREG/BR-0356, ML11343A026). The staff provided an informational briefing to the ACRS Subcommittee on Reliability and PRA on September 20, 2011.

Licensing Tabletop Exercise Summary

The staff held a one-day public workshop on risk-informed inservice inspection (RI-ISI) of piping on May 4, 2011. The staff observed that RI-ISI simply changes the locations for inservice inspection in a risk-informed manner and is risk-neutral. Neither the design nor plant operational configurations are affected by RI-ISI. The general consensus of the staff and participating stakeholders from the tabletop exercise is that use of the current guidance for RI-ISI for a new reactor design with sufficient operating experience would not result in any significant decrease in enhanced safety. The staff identified some potential regulatory and implementation issues that would need to be addressed if RI-ISI was applied to a new plant, such as the lack of plant-specific operating experience. A more detailed discussion can be found in Appendix A to this paper.

The staff held a two-day public workshop on May 26, 2011, and June 1, 2011, on risk-informed TS initiative 4b (RITS 4b) (completion times) and Section (a)(4) of the "maintenance rule," 10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants." The staff presented calculation results using Standardized Plant Analysis Risk (SPAR) models for internal events for the Advanced Boiling Water Reactor (ABWR) and AP1000 reactor designs. The configurations that were tested spanned a wide range from single equipment outages to multiple equipment outages across safety divisions. The staff identified some configurations of equipment outages with an incremental core damage probability (ICDP) that would, in effect, represent 10 or more years of core damage probability. Repeated entry into such condition over time could increase CDF by one or more orders of magnitude, approaching the baseline CDF of currently operating plants. The staff, however, believes these configurations are unlikely or unrealistic, and that numerous programmatic and regulatory controls would limit the aggregated risk increase, specifically:

- The risk-informed completion time is limited to a deterministic maximum of 30 days (referred to as the backstop completion time) from the time the TS action was first entered.

- Voluntary use of the risk-managed TS for a configuration which represents a loss of TS specified safety function, or inoperability of all required safety trains, is not permitted.

The staff also identified performance monitoring under NEI 06-09, "Risk-Managed Technical Specifications (RMTS) Guidelines," RG 1.174, and RG 1.177, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications," as key programmatic controls.

The general consensus of the staff and participating stakeholders from the tabletop exercise is that no substantive changes to methodology are necessary to implement RITS 4b for new reactor designs. Similar to RI-ISI, however, certain implementation and process issues may need to be addressed before implementing RITS 4b.

A topic related to RITS 4b is the implementation of 10 CFR 50.65(a)(4) for new reactor designs. The general consensus of the staff and participating stakeholders from the tabletop exercise on Section (a)(4) of the maintenance rule as it pertains to new reactor designs is that Section 11 of NUMARC 93-01, "Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants" (endorsed in RG 1.182, "Assessing and Managing Risk Before Maintenance Activities at Nuclear Power Plants") does not appear to need substantive change to address qualitative and quantitative considerations in the assessment and management of risk for new reactor designs.

The staff held a one-day public workshop on RITS 5b (surveillance frequency control program) on June 29, 2011. The staff identified the regulatory and programmatic controls that strengthen the RITS 5b program and tend to limit the decrease in enhanced safety margin of the new reactor designs such as monitoring, feedback and periodic program re-assessment. The general consensus of the staff and participating stakeholders from the tabletop exercise on RITS 5b is that the program is much more deterministically oriented than RITS 4b (completion times), in which the quantitative risk assessment is key to the application. Participants in the workshop recognized the need to obtain sufficient baseline operating experience on affected equipment during the initial cycle or cycles of reactor operation before commencing full implementation of RITS 5b in the new plants. The staff identified no substantive changes to guidance documents that would be necessary to implement the program at new reactors.

The staff held a one-day public workshop on risk-informed categorization and treatment of structures, systems and components (SSCs), 10 CFR 50.69, on August 9, 2011. The staff concluded that passive system categorization (e.g., piping) is similar to RI-ISI, which an earlier tabletop demonstrated no decrease in enhanced level of safety. Categorization of active components (e.g., pumps and valves) are based on *relative* risk importances, independent of baseline risk, so one should not expect adverse impact on enhanced safety for new designs.

The staff identified no substantive changes to guidance documents that would be necessary to implement the program at new reactors.

In conjunction with the Changes during Construction working group within the agency, staff held a one-day public workshop on December 2, 2010, prior to the issuance of the SRM on SECY-10-0121, to address the 10 CFR Part 52 change process specific to ex-vessel severe accident (EVSA) design features. Follow-up discussions were held on August 9, 2011, and November 15, 2011, in which the staff provided further comments on some of the broader 10 CFR Part 52 change processes in the draft Appendix C of NEI 96-07, "Guidelines for 10 CFR 50.59 Implementation."

During the 2010 workshop, staff discussed the requirements as codified in Section VIII.B.5.c of each appendix to 10 CFR Part 52 regarding the criteria for departures from Tier 2 affecting resolution of EVSA design features that would require a license amendment. There was consensus on the part of staff and stakeholders present that the current rules and guidance may not be complete. Certain severe accident features (e.g., features to prevent containment bypass and containment hydrogen mitigation equipment such as igniters) do not address "ex-vessel" conditions, as defined in the statement of considerations for the rule.

In the current regulation, changes to severe accident design features that are not specifically intended to address EVSAs are not addressed using severe accident criteria as in Section VIII.B.5.c. Depending on the nature of the change, the licensee must follow one of the other change procedures in the rule, either Section VIII.B.5.a or Section VIII.B.5.b, using the guidance in Section 4.4.3.2 of the draft Appendix C to NEI 96-07. If the change falls under the requirements of Section VIII.B.5.a, then the licensee could make the change without prior NRC approval. Section VIII.B.5.b, however, explicitly excludes changes to severe accident features. Moreover, the criteria of Section VIII.B.5.b generally ask if there is "more than a minimal increase" in the frequency of occurrence or consequences of an accident previously evaluated in the plant-specific design control document (DCD). While not stated explicitly in the rule, it is clear from the statement of considerations that design-basis accidents are intended here. The EVSA criteria in Section VIII.B.5.c use "substantial increase" in probability and public consequences as the standard for determining whether prior NRC approval is required. The latter criteria are less stringent and are more appropriate for non-ex-vessel severe accident design features given the large uncertainties associated with severe accident phenomena and the ability of analysts to precisely determine the impact of the change on probability and consequences.

Unless such non-ex-vessel severe accident design features also happen to have a dual function such as also addressing design basis accidents or aircraft impacts, risk-significant Tier 2 changes (e.g., Chapter 19 information related to prevention and mitigation of severe accidents other than those considered "ex-vessel") could be screened out altogether and not receive prior NRC approval. Fortuitously, staff has observed that Tier 1 descriptions usually have sufficient detail as to necessitate prior staff review for major changes to severe accident design features. The staff believes, however, that there is a "gap" with regard to the Tier 2 change process for non-ex-vessel design features, in that: a) such changes may be screened out or less appropriate criteria are applied when determining whether prior NRC approval is needed, and b) whether or not prior NRC approval is obtained may be highly dependent on the degree of detail in Tier 1, if any. The staff has provided options and a recommendation to the Commission in this paper to address the potential "gap" in the 10 CFR Part 52 change process.

The staff dedicated a significant portion of the October 5, 2011, public workshop to addressing the use of RG 1.174 for new reactors. The staff noted that, since it was highly unlikely that a combined license (COL) holder would propose a license amendment request to completely remove a Tier 1 system, the most likely changes would be regarding *how* the existing system is to be categorized, operated, and maintained. As a result of the tabletop exercise on RG 1.174, and considering the Commission's decision reaffirming the existing safety goals, the general consensus of the staff and participating stakeholders is that no substantive changes to the key principles and other guidance are necessary to address new reactors. The staff plans, however, to augment the existing discussion on long-term containment performance in Section 2.2 of RG 1.174 by referring to the containment performance objectives for new reactors as described in Commission-approved guidance such as SECY-90-016, "Evolutionary Light Water Reactor (LWR) Certification Issues and Their Relationship to Current Regulatory Requirements," dated January 12, 1990, and SECY-93-087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs," dated April 2, 1993.[1]

The second topic discussed during the October 5, 2011, workshop related to potential options for transitioning from LRF and, to a lesser extent, CCFP (the risk metrics used in new reactor design certifications and COL applications) to the large early release frequency (LERF) metric used in the risk-informed regulatory framework for currently operating reactors.

As discussed in Enclosure 1 to SECY-10-0121, the Commission had earlier requested the staff to provide a definition of LRF, but in SECY-93-138, "Recommendation on Large Release Definition," dated May 19, 1993, the staff recommended termination of work on a definition, and the Commission later approved. As a result, the definitions of LRF in the DCDs referenced in COL applications all differ to varying extents. Because of the conservative definitions of LRF used in the DCDs, however, staff has been able to review the PRA and severe accident evaluation portions of the DCDs to provide reasonable assurance that the Commission's objectives as described in key policy papers such as SECY-90-016 and SECY-93-087 are fully addressed.

The staff has identified three possible options for the transition from LRF to LERF, and discussed the advantages and disadvantages of each. The staff has provided options and a recommendation to the Commission in this paper to address the issues.

[1] The containment should maintain its role as a reliable, leak-tight barrier (for example, by ensuring that containment stresses do not exceed ASME Service Level C limits for metal containments, or Factored Load Category for concrete containments) for approximately 24 hours following the onset of core damage under the more likely severe accident challenges and, following this period, the containment should continue to provide a barrier against the uncontrolled release of fission products.

Other risk-informed initiatives that were not discussed in depth during the series of tabletop exercises were briefly reviewed during the October 5, 2011, workshop. These include:

- RG 1.175, “An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Testing”

- NEI 94-01, “Industry Guideline for Implementing Performance-Based Option of 10 CFR 50, Appendix J”

- RG 1.183, “Alternative Radiological Source Terms for Evaluating Design Basis Accidents at Nuclear Power Reactors”

- Draft Final Rule 10 CFR 50.46a, “Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements”

- NFPA 806, “Performance-Based Standard for Fire Protection for Advanced Nuclear Reactor Electric Generating Plants Change Process”

Participants in the workshop noted that for most of these activities there appeared to be very limited short-term interest by future COL holders, and the staff’s decision not to perform tabletops was reasonable. The staff noted that alternative radiological source terms already have been applied at most of the new reactor designs. Additionally, all risk-informed changes to the licensing basis would fall under the general guidance in RG 1.174.

<u>ROP Tabletop Exercise Summary</u>

The staff held a half-day public workshop to discuss the ROP-related tabletops on October 5, 2011. A brief follow-up public meeting was held on October 26, 2011. The ROP tabletops tested various realistic 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 decision-making 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.

Appendix B provides details on the ROP framework, existing risk-informed guidance, and results from the ROP tabletop exercises that have been considered in developing the staff’s conclusions and recommendations regarding potential changes to the ROP to address new reactor designs.

In summary, the tabletops demonstrated that current risk thresholds are appropriate; however, a few changes to the ROP may be warranted to implement the existing risk-informed concepts of RG 1.174 for new reactors. These changes will not infringe on the additional operational flexibility provided within the licensing basis of the new, more robust, reactor designs.

The risk-informed concept of RG 1.174 places a strong emphasis on the quantified increase in probability of CDF or LERF, but it also provides that basic deterministic principles such as diversity and defense in depth be maintained. Because of the history of design and modifications for the existing operating fleet, the extended loss of diversity or defense in depth, such as the loss of an entire safety system function in the initiating events or mitigating systems cornerstones, will nearly always result in crossing a threshold resulting in an increased regulatory response for quantified increase in CDF or LERF. As described below, the staff identified a few specific areas where, consistent with the integrated risk-informed decision-making framework in RG 1.174, additional deterministic backstops would complement the current set of risk-informed ROP tools, thereby ensuring regulatory responses to performance issues, events, and degraded conditions are reasonable and appropriate.

Within the ROP, the SDP is used to characterize inspection findings. All inspection findings require a performance deficiency, the vast majority of which are based on violations. Where the licensing basis, including the TS completion times and minimum equipment configuration requirements, allow greater flexibility in operation, that flexibility is not encroached upon by the ROP's inspection findings. The staff concluded that the existing risk-informed SDP is generally acceptable, and could generate an increased regulatory response based on greater-than-green results on occasion. The case studies, however, demonstrated that the performance deficiencies would likely have to involve common cause failures that affect multiple systems and/or involve long-term exposures of risk-significant components. In addition, the case study on reactor coolant system integrity demonstrates that the existing quantitative process does not provide the appropriate response for degradation of passive components and barriers. The intent of the ROP is to generally capture declining licensee performance by progression through the action matrix's columns. The staff believes that this would not be the case for passive plants, and there would be little NRC intervention above the baseline inspection program prior to an event with actual consequences.

More specifically, a case study involving reactor vessel head degradation resulted in a marginally white finding for the U.S. Advanced Pressurized Water Reactor (US-APWR) and a green finding for AP1000 for medium break and large break loss-of-coolant accidents based on the risk numbers. The calculations included increasing the initiating event frequencies by two orders of magnitude per the SDP guidelines to address the significant unanalyzed parameters, as was done for a similar case at Davis-Besse in 2002. Based on this calculation, the resultant regulatory response would be to move the US-APWR facility to the Regulatory Response Column (column 2) of the ROP Action Matrix and perform a single supplemental inspection of about 40 hours to ensure the causes of the performance issues are identified and that appropriate corrective actions are planned or taken to prevent recurrence. In this case, the staff believes that a more robust and diagnostic supplemental inspection would be warranted to ensure that the NRC and licensee identify and arrest root causes that led to the degradation in the integrity of barriers designed to protect the public from radionuclide releases caused by potential accidents. Unless the deterministic criteria and how they are applied are enhanced, this increased regulatory response would not be attainable using the current risk-informed SDP and a deviation from the ROP Action Matrix would need to be pursued to ensure an appropriate regulatory response.

To address the identified shortfall, the staff determined that the SDP analyses for new reactor designs should be augmented with additional qualitative considerations, consistent with the integrated risk-informed decision-making framework in RG 1.174, to provide a deterministic backstop as necessary to appropriately address performance issues. For example, deterministic backstops could be developed to reinforce the importance of maintaining barrier integrity for fuel cladding, reactor coolant system pressure boundary, and containment. For active safety system plants, the staff could also explore the feasibility of implementing a deterministic backstop for equipment outages resulting from degraded conditions (similar to the RITS 4b backstop completion time) and/or for the number of repetitive equipment failures that could degrade the reliability or availability of SSCs from performing their intended safety functions. These deterministic backstops should not infringe upon the operational flexibility afforded by the more robust new reactor designs, but should instead be designed to capture the infrequent yet potentially significant performance issues that would not otherwise be captured by the risk calculations to ensure an appropriate regulatory response.

Management Directive (MD) 8.3, “NRC Incident Investigation Program,” and Inspection Manual Chapter (IMC) 0309, “Reactive Inspection Decision Basis for Reactors,” establish the criteria for event response. Deterministic criteria are used for initial event screening, and risk thresholds are subsequently applied to determine if a reactive inspection will be launched. The threshold for launching the lowest level of reactive inspection, a special inspection team (SIT) is clearly defined as an estimated conditional core damage probability (CCDP) of 10^{-6}. Similarly, ranges of risk values are specified for launching augmented inspection team (AIT) and incident investigation team inspections. While these ranges offer some flexibility for determining the level of event response, they still involve thresholds based on risk values. As such, risk values significantly influence regulatory outcomes governing whether or not a reactive inspection is warranted and, if so, at what level.

The specific tabletop scenarios yielded mixed results: while most would have resulted in an appropriate response to events, the staff noted that one outcome would have been different depending on the risk model used for determining the level of reactive inspection. In either case, the scenarios indicated that risk thresholds are adequate for new reactors. The staff, however, recognized the potential for inadequate response as a function of variations in or minor revisions to the risk models used in the calculations. In addition, since MD 8.3 determinations are largely influenced by risk information, the staff acknowledged the potential for inadequate response based on the results of the tabletop scenarios used in the SDP and MSPI applications. For these reasons, the staff perceived the need to temper both the uncertainty associated with risk insights and the relative weight of risk information such that an appropriate level of regulatory response is achieved for new reactors. The staff concluded that the contribution of the existing deterministic criteria may need to be modified, or new deterministic criteria could be developed, for initiating a reactive inspection to assess events or degraded conditions at new reactor facilities. Similar backstops to those discussed above for the SDP could be explored to ensure regulatory response to plant events and conditions is appropriate and commensurate with the significance of the event (or condition).

For example, consider the case of a steam generator tube rupture at an AP1000 facility. Prior to the case study, the staff used the submitted Westinghouse PRA to calculate that only an SIT could be performed in accordance with the existing MD and IMC guidance. During the case study, the staff used the recently completed, and slightly more conservative, SPAR model to calculate results that were just over the threshold where either a SIT or an AIT could be considered. The staff believes that performance of an AIT is appropriate for any steam generator tube rupture (an event that involves the breach of the reactor coolant system pressure boundary and potentially bypasses containment), and an overreliance on the risk numbers could result in an insufficient regulatory response.

Finally, 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 decision-making process. There were numerous case studies that 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 may not even be possible for passive systems using the current formulation of the indicator. The existing performance limit approach would play a more significant role and could potentially be emphasized and modified for the active new reactor designs.

For example, one case study identified that it would take greater than 25 emergency diesel generator (EDG) start failures or greater than 25 EDG run failures for the U.S. Evolutionary Power Reactor (EPR) to exceed the green-white risk threshold, and 12 failures to reach the performance limit. In another case, it would take 14 or more turbine-driven emergency feedwater pump failures or greater than 25 motor-driven pump failures for the US-APWR to exceed the green-white threshold using the licensee's PRA model, and the performance limit would not be exceeded until 6 or more pump failures in a 3-year time frame occurred. Taken as a whole, it would be highly improbable to have a greater-than-green indicator for any MSPI system at any of the new reactor facilities, even taking into account the performance limit (backstop) as it is currently formulated. Therefore, the existing MSPI would provide little if any insight into plant performance for new reactors and would not trigger an appropriate regulatory response to address performance issues. The staff determined that alternate performance indicators (PIs) in the mitigating systems cornerstone could potentially be developed and/or additional inspection could be used to supplement insights currently gained through MSPI.

RECOMMENDATIONS:

Based on staff's observations of the tabletop exercises, and considering the Commission's decision reaffirming the existing safety goals, staff could not conclude that the enhanced safety margins for new plants will significantly decrease without regulatory policy changes for risk-informed licensing activities. Thus, the staff has no specific list of options with regard to changes to existing guidance in this category to propose to the Commission.

1. Tier 2 Change Process

As noted in the tabletop exercise results section above, staff did identify a potential gap in the Tier 2 change process regarding severe accident features that are not related to ex-vessel severe accident prevention and mitigation. The current change process does not address all of the severe accidents defined in 10 CFR 52.47(a)(23) and § 52.79(a)(38). The current regulation and its implementation via the guidance in draft Appendix C of NEI 96-07 could result in the licensee screening out changes in Chapter 19 (and other sections) of Tier 2 of the DCD and Final Safety Analysis Report (FSAR) that do not affect ex-vessel severe accident design features. In a worst case, significant Tier 2 changes to non-ex-vessel severe accident features, up to and including permanent removal from service, could be made without prior NRC approval. The staff thus proposes two options for Commission consideration.

Option 1A: Accept the potential gap and allow changes to severe accident design features that are not related to ex-vessel prevention and mitigation to take place outside of the Section VIII.B.5.c change control rule

Under this option, licensees would continue to use the existing change rules provided in Section VIII of each appendix to 10 CFR Part 52, using guidance as currently drafted in NEI 96-07 Appendix C and expected to be endorsed in a revision to RG 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments." Because Section VIII.B.5.c addresses only Tier 2 changes to ex-vessel severe accident design features, changes to other severe accident features such as containment bypass prevention and mitigation or containment hydrogen mitigation equipment such as igniters would not be evaluated by the criteria in Section VIII.B.5.c. Only if the change affected other aspects of the licensing basis such as design basis accidents might the change be evaluated against Section VIII.B.5.b criteria or other criteria. As discussed above, the Section VIII.B.5.b criteria do not apply to severe accidents and are not appropriate for severe accidents. The staff believes there are no advantages to this option other than burden relief for the licensee in that there is one less change control process to address. A significant disadvantage is that the licensee, under some circumstances, could make Tier 2 changes to non-ex-vessel severe accident features, up to and including removal of the equipment without prior NRC approval, if there is no Tier 1 discussion of the feature and no other regulation or change process applies.

Option 1B: Address the potential gap, by a) ensuring that there are sufficient details on all key severe accident features in Tier 1, and b) including a change process in future design certification rulemakings in Section VIII for *non-ex-vessel severe accident features* similar to Section VIII.B.5.c for *ex-vessel severe accident features*

Under this option, the staff would issue appropriate regulatory guidance to ensure that, for future design certifications, severe accident features previously reviewed by the staff and deemed important to prevent and/or mitigate the full range of severe accidents have sufficient detail in Tier 1 so as to preclude major plant changes that could remove (or significantly degrade) the performance of this equipment without prior NRC approval. Additionally, future rulemaking on design certifications could include a change process for non-ex-vessel severe accident design features that uses criteria similar to the current criteria in Section VIII.B.5.c. This option has the advantage of addressing the identified gap in the Tier 2 change control process and ensuring that significant changes to non-ex-vessel severe accident features receive the same level of screening and review as ex-vessel severe accident features. A disadvantage of this option is that it adds one or more steps in the overall change control process used by the licensees. The new guidance would not apply to already-certified designs unless backfits were pursued. Based on preliminary reviews of the DCDs for AP1000, the ABWR, and the Economic Simplified Boiling Water Reactor (ESBWR), the staff does not believe backfits are justified at this time.

Recommendation 1: The staff recommends Option 1B. The staff believes that Option 1B addresses the identified gap in the Tier 2 change control process. As discussed above, changes affecting non-ex-vessel severe accident design features would be evaluated against criteria more appropriate for severe accidents. Having sufficient detail on all key severe accident features in Tier 1 would preclude major plant changes that could remove this equipment without prior NRC approval.

2. <u>Transition from LRF to LERF</u>

As noted in the tabletop exercise results section above, staff proposes several options for Commission consideration to address the different risk metrics used during new reactor licensing and the risk-informed framework for currently operating reactors.

Option 2A: Continue use of LRF (and CCFP) indefinitely

Under this option, COL holders would continue to apply the same risk metrics used during design certification and in the COL application (i.e., CDF, LRF, and CCFP) for all risk-informed applications throughout commercial operation. This option has the advantage of maintaining the same definition of LRF and using the same risk metrics as documented in the DCD, FSAR, and the staff review documented in the final safety evaluation report (FSER). A major disadvantage is that there is presently no common definition of LRF and CCFP, neither within the NRC nor in existing or proposed consensus standards on PRA. Moreover, this option may be inconsistent with the direction provided to the staff in the SRM on SECY-10-0121, in which the Commission reaffirmed that the existing quantitative metrics for implementing risk-informed decision making are sufficient for new reactors. Implementing acceptance guidelines in RG 1.174 as well as the ROP, both of which explicitly use LERF, would be problematic for new reactors.

Option 2B: Continue use of LRF (and CCFP) indefinitely and add LERF at or prior to initial fuel load

Under this option, COL holders would continue to apply CDF, LRF, and CCFP throughout commercial operation. LERF would be added at or prior to initial fuel load, depending on whether or not the licensee proposes to implement one or more risk-informed initiative. Like Option 2A, this option has the advantage of maintaining the same definition of LRF and using the same risk metrics as documented in the DCD, FSAR, and the staff review documented in the FSER. The use of CDF and LERF for risk-informed changes to the licensing basis is consistent with RG 1.174 for currently operating reactors. Another advantage is that continued use of LRF and CCFP would support the calculation of long-term containment performance as discussed in Section 2.2 of RG 1.174. A major disadvantage is that there is presently no common definition of LRF and CCFP, neither within the NRC nor in existing or proposed consensus standards on PRA. The continued use of both LRF and LERF into commercial operation adds confusion and may be viewed as an unnecessary burden on licensees. Like Option 2A, this option may be inconsistent with the direction provided to the staff in the SRM on

SECY-10-0121 in which the Commission reaffirmed that the existing quantitative metrics for implementing risk-informed decision making are sufficient for new reactors.

Option 2C: Transition from LRF to LERF at or prior to initial fuel load; discontinue regulatory use of LRF (and CCFP) thereafter

Under this option, COL holders would not need to calculate LRF and CCFP in regulatory applications following their transition to LERF at or prior to initial fuel load, consistent with the requirement in 10 CFR 50.71(h)(1) that states that no later than the scheduled date for initial loading of fuel, each holder of a COL shall develop a level 1 and a level 2 PRA. The PRA must cover those initiating events and modes for which NRC-endorsed consensus standards on PRA exist one year prior to the scheduled date for initial loading of fuel. The current level 1 PRA standard endorsed by the NRC uses LERF. A consensus level 2 PRA standard using radionuclide release categories as end states has been drafted but, as of the issuance of this paper, has not been issued for use nor endorsed by the staff. It is expected that, by the time of initial fuel load for the first set of COL holders, such a level 2 PRA standard will be endorsed by the NRC. The staff expects that COL holders would use the level 2 PRA radionuclide release category frequencies and appropriately roll these up to LERF to meet 10 CFR 50.71(h)(1). No existing or proposed PRA standard provides a universal definition of LRF.

This option has the advantage of harmonizing the risk metrics for all reactors, both those currently operating and new reactors, going forward after commercial operation. Moreover, the option is consistent with the direction provided to the staff in the SRM on SECY-10-0121 in which the Commission reaffirmed that the existing quantitative metrics for implementing risk-informed decision making are sufficient for new reactors. A disadvantage of this option is that LRF and CCFP, which form part of the original design objective in the design certification, would no longer be tracked into commercial operation. LRF, which could be used as a measure of determining the impact of risk-informed changes on late containment failure, would no longer be available. This latter disadvantage would be partly offset by the staff's plan as discussed above to augment the existing discussion on long-term containment performance for new reactors in RG 1.174 by referring to the containment performance objectives in SECY-90-016 and SECY-93-087.

Recommendation 2: The staff recommends Option 2C. This option harmonizes the risk-informed applications for the new reactors consistent with the risk metrics used by the currently operating fleet. Moreover, the option does not introduce confusion and create burden on licensees as would be the case if both LRF and LERF were used going forward. The staff believes that adding a reference to containment performance for new reactors in RG 1.174 per SECY-90-016 and SECY-93-087 is appropriate and entirely consistent with established Commission policy.

3. ROP

As a result of the tabletop exercises, the staff has developed three options for the Commission's consideration for applying the risk-informed regulatory framework of the ROP to new reactors. These options maintain the existing risk thresholds in the current ROP risk-informed processes and are consistent with the integrated risk-informed decision-making framework in RG 1.174. In addition, these options afford new reactor licensees with greater operational flexibility than current reactors based on the enhanced safety margins of the new reactor designs. These options apply to the risk-informed reactor safety cornerstones of initiating events, mitigating systems, and barrier integrity, while the other four more deterministic cornerstones would not be directly affected. These options provide for a transparent and predictable means for the NRC to respond to events and performance issues at new reactors and perform assessments of licensee performance.

Option 3A: Use as is

Under this option, the staff would use the existing risk-informed ROP tools for new reactor applications without making any changes. The staff would:

(1) Continue to use the current SDP to process inspection findings in the reactor safety cornerstones as stipulated in Appendix A to IMC 0609, "Significance Determination Process"

(2) Continue to use the current event response guidance as stipulated in MD 8.3 and IMC 0309

(3) Continue to use the existing MSPI guidance as stipulated in NEI 99-02, "Regulatory Assessment Performance Indicator Guideline," and IMC 0608, "Performance Indicator Program," recognizing that the current MSPI guidance does not apply to passive systems

An advantage to this option is that no additional action or resources would be necessary. A disadvantage to this option is that the existing tools may not always provide for an appropriate regulatory response to address performance issues and plant events for new reactor designs.

Option 3B: Augment existing processes

Under this option, the staff would use the existing risk-informed ROP tools, but augment the qualitative tools with deterministic backstops to ensure an appropriate regulatory response for the new reactor designs. These deterministic backstops would be consistent with the licensing basis and the existing defense in depth, safety margins, and other traditional engineering principles described in RG 1.174. 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) Develop a risk-informed alternative to MSPI (new PIs or risk-informed inspection), or augment the existing MSPI guidance to place a more significant emphasis on and potentially revise the performance limit (backstop) for the active new reactor designs; also, increase inspection of passive mitigating systems as necessary to supplement insights that will not be afforded with MSPI for passive new reactor designs

Deterministic backstops would be developed and inserted into the existing risk-informed framework to address the noted shortfalls identified during the tabletop exercises under this option. The staff envisions that augmenting the existing tools with deterministic backstops would provide for a more appropriate response to performance issues and plant events for the new reactor designs, and the impact on the current fleet would be minimal because the existing risk thresholds would likely be surpassed in most cases prior to the potentially new backstops being applied. The staff also anticipates that deterministic backstops would only affect the inputs to the ROP Action Matrix (i.e., risk-informed SDP and PIs), and the ROP Action Matrix would function the same for new reactors as it does for the current fleet in determining regulatory response. The staff expects that the proposed process enhancements could be researched and developed over the next few years, using existing resources, well in advance of their potential implementation for oversight of new reactor operations. These process enhancements, if approved and implemented, would be refined based on experience and lessons learned consistent with existing provisions for ROP continuous improvement. More specific potential guidance changes to address the noted gaps in the risk-informed ROP processes are presented in Appendix B.

Under this option, the staff would obtain Commission approval for the proposed changes to the ROP prior to implementation.

Option 3C: Develop deterministic tools

Under this option, the staff would not use the existing risk-informed ROP tools for new reactor applications, but rather capture risk insights in a more simplified manner using deterministic guidance for regulatory decision making consistent with new reactor design certification and licensing basis. The staff would:

(1) Develop a deterministic SDP to characterize the significance of inspection findings in the reactor safety cornerstones for new reactor designs

(2) Develop deterministic event response criteria for MD 8.3 that would apply to new reactors and guide reactive inspection outcomes

(3) Develop deterministic PIs or additional inspection activities in the mitigating systems cornerstone to replace the MSPI for the new reactor designs

New deterministic guidance would be developed to replace the existing risk-informed ROP tools under this option. Risk insights would be captured, but to a much lesser extent than they are for the current fleet. Additional resources may be necessary to research and develop the new guidance documents.

Under this option, staff would obtain Commission approval for the proposed changes to the ROP prior to implementation.

Recommendation 3: Staff recommends Option 3B. The staff would work with internal and external stakeholders to formulate the process changes as necessary to provide for an appropriate regulatory response for new reactor applications. The staff would provide a paper to the Commission with its proposed ROP guidance changes at least one year prior to their scheduled implementation.

COORDINATION:

This paper has been coordinated with the Office of the General Counsel, which has no legal objection. A copy of this paper has been provided to the Advisory Committee on Reactor Safeguards.

R. W. Borchardt
Executive Director
for Operations

Appendix A: Licensing Tabletop Exercise Results

1. Risk-Informed Inservice Inspection of Piping

The staff held a one-day public workshop on May 4, 2011. The Electric Power Research Institute (EPRI) first provided an overview of its methodologies on RI-ISI of piping. The staff then provided sample results from actual licensee submittals for currently operating reactors supporting the point that the theoretically calculated changes in CDF and LERF are sometimes positive, sometimes negative, but virtually always low in absolute magnitude. EPRI also provided scoping calculations of the potential impact of a RI-ISI program for a new active plant and a new passive plant that showed the effects continued to be risk-neutral, even when sensitivity studies using more restrictive acceptance criteria were assumed. The staff observed that RI-ISI simply changes the locations for inservice inspection in a risk-informed manner. Neither the design nor plant operational configurations are affected by RI-ISI.

Staff identified the features as well as regulatory and programmatic controls that strengthen the RI-ISI program and tend to limit the decrease in enhanced safety margin of the new reactor designs. These controls are discussed in greater detail in the meeting summary package (ML111330381). Several key features include, for example:

- The guidelines on potential increases to the baseline CDF and LERF are imposed at a system level as well as the overall totals. This ensures that no one system absorbs most of the change in risk, and helps to address uncertainty in system-level risk results.
- Inspection of a minimum set of weld locations is required regardless of what the risk levels are calculated to be. This is a deterministic feature providing additional safety margins.
- A number of programs remain in place to address degradation mechanisms such as flow accelerated corrosion and microbiologically induced corrosion. These programs provide added levels of assurance to the risk-informed elements of RI-ISI.

The general consensus of the staff and participating stakeholders from the tabletop exercise is that use of the current guidance for RI-ISI for a new reactor design with sufficient operating experience would not result in any significant decrease in enhanced safety.

There are some potential regulatory and implementation issues that would need to be addressed if RI-ISI was applied to a new plant lacking operating experience. Also, a conventional ISI program per 10 CFR 50.55a, “Codes and Standards,” is presently a requirement to implement RI-ISI. However, these are not issues central to the risk-informed framework.

2. Risk-Informed TS Initiative 4b (Completion Times) and Maintenance Rule Section (a)(4)

The staff held a two-day public workshop on May 26, 2011, and June 1, 2011. The staff addressed RITS 4b and (a)(4) of 10 CFR 50.65 together because of the complementary nature of risk-managed TS and the management of the risk increase that may result from the proposed maintenance activities. The staff led the workshop by providing a brief overview of the RITS 4b methodology. A representative of the South Texas Project (STP) provided a comprehensive discussion of the implementation of RITS 4b at STP Units 1 and 2. The representative also highlighted the use of the on-line risk monitoring tools, case studies, best practices, and important lessons learned. The staff then presented calculation results using SPAR models for internal events for the ABWR and AP1000 reactor designs. The configurations that were tested spanned a wide range from single equipment outages to multiple equipment outages across safety divisions. The staff identified some configurations of equipment outages with an ICDP that would, in effect, represent 10 or more years of core damage probability. Repeated entry into such condition over time could increase CDF by one or more orders of magnitude, which could approach the baseline CDF of currently operating plants. The staff, however, believes these configurations are unlikely or unrealistic, and that there were numerous programmatic and regulatory controls that would limit the aggregated risk increase.

Representatives from Mitsubishi Heavy Industries (MHI), General Electric-Hitachi, and AREVA presented the results of case study calculations for the US-APWR, ESBWR, and U.S. EPR designs, respectively. In addition, the Westinghouse representative provided comments on calculations he performed that generally confirmed staff calculations using the AP1000 SPAR model. Taken as a whole, the calculations indicated that two major features of RITS 4b tended to limit the potential risk increase from various maintenance configurations, specifically:

- The risk-informed completion time is limited to a deterministic maximum of 30 days (referred to as the backstop completion time) from the time the TS action was first entered.

- Voluntary use of the risk-managed TS for a configuration which represents a loss of TS specified safety function, or inoperability of all required safety trains, is not permitted.

When comparing RITS 4b to existing standard TS that provide fewer controls on the frequency of entering certain limiting conditions for operation, staff notes that it is conceivable that implementation of RITS 4b may be shown to be no worse than “risk neutral.” The key to ensure that risk does not increase over time is to limit the frequency of entering higher risk maintenance configurations that could otherwise have the effect of increasing the baseline CDF. Performance monitoring under NEI 06-09, RG 1.174, and RG 1.177 are therefore key programmatic controls. Additional discussion on regulatory and programmatic controls can be found in the meeting summary packages (ML111650176 and ML111650341).

The general consensus of the staff and participating stakeholders from the tabletop exercise is that no substantive changes to methodology are necessary to implement RITS 4b for new reactor designs. Similar to RI-ISI, however, certain implementation and process issues may need to be addressed before implementing RITS 4b. The MHI application for RITS 4b in the US-APWR standard design and Luminant’s COL application for Comanche Peak Units 3 and 4 in particular, will in essence pilot this effort for new reactor designs. Lessons learned may result in a supplement to NEI 06-09.

A related topic to RITS 4b is implementation of 10 CFR 50.65(a)(4) at new reactor designs. Industry representatives began the discussion by providing a detailed overview of the

10 CFR 50.65(a)(4) experience, as well as a demonstration of a widely-used risk monitor tool. The blended approach whereby the PRA is combined with inputs on the degree of defense in depth and plant transient assessment was highlighted. The staff observed that factors other than PRA were often more limiting in terms of the risk management action level. Finally, the staff presented the results of 10 CFR 50.65(a)(4) inspection experience over a 10-year time frame. Of 116 violations that occurred during this time, all were categorized as very low risk significance (green) findings.

The general consensus of the staff and participating stakeholders from the tabletop exercise on Section (a)(4) of the maintenance rule as it pertains to new reactor designs is that Section 11 of NUMARC 93-01 (endorsed in RG 1.182) does not appear to need substantive change to address qualitative and quantitative considerations in the assessment and management of risk for new reactor designs. Of note is Section 11.3.7.2 of NUMARC 93-01 that states:

> Due to differences in plant type and design, there is acknowledged variability in baseline core damage frequency and large early release frequency. Further, there is variability in containment performance that may impact the relationship between baseline core damage frequency and baseline large early release frequency for a given plant or class of plants. Therefore, determination of the appropriate method or combination of methods as discussed above, and the corresponding quantitative risk management action thresholds, are plant-unique activities.

It is noted that some changes to NUMARC 93-01 may be necessary to address changes of scope because of new and different SSCs in the new reactor designs.

3. <u>Risk-Informed TS Initiative 5b (Surveillance Frequency Control Program)</u>

The staff held a one-day public workshop on June 29, 2011. The staff began by providing an overview of the surveillance frequency control program (SFCP). The implementation process and administrative controls were also discussed. Representatives from industry discussed their experience of implementing RITS 5b per NEI 04-10, "Risk-Informed Method for Control of Surveillance Frequencies," at several operating nuclear power plants. Issues such as scope, commitment review, defense-in-depth review, operating experience review, and performance monitoring were highlighted. The results of several sensitivity studies performed by Westinghouse for the AP1000 reactor design were also summarized. Potential risk increases were calculated to be very low, with changes in CDF in the range of 10^{-9}/yr to 10^{-7}/yr.

Staff identified the regulatory and programmatic controls that strengthen the RITS 5b program and tend to limit the decrease in enhanced safety margin of the new reactor designs. These include, for example:

- Surveillance frequencies that are controlled by other programs are excluded from the SFCP. Equipment covered by inservice testing, for example major pumps and valves, tend to have some of the highest risk importance values but are excluded. What remains to be implemented under RITS 5b generally are lower risk importance components.

- The integrated decision-making panel's (IDP) review of proposed changes is seen as strengthening the process. A broad range of expertise is brought to bear on the subject matter.

- RITS 5b is implemented using a phased approach whereby surveillance test intervals are gradually increased from, for example, monthly to quarterly to annually. This provides reasonable assurance that failure rate changes are identified and addressed before becoming unacceptably high.

- Monitoring and feedback, and periodic re-assessment (e.g., every six months) are fed back to the IDP. Actual changes in the reliability of equipment modeled in the PRA are included in the periodic updates. If a change is found to result in unacceptable equipment performance, the IDP may take corrective action by returning the surveillance frequency to the previous setting.

- The impact of changes under the SFCP on defense in depth, maintenance rule (e.g., Section (a)(1)), the MSPI, and other programs are generally assessed. Often, these programs limit the scope of RITS 5b changes because of the potential to reduce operational and safety margins.

The general consensus of the staff and participating stakeholders from the tabletop exercise on RITS 5b is that the program is much more deterministically oriented than RITS 4b (completion times) where the quantitative risk assessment is key to the application. In RITS 5b, risk impact is only a secondary consideration in the criteria for changing surveillance test interval. Participants in the workshop recognized the need to obtain sufficient baseline operating experience on affected equipment during the initial cycle or cycles of reactor operation before commencing full implementation of RITS 5b in the new plants. A detailed discussion of the workshop can be found in the meeting summary package (ML11182A976).

4. <u>Risk-Informed Categorization and Treatment of Structures, Systems and Components, 10 CFR 50.69</u>

The staff held a one-day public workshop on August 9, 2011. EPRI first provided an overview of the methodologies on risk-informed categorization and treatment of active and passive components under 10 CFR 50.69 per guidance in NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline." ASME Code Cases N-660, "Risk-Informed Safety Classification for Use in Risk-Informed Repair/Replacement Activities," and draft N-752, "Risk-Informed Safety Classification and Treatment for Repair/Replacement Activities in Class 2 and 3 Moderate Energy Systems" were also briefly discussed. For passive components (e.g., piping), there is consistency with the risk-informed inservice inspection of piping program. The important role of the IDP was also highlighted. Representatives from industry discussed some of the considerations for new reactor designs. Participants noted that typically only 2000 components may be modeled in the PRA, leaving thousands of other components to be classified on the basis of criteria other than risk. Finally, EPRI discussed sample categorization for a new pressurized water reactor design with active safety features. The RISC-1, 2, 3, and 4 categorization distribution mirrored results from STP Units 1 and 2, recognizing that the classification for the new design was based strictly on risk importance measures and had not been through the IDP. A sample categorization for active and passive components in a new reactor safety injection system was also provided.

Meeting participants identified the features as well as regulatory and programmatic controls that strengthen the 10 CFR 50.69 program and tend to limit the decrease in enhanced safety margin of the new reactor designs. These include, for example:

- 10 CFR 50.69 does not change the nuclear plant system designs, but simply changes the treatment of SSCs.

- NRC staff review and approval of a license amendment request is required. Typically, methods and sample results are provided to the staff as part of the review cycle.

- For passive reactor designs, there is strong overlap between the regulatory treatment of non-safety systems (RTNSS), previously reviewed by the staff, and the RISC-2 SSC components.

- For RISC-3 components, there are regulatory requirements for performance monitoring and timely corrective action. Periodic review of the program is also required.

The staff has concluded that passive system categorization (e.g., piping) is similar to RI-ISI, which an earlier tabletop demonstrated no decrease in enhanced level of safety. Categorization of active components (e.g., pumps and valves) are based on *relative* risk importances, independent of baseline risk, so one should not expect adverse impact on enhanced safety for new designs. A detailed discussion of the workshop can be found in the meeting summary package (ML112290891).

5. <u>Guidance in NEI 96-07 Appendix C on the 10 CFR Part 52 Change Process</u>

In conjunction with the Changes during Construction working group within the agency, the staff held a one-day public workshop on December 2, 2010, prior to the issuance of the Commission’s SRM on SECY-10-0121, to address the 10 CFR Part 52 change process specific to EVSA design features (ML110130408). Follow-up discussions were held on August 9, 2011 (ML112290891), and again on November 15, 2011 (ML113320197), in which the staff provided further comments on some of the broader 10 CFR Part 52 change processes in the draft Appendix C of NEI 96-07.

During the 2010 workshop, staff discussed the requirements as codified in Section VIII.B.5.c of each appendix to 10 CFR Part 52 regarding the criteria for departures from Tier 2 affecting resolution of EVSA design features that would require a license amendment. There was consensus on the part of staff and stakeholders present that the current rules and guidance may not be complete. Certain severe accident features (e.g., features to prevent containment bypass and containment hydrogen mitigation equipment such as igniters) do not address “ex-vessel” conditions, as defined in the statement of considerations for the rule.

In the current regulation, changes to severe accident design features that are not specifically intended to address EVSAs are not addressed using severe accident criteria as in Section VIII.B.5.c. Depending on the nature of the change, the licensee must follow one of the other change procedures in the rule, either Section VIII.B.5.a or VIII.B.5.b, using the guidance in Section 4.4.3.2 of the draft Appendix C to NEI 96-07. If the change falls under the requirements of Section VIII.B.5.a, then the licensee could make the change without prior NRC approval. Section VIII.B.5.b, however, explicitly excludes changes to severe accident features. Moreover, the criteria of VIII.B.5.b generally ask if there is “more than a minimal increase” in frequency of occurrence or consequences of an accident previously evaluated in the plant-specific DCD. While not stated explicitly in the rule, it is clear from the statement of considerations that design basis accidents are intended here. The EVSA criteria in Section VIII.B.5.c use “substantial increase” in probability and public consequences as the standard for determining whether prior NRC approval is required. The latter criteria are less stringent and are more appropriate for non-ex-vessel severe accident design features given the large uncertainties associated with severe accident phenomena and the ability of analysts to precisely determine the impact of the change on probability and consequences.

Unless such non-ex-vessel severe accident design features also happen to have a dual function such as also addressing design basis accidents or aircraft impacts, risk-significant Tier 2 changes (e.g., Chapter 19 information related to prevention and mitigation of severe accidents other than those considered “ex-vessel”) could be screened out altogether and not receive prior NRC approval. Fortuitously, the staff has observed that Tier 1 descriptions usually have sufficient detail as to necessitate prior staff review for major changes to severe accident design features. The staff believes, however, that there is a “gap” with regard to the Tier 2 change process for non-ex-vessel design features, in that: a) such changes may be screened out or less appropriate criteria are applied when determining whether prior NRC approval is needed, and b) whether or not prior NRC approval is obtained may be highly dependent on the degree of detail in Tier 1, if any. The staff has provided options and a recommendation to the Commission in this paper to address the potential “gap” in the 10 CFR Part 52 change process.

6. <u>Guidance on Risk-Informed Changes to the Licensing Basis, RG 1.174</u>

The staff dedicated a significant portion of the October 5, 2011, public workshop to addressing the use of RG 1.174 for new reactors. The staff first discussed the five principles of risk-informed decision making, including the defense-in-depth philosophy and the acceptance guidelines for change in risk. To test the application of RG 1.174, eight cases representing actual or hypothetical changes were presented and the assessment process for determining the acceptability of the change was discussed. The staff noted that since it was highly unlikely that a COL holder would propose a license amendment request to completely remove a Tier 1 system, the most likely changes would be regarding *how* the existing system is to be categorized, operated, and maintained.

The following observations from the tabletop exercise are noted:

- While a proposed change might have acceptably low change in CDF (ΔCDF) and low change in LERF (ΔLERF), if the change adversely impacts equipment that provides defense-in-depth capability via redundancy and/or diversity, this could be cause of staff rejection of the proposed change. Thus, a low ΔCDF and low ΔLERF are necessary but not sufficient conditions for a change to be considered acceptable by the staff.

- A significant change in risk profile, or where operator action is substituted for an automatic function, also would be areas of close review by the staff.

- Proposed changes in or near the boundary of Region II in the acceptance guidelines would undergo close scrutiny by the staff, and there would need to be a compelling reason on the part of the license holder for the proposed change. Serious consideration of alternatives with lower risk impact would need to be assessed by the licensee.

The general consensus of the staff and participating stakeholders from the tabletop exercise on RG 1.174 is that no substantive changes to the key principles and other guidance to address new reactors are necessary. However, staff plans to augment the existing discussion on long-term containment performance in Section 2.2 of RG 1.174 by referring to the containment performance objectives for new reactors as described in Commission-approved guidance such as SECY-90-016 and SECY-93-087. A detailed discussion of the workshop can be found in the meeting summary package (ML11291A076).

7. <u>Transition from LRF to LERF</u>

The second topic discussed during the October 5, 2011, workshop was regarding potential options for transitioning from LRF and to a lesser extent on CCFP as risk metrics used in new reactor design certifications and COL applications, to LERF used in the risk-informed regulatory framework for currently operating reactors.

As discussed in Enclosure 1 to SECY-10-0121, the Commission had earlier requested the staff to provide a definition of LRF, but in SECY-93-138, “Recommendation on Large Release Definition,” dated May 19, 1993, the staff recommended, and the Commission approved, termination of work on a definition. As a result, the definitions of LRF in the DCDs referenced in COL applications all differ to varying extents. Because of the conservative definitions of LRF used in the DCDs, however, the staff has been able to review the PRA and severe accident evaluation portions of the DCDs to provide reasonable assurance that the Commission’s objectives as described in key policy papers such as SECY-90-016 and SECY-93-087 are fully addressed. Additional discussion on the evolution of LERF from LRF can be found in the attachment of Enclosure 2 to SECY-10-0121.

The staff identified three possible options for the transition from LRF to LERF, and discussed the advantages and disadvantages of each. While the staff reserved final judgment during the workshop regarding which of three possible options it preferred, the industry representatives clearly preferred the option in which the use of LRF would no longer be required for regulatory applications once they transitioned to LERF at or before initial fuel load; LERF would be used going forward during plant commercial operation. The staff has provided options and a recommendation to the Commission in this paper to address the issues.

8. Other Risk-Informed Applications *Not* in Tabletop Exercises

Other risk-informed initiatives that were not discussed in any depth during the series of tabletop exercises were briefly reviewed during the October 5, 2011, workshop. These include:

- RG 1.175
- NEI 94-01
- RG 1.183
- Draft Final Rule 10 CFR 50.46a
- NFPA 806

Participants in the workshop noted that for most of these activities there appeared to be very limited short-term interest by future COL holders, and the staff's decision not to perform tabletops was reasonable. The staff noted that alternative radiological source terms already have been applied at most of the new reactor designs. Additionally, all risk-informed changes to the licensing basis would fall under the general guidance in RG 1.174.

Appendix B: ROP Background and Tabletop Exercise Results

ROP Framework and Risk-Informed Guidance

Some of the key tenets of the ROP and the drivers in its development were (1) to improve the objectivity of the oversight processes such that subjective decision-making is minimized, (2) to improve the scrutability and predictability of NRC actions such that regulatory response has a clear tie to licensee performance, and (3) to risk-inform the processes so that NRC and licensee resources are focused on performance issues with the greatest impact on safe plant operation. Consistent with RG 1.174, the ROP's risk-informed processes integrate risk insights with more traditional deterministic factors (such as defense in depth and maintaining safety margins) to guide regulatory decision making.

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 cornerstones that reflect the essential safety aspects of facility operation. These seven cornerstones include: 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 of safe facility operation and that the NRC's safety mission is being accomplished. Each cornerstone contains inspection procedures and PIs to ensure that their objectives are being met. Both inspection findings and PIs are evaluated and given a color designation based on their safety significance, and this designation feeds the ROP Action Matrix to determine a predictable regulatory response.

SDP implementation guidance is contained in IMC 0609. IMC 0609, Appendix A, "Determining the Significance of Reactor Inspection Findings for At-Power Situations," is used to determine risk-significance of performance deficiencies in the initiating events, mitigating systems, and barrier integrity cornerstones. Risk thresholds are a function of changes in CDF and LERF against a plant's baseline risk. For those relatively infrequent cases when the PRA methods and tools are not adequate to provide reasonable and timely estimates of safety significance, the staff uses Appendix M, "Significance Determination Process Using Qualitative Criteria," and considers the best available information and factors such as defense in depth, safety margins, and the potential for plant-wide impacts attributable to the performance deficiency to determine the safety significance in those cases. Several additional SDPs are more subjective to determine an equivalent regulatory response (i.e., emergency preparedness, radiation safety, security, etc).

Implementation guidance for the PI program, including but not limited to MSPI, is contained in IMC 0608. More detailed guidance on the data collection and PI calculations are contained in NEI 99-02, which is jointly produced and maintained by NEI and the NRC. The MSPI covers five systems important to safety, and tracks the unavailability of monitored trains and the unreliability of monitored components. The MSPI calculation reflects the deviation of a specific unit's performance from an industry baseline, converted to a simplified ΔCDF. A performance limit, or deterministic backstop, is also used for determining degraded performance.

The implementation guidance for NRC's response to events is contained in MD 8.3 and supplemented by IMC 0309. Deterministic criteria are used for initial event screening, and a range of risk thresholds are subsequently applied to determine if a reactive inspection will be launched. The risk-informed reactive inspection thresholds are a function of CCDP and conditional large early release probability (CLERP). An overlap of options provides flexibility based on uncertainty and deterministic insights, and additional deterministic criteria are reviewed and documented as the basis for staff decisions on the appropriate regulatory response. While these ranges offer some flexibility for determining the level of event response, they still involve thresholds based on risk values.

<u>ROP Tabletop Results</u>

The staff held a half-day public workshop to discuss the ROP-related tabletops on the afternoon of October 5, 2011 (ML11291A076). A brief follow-up public meeting was held on October 26, 2011 (ML11308A542). The ROP tabletops tested various realistic 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 decision-making 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 SDP findings, 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 (ML11308A354).

As a result of the ROP tabletops, the staff noted the following observations and potential process improvements.

- **SDP:** Although less likely (and less frequently), the case studies demonstrated that an increased regulatory response can be triggered based on surpassing greater-than-green risk-thresholds for inspection findings, but it would likely take common-cause failures that affect multiple systems and/or long-term exposures of risk-significant components. In addition, the analyses for the current fleet are often influenced by uncertainties and/or sensitivities of critical parameters which influence the numerical results, and this is expected to continue to be true for future reactors. The SDP analyses for new reactor designs may need to be augmented with additional qualitative considerations to provide a deterministic backstop to appropriately respond to performance issues.

- **Event Response:** Although less likely (and less frequently), the case studies demonstrated that the numeric thresholds for invoking reactive inspections, including AITs, can be met. In the current guidance and practice, deterministic criteria are used for initial event screening, and ranges of risk values are subsequently applied to determine the level of reactive inspection. While these ranges offer some flexibility in determining the regulatory response, they involve thresholds based on risk values that significantly influence regulatory outcomes governing whether or not a reactive inspection is warranted and, if so, at what level. The tabletop exercises also revealed the potential for inadequate response as a function of variations in or minor revisions to the risk models used in the calculations. Therefore, the contribution of the existing deterministic criteria may need to be modified, or new deterministic criteria or backstops may need to be developed, to appropriately respond to plant events.

- **MSPI:** The cases indicated that it would be rare and unlikely to cross greater-than-green MSPI thresholds for active new reactor designs. The performance limit (deterministic backstop) would play a more significant role and could be emphasized for the new reactor MSPI. Passive designs are too different to evaluate at this time and an MSPI may not be possible for passive systems without significantly altering the fundamental methodology in NEI 99-02 used for active safety systems. Given the anticipated low utility of this indicator for new reactor designs, it may be of limited value for licensees to create an MSPI basis document and track and report MSPI data. Alternate mitigating system performance indicators could be developed, and/or additional inspection could be used to supplement or complement insights currently gained through MSPI.

The staff also noted that several current regulatory and programmatic controls exist and can be leveraged as necessary, including:

- The ROP self-assessment process 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.

- All performance deficiencies (including green) are entered into the licensee's corrective action program, and receive attention by licensees and the NRC. They would also be considered for cross-cutting aspects in accordance with the current process.

- 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 identified the following limitations in the scope of its tabletop analysis:

- The best available data were used to perform the analyses for the tabletop exercises. The SPAR models and new reactor vendors' risk models used for these case studies are still being refined and reviewed for quality and accuracy, and any future changes could potentially affect the risk values.

- Only limited consideration was given to passive systems and components for these case studies. Potential passive design issues may need to be taken into account for the new reactor designs in the future.

- The ROP tabletops were limited to the risk-informed reactor safety cornerstones of the ROP: initiating events, mitigating systems, and barrier integrity. The more deterministic cornerstones of emergency preparedness, public radiation safety, occupational radiation safety, and security were not directly addressed.

Potential Changes to ROP Guidance Documents to Address Shortfalls

The staff could revise existing guidance to address the noted gaps in the risk-informed SDP, event response, and MSPI applications for new reactors identified by participants during the ROP tabletop exercises.

For example, the staff could revise relevant portions of IMC 0609 and its appendices to reflect the additional deterministic criteria for use in the SDP, which could involve revising Appendix A, Appendix M, and/or creating an additional appendix as necessary. The staff could also revise IMC 0309, and potentially MD 8.3, to add specific deterministic criteria and/or clarify the guidance to promote a more holistic and integrated approach to event response based on both risk-informed and deterministic factors. The staff could also revise the PI guidance in IMC 0608 and/or inspection guidance in IMC 2515, "Light-Water Reactor Inspection Program – Operations Phase," and work with industry to revise NEI 99-02 to reflect the program revisions necessary to compensate for the loss of MSPI insights.