

**NOTE:** *Public availability of this draft document in advance of its discussion at the October 19, 2015, ACRS subcommittee meeting is intended to inform stakeholders of the current status of the NRC staff's evaluation of possible activities in response to NUREG-2150, "A Proposed Risk Management Regulatory Framework."*

*The NRC is not currently accepting public comments on the information below.*

*Please note that this draft document may be incomplete or in error in one or more respects and may be subject to further revision before the NRC staff provides its formal recommendations to the Commission in a SECY paper expected in December 2015.*

**FOR:** The Commissioners

**FROM:** Victor M. McCree  
Executive Director for Operations

**SUBJECT:** RECOMMENDATIONS ON ISSUES RELATED TO IMPLEMENTATION OF A RISK MANAGEMENT REGULATORY FRAMEWORK

**PURPOSE:**

The purpose of this paper is to seek Commission direction on two issues related to the U.S. Nuclear Regulatory Commission (NRC) staff's evaluation of NUREG-2150, "A Proposed Risk Management Regulatory Framework," (RMRF) (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12109A277, dated April 2012). The paper also informs the Commission of planned actions related to two improvement activities that the staff is pursuing and provides the Commission with a "description of any interrelationships of ongoing risk-informed initiatives" as requested in the staff requirements memorandum (SRM) for SECY-13-0132, "U.S. Nuclear Regulatory Commission Staff Recommendation for the Disposition of Recommendation 1 of the Near-Term Task Force Report," (ADAMS Accession No. ML14139A104, dated May 19, 2014).

**SUMMARY:**

This paper has four sections. In Section I and Section III, the NRC staff requests Commission direction on two issues related to an RMRF. In Section II, the staff provides its plans for two "improvement activities" from Fukushima Near-Term Task Force (NTTF) Recommendation 1. In Section IV, the NRC staff presents the interrelationships of ongoing risk-informed initiatives.

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These sections are summarized as follows:

- I. Path forward for enhancing the risk management approach used to ensure nuclear power reactor safety. The staff recommends that the Commission use its existing regulatory framework to continue to make risk-informed regulatory improvements in an incremental manner.
- II. Re-evaluation of Improvement Activities 1 and 2 from Fukushima NTTF Recommendation 1. The staff does not plan to establish a formal design basis extension category of requirements or to develop a definition of and criteria for determining adequacy of defense in depth at the current time.
- III. Consideration of an overarching, agencywide policy statement on using the risk management approach. The staff recommends that the Commission not develop and issue an agencywide risk management policy statement.
- IV. Description of the interrelationships between ongoing risk-informed nuclear power reactor safety initiatives.

## I. PATH FORWARD FOR ENHANCING THE RISK MANAGEMENT APPROACH USED TO ENSURE NUCLEAR POWER REACTOR SAFETY

### Background

In early 2011, the NRC formed a Risk Management Task Force (RMTF) to evaluate how the agency should be regulating 10 to 15 years in the future. The task force report, NUREG-2150, was published in April 2012. The report provides findings and recommendations in two categories. The first category addresses strategic, agencywide issues, and recommends that “[t]he NRC should formally adopt the proposed Risk Management Regulatory Framework through a Commission Policy Statement.” The second category addresses what changes could be made in specific regulatory program areas (power reactors, nuclear materials, etc.) in the next several years to support implementation of the risk management regulatory framework.

On June 14, 2012, the NRC Chairman issued a tasking memorandum, “Evaluating Options Proposed for a More Holistic Risk-Informed, Performance-Based Regulatory Approach” (ADAMS Accession No. ML121660102). In it he directs the NRC staff to “... review NUREG-2150 and provide a paper to the Commission that would identify options and make recommendations, including the potential development of a Commission policy statement.”

### NRC Staff Evaluation and Recommendation

The NRC staff determined that the existing Policy Statements on “Safety Goals for the Operation of Nuclear Power Plants” (51 FR 30028; August 21, 1986), and “Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities” (60 FR 42622; August 16, 1995), in concert with regulatory guidance and increasing experience with risk-informed regulation and integrated risk-informed decision-making processes, have established most of the key aspects

of an RMRF<sup>1,2</sup> for the nuclear power reactor safety program area. The staff then considered whether the NRC should continue to improve its risk-informed approach to nuclear power reactor safety in an incremental manner under the present framework or undertake a larger effort to make more sweeping changes. The staff recommends that the NRC maintain its current regulatory framework and continue to make risk-informed regulatory improvements on an incremental basis.

Recent regulatory improvements undertaken in response to the Fukushima Dai-ichi accident are being successfully implemented under the current regulatory framework. Maintaining the existing regulatory framework and processes would maintain the approach to regulation that has been successful and is well-understood. Although there would be no wholesale or programmatic changes to existing NRC policies or processes, the NRC would continue to make regulatory improvements as needed on a case-by-case basis, whenever identified in the course of existing regulatory processes and programs. Emergent issues with potential safety impact, such as the actions stemming from the Fukushima accident, would continue to be handled by existing regulatory processes. All ongoing and planned risk-informed initiatives would continue. The current framework and regulatory processes would continue to evolve and improve in response to new operating experience and new information, just as they have in the past.

Furthermore, in its SRM on SECY-15-0050, “Cumulative Effects of Regulation Process Enhancements and Risk Prioritization Initiative” (August 25, 2015), the Commission stated:

*The staff should use its existing authority to ensure that the NRC’s regulatory actions are properly prioritized, taking into account risk information and other factors. The staff should also use existing agency processes under 10 CFR 50.12 and 10 CFR 50.90 to apply risk-informed decision-making in its review of relief requests such as licensee exemption requests.*

Consistent with this direction, numerous initiatives are already underway that will advance risk-informed decision-making by using existing agency processes under the current regulatory

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<sup>1</sup> NUREG-2150 identifies four elements as being the components of an RMRF. The existing nuclear power reactor safety regulatory framework includes similar elements as indicated below:

1. Mission – Public health and safety; common defense and security; protect the environment
2. Objective – Manage the risks via current regulations, guidance, and oversight (including defense-in-depth, safety margins, single failure criterion, fail-safe design, reactor oversight program, etc.)
3. Goal – Provide sufficient risk-informed and performance-based protections to ensure risks are acceptably low (using the Commission’s Safety Goal Policy Statement and subsidiary risk metrics)
4. Decision-making Process that includes monitoring and feedback - LIC-504, “Integrated Risk-Informed Decision-Making Process for Emergent Issues;” Regulatory Guide 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis;” Generic Issues Program; Operating Experience Program; Accident Sequence Precursor Program; Industry Trends Program, etc.

<sup>2</sup> The NRC’s current regulatory framework for power reactor safety is similar to RMRF Alternative 1: NRC Identifies Design Enhancement Events, as described in Section H.2.1 of Appendix H to NUREG-2150. NUREG- 2150, however, did not recommend Alternative 1 because this approach does not systematically use plant-specific risk information to identify and mitigate possible vulnerabilities that are not identified by a generic regulatory framework.

framework. For example, the staff is applying lessons learned from the NFPA-805 (Risk-Informed Fire Protection) experience that will facilitate more efficient and effective risk-informed licensing reviews in the future. Multiple risk-informed technical specification initiatives are being pursued. In the area of oversight, the staff is looking at options for risk-informing operability issues of low safety significance. In rulemaking, the staff is evaluating how risk insights can be considered at an early stage in the decision on whether to pursue a new requirement. Both industry's and NRC's Risk-Informed Steering Committees are working together to expand the use of risk information in regulatory decision-making. The staff will continue to use risk insights to evaluate existing processes to ensure that they maintain safety in an efficient and effective manner.

During its evaluation, the NRC staff requested public comments on various regulatory framework alternatives. These comments are summarized in Enclosure 1. As shown in Enclosure 1, public comments were highly supportive of maintaining the current regulatory framework.

### Consideration of Alternatives

The staff considered several different alternatives in its evaluation. One alternative was to implement an RMRF approach derived from NUREG-2150<sup>3</sup> under which the NRC would develop a plant-specific regulatory framework for nuclear power reactors. Under this approach, the NRC would develop a regulation requiring all licensees to have plant-specific PRAs meeting specified criteria.

The NRC would specify criteria to create a "design enhancement category" of events that complement design-basis accidents and transients to provide additional safety and facilitate future plant-specific changes to existing design basis requirements. A formal, risk-informed decision-making process would be implemented similar to the process described in Chapter 3 of NUREG-2150.

Public comments received on this alternative (see Enclosure 1) were not supportive, noting that the substantial resource burden<sup>4</sup> it would impose on current operating reactor licensees is not likely to be justified by its benefits. The staff agrees with public commenters that this approach should not be implemented for currently operating nuclear power reactors.

The NRC staff also evaluated an "in between" approach that would allow licensees to voluntarily choose to implement a risk-informed alternative licensing basis. Under this alternative, licensees and applicants of plants with suitable PRA models would be able to risk inform how they address certain accidents and transients included in their licensing basis without the need

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<sup>3</sup> NUREG-2150 described how the suggested approach could enable cost-effective changes in the handling of design-basis events if pursued in a planned and deliberate manner. Such a long term approach would, however, require coordinated programs within the NRC and with the nuclear industry and other stakeholders. Internal discussions and the NRC staff's interactions with external stakeholders have not identified the agreements and commitments needed to support the long-term approach envisioned by the RMRF.

<sup>4</sup> This burden is mostly related to the high cost of upgrading licensee PRAs to a level that would be suitable for making substantive changes to a facility's current licensing basis. The staff's estimate of the cost to upgrade PRAs for the existing operating reactor fleet are provided in Attachment 1 to Enclosure 1 of SECY-13-0132.

for submitting an exemption request under 10 CFR 50.12. Licensees and applicants would also be required to mitigate any identified risk-significant events and accident sequences in accordance with criteria to be developed by the NRC. The NRC staff held a public meeting on July 29, 2015, to discuss this approach with stakeholders<sup>5</sup>. As a result of this meeting, the NRC re-opened the public comment period to ensure that stakeholders could provide their views on the “in-between” alternative.

After reviewing public comments, the staff decided not to recommend this approach. As previously discussed, a number of licensing initiatives and rulemakings that would allow for greater risk-informed decision-making are already underway. These initiatives will result in risk-informed changes to the licensing basis that will allow both the NRC staff and licensees to focus resources on issues of greatest safety significance. Also, based on the stakeholder comments received (see Enclosure 1), there does not appear to be widespread stakeholder support for the “in-between” approach. Furthermore, many of the NRC and licensee resources needed to implement this option are currently assigned to other risk-informed initiatives.

## II. RE-EVALUATION OF IMPROVEMENT ACTIVITIES 1 AND 2 FROM FUKUSHIMA NTTF RECOMMENDATION 1

### Background

Recommendation 1 of the Fukushima NTTF report, “Recommendations for Enhancing Reactor Safety in the 21<sup>st</sup> Century,” (ADAMS Accession No. ML11861807, dated July 12, 2011), was to establish a “logical, systematic, and coherent regulatory framework for adequate protection that appropriately balances defense-in-depth and risk considerations.” The Chairman’s June 14, 2012, tasking memorandum on the RMTF report (NUREG-2150) directed the NRC staff to consider, when developing options for the disposition of NTTF Recommendation 1, the regulatory framework recommendations for nuclear power reactors in the RMTF report. The staff provided its evaluation of NTTF Recommendation 1 and the RMTF report recommendations related to nuclear power reactors on December 6, 2013, in SECY-13-0132. In the SRM on SECY-13-0132, the Commission closed NTTF Recommendation 1. The Commission directed the staff to re-evaluate the objectives of the staff’s proposed Improvement Activity 1 (establish a new design-basis extension category) and Improvement Activity 2 (establish Commission expectations for defense in depth) “in the context of the Commission direction on a long-term Risk Management Regulatory Framework (RMRF), more specifically, the proposed policy statement.” The staff believes that these two improvement activities are key elements involved in evaluating an RMRF for nuclear power reactors as described in NUREG-2150. Thus, the staff has re-evaluated these activities and provides its plans below to address the underlying concerns associated with these improvement activities.

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<sup>5</sup> Stakeholder feedback from industry representatives during the July 29, 2015, meeting indicated that the draft final 10 CFR 50.46a Risk-Informed Emergency Core Cooling System rule in SECY-10-0161, “Final Rule: Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements (10 CFR 50.46a),” was unlikely to be implemented by licensees because of high implementation costs. The staff believes that further stakeholder interaction is needed to determine the appropriate next steps for this potential rule. Four months after receiving the Commission’s SRM on this SECY paper, the staff will prepare a COMSECY to inform the Commission of the results of this stakeholder interaction and the staff’s associated plans and schedule for addressing 10 CFR 50.46a.

## II.A. SECY-13-0132 Improvement Activity 1 - Establish Design-Basis Extension Category

Improvement Activity 1 in SECY-13-0132 recommended that the NRC adopt a new term -- “design-basis extension” -- to define and describe the events and requirements for nuclear power plants that have typically been characterized as “beyond-design-basis” events and accidents, even though they are within the “design bases” as defined in 10 CFR Section 50.2, “Definitions.” The staff also proposed developing a standard set of “attributes<sup>6</sup>” and a standard set of treatment guidelines for each of the attributes that must be addressed for future requirements in the design-basis extension category.

### Staff Re-evaluation of Improvement Activity 1 – Design-Basis Extension Category

The primary purpose of establishing a design-basis extension category would be to ensure that all new beyond design-basis regulatory requirements properly consider each of the appropriate regulatory attributes identified in SECY-13-0132. Formal development of this new category is unnecessary if the staff develops and implements clear internal rulemaking guidance (through office instructions, etc.) to ensure consistency in specifying all necessary regulatory attributes (performance goals, treatment requirements, documentation requirements, change processes, and reporting requirements) whenever new regulations are developed. Accordingly, the NRC staff intends to use existing resources (< 0.5 full time equivalent (FTE)) to develop internal rulemaking guidance to ensure consistency in specifying necessary regulatory attributes for all new regulations.

The NRC requested public comments on its re-evaluation the NTTF Recommendation 1 improvement activities. Three public commenters provided comments (see Enclosure 1) on establishing the design-basis extension category. All three commenters agreed with the NRC staff’s preliminary determination in a May 2015 white paper that it is not necessary to establish a new category of events and associated requirements.

### NRC Staff Conclusion:

The NRC staff now believes that a new category of events should not be established. The Commission should note that the staff intends to use existing resources to develop and implement internal rulemaking guidance to ensure that all future nuclear power reactor regulations (especially those imposing beyond-design-basis requirements) include consistent and comprehensive rule language addressing all necessary regulatory attributes. This guidance will provide most of the benefits identified by the staff when Improvement Activity 1 was originally recommended to the Commission.

## II.B. SECY-13-0132 Improvement Activity 2 – Establish Commission Expectations for Defense in Depth

Improvement Activity 2 in SECY-13-0132 recommended that the NRC:

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<sup>6</sup> Attributes identified in SECY-13-0132 that should be addressed when specifying beyond-design-basis regulatory requirements include performance goals, treatment requirements, documentation requirements, change processes, and reporting requirements.

*Establish Commission expectations for defense-in-depth through the development of a policy statement that includes: the definition, objectives, and principles of defense-in-depth; associated implementation guidance containing decision criteria for ensuring adequacy of defense-in-depth; and conforming guidance to ensure integration of defense-in-depth with risk.*

The conforming guidance associated with this improvement activity would include revisions to the regulatory analysis guidelines and conforming changes to existing regulatory guides.<sup>7</sup>

#### Staff Re-evaluation of Improvement Activity 2 - Establish Expectations for Defense in Depth

The NRC staff re-evaluation concluded that developing a policy statement on defense in depth for power reactor safety was unnecessary, and that further efforts to develop a definition of and criteria for determining adequacy of defense in depth should not be pursued at this time. Instead of a policy statement, definition, and decision criteria, the staff intends to update the existing defense in depth guidance for NRC's current risk-informed evaluation process in Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis" as directed by the Commission in the SRM to SECY-11-0014, "Use of Containment Accident Pressure in Analyzing Emergency Core Cooling System and Containment Heat Removal System Pump Performance in Postulated Accidents" (ADAMS Accession No. ML110740254, dated March 15, 2011). This SRM directs the staff to revise Regulatory Guide 1.174 "using precise language to assure that the defense-in-depth philosophy is interpreted and implemented consistently. To the extent that other regulatory guidance refers to defense in depth, the relevant documents should be updated also, as appropriate." This revision was largely completed in 2011, but the activity was deferred to ensure compatibility with anticipated further direction from the Commission on the staff's recommendation in SECY-13-0132 to establish Commission expectations for defense in depth.

Public stakeholder input on the defense-in-depth improvement activity (see Enclosure 1) was provided by three parties. Two commenters supported<sup>8</sup> the development of criteria and guidance for determining the adequacy of defense in depth. Another commenter stated that the NRC needs to better define how defense in depth will be applied, but cautioned that the regulatory approach developed for nuclear power reactors may not apply uniformly to the regulation of material, waste, fuel cycle, and security.

The basis for the staff's re-evaluation of Improvement Activity 2 follows. Regarding the need for a policy statement on defense-in-depth for nuclear power reactor safety, the staff judged that the benefits of such a policy statement would not justify the resource expenditure because the defense-in-depth philosophy is already well-established in the regulations and existing Commission policy statements, such as the Safety Goal and PRA policy statements. Furthermore, the staff agrees with stakeholder comments that defense-in-depth criteria will likely differ across the various program areas, necessitating different Commission policy statements

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<sup>7</sup> A search of all power reactor regulatory guidance would be conducted to identify guidance documents that would need to be updated.

<sup>8</sup> This support was conditioned with the provision that when developed, the guidance will meaningfully integrate defense-in-depth with risk information (instead of treating the two approaches as separate decision criteria).

for program areas which develop defense-in-depth criteria. Multiple Commission policy statements could be confusing to the public and would be resource-intensive to develop.

As for defining defense in depth and developing criteria for determining its adequacy, the staff's re-evaluation of this proposed effort determined that although it could potentially succeed in establishing predictable, objective criteria for determining the adequacy of defense in depth for power reactor safety, the estimated resource requirements (6.3 FTE over a period of 3 to 4 years<sup>9</sup>) are significant. It is also possible that after spending these resources, the staff would be unable to establish predictable, objective criteria acceptable to the Commission. Based on current resource limitations, the staff believes that the NRC should not undertake this activity at the present time<sup>10</sup>.

The staff notes that the philosophy of defense in depth has been implemented in the regulations, policy statements, guidance documents, and nuclear power plant designs even without a formal definition or objective criteria for determining the adequacy of defense in depth. Under the current regulatory framework without formal decision criteria for defense in depth, the staff and the Commission have been able to make regulatory decisions on the various requirements in response to the Fukushima accident that involve major defense in depth considerations. Furthermore, in response to the Commission's SRM on SECY-11-0014, the staff will modify the Regulatory Guide 1.174 guidance on defense in depth to (1) remove ambiguity, (2) re-structure the seven elements of defense in depth to more appropriately demonstrate their relationship, and (3) add examples to provide further clarification.

#### NRC Staff Conclusion:

The NRC staff now believes that developing a policy statement on defense in depth for power reactor safety is unnecessary, and that further efforts to develop a definition of and criteria for determining adequacy of defense in depth should not be pursued at this time.

### III. CONSIDERATION OF AN OVERARCHING, AGENCYWIDE POLICY STATEMENT ON USING THE RISK MANAGEMENT APPROACH

#### Background

NUREG-2150 recommends that an agencywide RMRF be adopted by the NRC by issuing a Commission Policy Statement. If an agencywide risk management policy statement were developed and implemented, the staff believes that it could potentially make more consistent the regulatory approaches used for all program areas including reactors; industrial and medical uses of radioactive material; nuclear waste storage and disposal; fuel cycle facilities; and radioactive material transportation for both radiological safety and common defense and security.

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<sup>9</sup> See page 27 of Enclosure 1 to SECY-13-0132 on Fukushima NTF Recommendation 1.

<sup>10</sup> In a letter on August 15, 2013, (ADAMS Accession no. ML13234A022) the Nuclear Energy Institute stated its intent to develop a paper discussing appropriate considerations for a structured, risk-informed approach to defense-in-depth. Thus, it is possible that this initiative could be undertaken at a more opportune time in the future.



The NRC staff drafted an initial white paper describing a conceptual example of an RMRF policy statement (ADAMS Accession No. ML13273A517) and published a notice in the *Federal Register* on November 25, 2013 (78 FR 70354), seeking public comments on the white paper. The staff held public meetings on June 5, 2013 (ADAMS Accession No. ML13197A216) and January 30, 2014 (ADAMS Accession No. ML14064A550). Public comments on the white paper were accepted through the Federal Rulemaking Web site (<http://www.regulations.gov>) under Docket ID NRC-2013-0254. The public comments received in early 2014 on the draft conceptual agencywide policy statement varied greatly. The NRC staff's overall assessment was that the comments indicated a need for some revision to the staff's approach. A summary showing the range and variability of these public comments is available in ADAMS (see Accession No. ML15104A718).

After reviewing public comments on the initial white paper, the staff developed a revised example of an overarching risk management policy statement. This revised example policy statement was one of three issues discussed by the NRC staff in a second RMRF white paper released for public comment on May 6, 2015 (ADAMS Accession No. ML15107A402). Public comments received on the second white paper are summarized in Enclosure 1. Nine of the ten commenters recommended against developing an agencywide risk management policy statement. These commenters generally believed that the NRC could appropriately risk-inform its regulatory programs without first preparing an agencywide policy statement. The remaining commenter supported an agencywide policy statement; but stated, with respect to two key concepts that would be included, "We cannot state or endorse the concept that there is a general understanding of the terms risk-informed and defense-in-depth ..." [emphasis in original].

#### NRC Staff Recommendation:

Based on the negative feedback from public stakeholders, the NRC staff recommends against developing an agencywide policy statement. The staff believes that it would not be appropriate to divert scarce NRC and licensee resources away from more safety-significant ongoing activities.

#### IV. DESCRIPTION OF THE INTERRELATIONSHIPS BETWEEN ONGOING RISK-INFORMED NUCLEAR POWER REACTOR SAFETY INITIATIVES

Enclosure 2 provides the NRC staff's response to the Commission's request for a description of the interrelationships of ongoing risk-informed initiatives for nuclear power reactor safety.

#### COMMITMENTS:

1. The staff will use existing resources to develop and implement internal rulemaking guidance to ensure that all new nuclear power reactor regulations (especially those imposing beyond design-basis requirements) include consistent and comprehensive rule language addressing all necessary regulatory attributes (i.e., performance goals, treatment requirements, documentation requirements, change processes, and reporting requirements).
2. The staff will meet with interested stakeholders to discuss how to proceed with the draft final 10 CFR 50.46a Risk-Informed Emergency Core Cooling System rule. Four months

after receiving the Commission's SRM on this SECY paper, the staff will prepare a COMSECY to inform the Commission of the resulting plans and schedule for addressing 10 CFR 50.46a. (See Footnote 6 on page 5.)

SUMMARY OF RECOMMENDATIONS:

The NRC staff recommends that the Commission direct the staff to:

1. Maintain the current regulatory framework. All ongoing and planned risk-informed initiatives to enhance the current framework would continue.
2. Refrain from developing an overarching, agencywide risk management policy statement.

RESOURCES:

Resource needs for the staff's planned activities are minimal (less than 1 FTE) and thus are not detailed in this paper.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.

The staff met five times with the ACRS subcommittee, and once with the ACRS full committee to discuss the staff's recommendations for an RMRF. In a letter dated <INSERT DATE>, the ACRS provided its views on these recommendations (Enclosure 3). These views were addressed by the staff in its November xx, 2015, response to the Committee (Enclosure 4).

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Enclosures:

1. Summary of Public Comments on NRC Staff White Paper
2. Interrelationships of Ongoing Risk-Informed Initiatives
3. ACRS letter
4. Staff response to ACRS letter

## Summary of Public Comments on NRC Staff White Paper

The U.S. Nuclear Regulatory Commission (NRC) staff prepared a draft white paper, "NRC Staff White Paper on Options for Responding to the June 14, 2012, Chairman's Tasking Memorandum on 'Evaluating Options Proposed for a More Holistic Risk-Informed, Performance-Based Regulatory Approach'" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15107A402, dated April 20, 2015). On May 12, 2015, the NRC published a *Federal Register* notice of availability of the white paper (80 FR 27191) and provided an opportunity for public comments.

The NRC requested comments on the following topics:

- I. Three options for enhancing the risk management approach used to ensure nuclear power reactor safety.
- II. Re-evaluations of Fukushima Near Term Task Force Recommendation 1 Improvement Activity 1 – Establish a Design-Basis Extension Category of Events and Associated Regulatory Requirements and Improvement Activity 2 – Establish Commission Expectations for Defense-in-Depth.
- III. Consideration of an overarching, agencywide policy statement on using the risk management approach to ensure safety and security.

Comments were received from the following commenters:

- Commonwealth of Virginia (VA)
- Organization of Agreement States (OAS)
- Daniel Cronin (Cronin)
- Narasimha Prasad Kadambi (Kadambi)
- Nuclear Energy Institute (NEI) (2 letters)
- Connecticut Yankee Atomic Power Company (CY)
- Yankee Atomic Electric Power Company (YAEC)
- Maine Yankee Atomic Power Company (MY)
- FirstEnergy Nuclear Operating Company (FENOC)
- EnergySolutions (ES)

These comments are summarized by topic in the following discussion.

### I. Three Options for Enhancing the Risk Management Approach Used to Ensure Nuclear Power Reactor Safety

*Option 1 - Maintain the Current Regulatory Framework. All ongoing and planned risk-informed initiatives would continue.*

Four commenters (Kadambi, NEI, FENOC, and ES) provided comments on this option and all of them were in favor of maintaining the current framework.

*Option 2 - Implement a Risk-Informed Alternative Licensing Basis. The NRC would retain its existing generic regulatory structure but would promulgate a rule that allows licensees and applicants to comply with a risk-informed alternative licensing basis. The alternative licensing basis would utilize a suitable PRA model to provide plant-specific risk insights, which would be used along with the other elements of risk-informed regulation such as defense-in-depth, safety margins, and performance measurement strategies. Licensees/applicants of plants with a suitable PRA model would be able to risk inform how they address certain regulations and aspects of their licensing basis (e.g., which accidents and transients are to be included in their licensing basis). They would also be able to use the suitable PRA model to provide additional operational flexibility in responding to generic issues and informing NRC oversight activities. Licensees/applicants that choose to adopt the risk-informed alternative licensing basis would also be required to address vulnerabilities that might be identified by the plant-specific PRA. Criteria to define vulnerabilities would be developed. This option could result in eliminating or reducing requirements associated with some design-basis accidents included in a plant's licensing basis. If vulnerabilities were identified, a licensee might have to address some currently unregulated events.*

Three commenters (NEI, FENOC, and ES) provided comments on this option. All three expressed some level of interest in this approach but stated that the NRC had not yet developed sufficient implementation details regarding Option 2 to enable commenters to satisfactorily analyze its potential costs and benefits. None of these commenters recommended pursuing Option 2. One commenter (ES) stated that because of the insufficient analysis and level of detail associated with Option 2, the NRC staff should not include Option 2 in its SECY paper for the Commission.

*Option 3 - Implement the NUREG-2150 Plant-Specific Risk Management Regulatory Framework. The NRC would develop a plant-specific regulatory framework for nuclear power reactors derived from the approach recommended in NUREG-2150. A risk management goal would be established to provide protections to meet the higher level risk management objective. The NRC would issue a regulation requiring all licensees to have plant-specific PRAs meeting specified criteria. The NRC would create a "design enhancement category" of events that complement the design-basis accidents and transients to provide additional safety. A formal, risk-informed decision-making process would be implemented similar to the process described in Chapter 3 of NUREG-2150.*

Two commenters (NEI and ES) provided comments on this option. Neither commenter supported Option 3 for currently operating reactors. One commenter (NEI) stated that the approach was not viable. The other commenter (ES) stated that although insufficient implementation details had been provided by the NRC to allow an evaluation of its safety and cost benefits, Option 3 is unlikely to be justifiable for the current fleet of operating reactors. This commenter stated that Option 3 would be better applied to the next generation of power reactors.

## II. Staff Re-evaluation of NTTF Recommendation 1 Improvement Activities 1 and 2

### *Improvement Activity 1 – Design Basis Extension Category*

Three commenters (NEI, FENOC, and ES) provided comments on establishing the design basis extension category. All three commenters agreed with the NRC staff's determination that it is

not necessary to establish a new design basis extension category of events and associated requirements.

*Improvement Activity 2 – Establish Commission Expectations for Defense-in-Depth*

Three commenters (NEI, FENOC, and ES) provided comments on establishing the Commission's expectations for defense-in-depth for power reactor safety. Two of these commenters (NEI and FENOC) supported the NRC staff's recommendation to develop additional criteria and guidance on the treatment of defense-in-depth as long as the guidance meaningfully integrates defense-in-depth with risk information (instead of treating the two approaches as separate decision criteria). The third commenter (ES) also stated that the NRC needs to better define how defense-in-depth will be applied across all regulated program areas, but cautioned that the same regulatory approach may not apply uniformly to regulation of reactors, material, waste, fuel cycle, and security.

III. Consideration of an overarching, agencywide policy statement on using the risk management approach to ensure safety and security

All ten commenters provided comments on the agencywide policy statement. One commenter (OAS) supported an agencywide policy statement; but with respect to two key concepts that would be included in such a policy statement, stated:

“We cannot state or endorse the concept that there is a general understanding of the terms risk-informed and defense-in-depth ... As to defense-in-depth, this term seems to be used in multiple agencies, and we are not sure if the definition is consistent across all those agencies. If the intent is to use the same definition as that for nuclear power plants, we are not sure it transfers well to the material licensee realm.”

OAS and another commenter (VA) also stated that an agencywide policy statement should not use a risk management approach to ensure adequate protection of public health and safety. These commenters stated that the current regulatory system and processes already ensure adequate protection; thus, the policy statement should say to “[r]eview the current practices ... and provide recommendations for enhancement.”

Seven other commenters (Kadambi, NEI, CY, YAEC, MY, FENOC, and ES) recommended against developing an agencywide policy statement. In general, these commenters believed that the NRC could appropriately risk-inform its regulatory programs without first preparing an agencywide policy statement. One commenter (ES) said that a “risk management policy statement would require substantial industry resources to develop and implement without clear safety benefits.” Another commenter (FENOC) stated that “a high-level risk management policy statement that would apply to all program areas ... would be difficult to develop and implement ... [and] the resources that would be required ... could be used more effectively in other areas.”

NEI reiterated a previous PWR Owners Group comment that:

“... [t]he development, testing, and implementation of such a regulatory framework would be a significant task for one area within the NRC. Accomplishing this across the entire agency in a coordinated, consistent manner

would appear to be an extremely challenging task for the NRC that will require a long period of time, inter-agency coordination, and perhaps a dilution of methodological approaches to satisfy all of the agency's desires.”

Another commenter (Cronin) said:

“To limit premature decommissioning of low-power NRC-licensed research reactor facilities, it is imperative that any proposed Risk Management or Defense-in-Depth policy should be carefully weighed against Section 104c of the Atomic Energy Act of 1954. ... Section 104c requires the Commission to impose the minimum amount of such regulation and terms of license that will permit the agency to fulfill its obligation under th[e] Act ... with the intent of permitting the conduct of widespread and diverse research and development.”

## **Interrelationships Between Ongoing Risk-informed Power Reactor Safety Initiatives**

### Background

The Commission's staff requirements memorandum (SRM)-SECY-13-0132, "Staff Requirements – SECY-13-0132 – 'U.S. Nuclear Regulatory Commission Staff Recommendation for the Disposition of Recommendation 1 of the Near-Term Task Force Report,'" (Agencywide Document Access and Management System (ADAMS) Accession No. ML14139A104, dated May 19, 2014), directed the staff to provide in the Risk Management Regulatory Framework (RMRF) Commission paper "a description of any interrelationships of ongoing risk-informed initiatives to ensure the activities are well coordinated, and effectively planned and implemented." The Commission stated that this description should, as a minimum, include:

- a. The RMRF working group development of "a policy to establish a common risk management regulatory framework that has consistent implementation elements to be applied to all NRC licensed uses of byproduct, source and special nuclear materials;
- b. The SECY paper being developed as directed in the SRM for COMGEA-12-001/COMWDM-12-0002, "Proposed Initiative to Improve Nuclear Safety and Regulatory Efficiency" (November 5, 2012; ADAMS Accession No. ML12314A262) to evaluate using a site specific, risk-informed approach for prioritizing regulatory actions;
- c. Efforts of the NRC's Risk-Informed Steering Committee (RISC) to address a number of policy and technical issues related to the use of PRA in risk-informed regulatory decisionmaking;
- d. Industry related initiatives, such as the December 2011 EPRI Report 1022997, entitled, "Identification of External Hazards for Analysis in Probabilistic Risk Assessment," and tabletop exercises to explore regulatory prioritization; and
- e. Staff efforts to address the defense-in-depth direction in SRM-SECY-11-0014, "Use of Containment Accident Pressure in Analyzing Emergency Core Cooling System and Containment Heat Removal System Pump Performance in Postulated Accidents," which directed the staff to revise Regulatory Guide (RG) 1.174 to use precise language to assure that the defense-in-depth philosophy is interpreted and implemented consistently and to update other documents to the extent that they refer to defense-in-depth.

### Identification of Additional Risk-Informed Activities

The RMRF working group reviewed ongoing risk-informed activities being performed to support the power reactor safety program. In addition to the activities identified in the Commission SRM, the staff identified the following interrelated activities (some of which are being conducted by entities outside the Agency):

- a. Activities addressing the SRM-SECY-13-0132 to consider NTTF Recommendation 1 Improvement Activity 1 (new design-basis extension category of events) and Activity 2 (definition of and criteria for adequacy of defense-in-depth).

- b. Activities addressing the SRM-SECY-13-0132 to “enshrine” the history and insights related to defense-in-depth.
- c. Activities within the agency, activities conducted by the Electric Power Research Institute (EPRI), and activities undertaken by the RISC working groups associated with addressing uncertainty in decisionmaking; including revisions and workshops on NUREG-1855, “Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decision Making” and associated EPRI Reports (EPRI 1013491, “Guideline for the Treatment of Uncertainty in Risk-Informed Applications Guide,” October 2006; EPRI 1016737, “Treatment of Parameter and Model Uncertainty for Probabilistic Risk Assessments,” December 2008; and EPRI 1026511, “Practical Guidance on the Use of PRA in Risk-Informed Applications with a Focus on the Treatment of Uncertainty,” December 2012.
- d. Activities associated with addressing external hazards, such as EPRI Report 3002003116, “An Approach to Risk Aggregation for Risk-Informed Decision Making,” April 2015; as a companion to EPRI 1022977.
- e. Activities addressing the SRM-SECY-14-0002, “Plan for Updating the U.S. Nuclear Regulatory Commission's Cost-Benefit Guidance,” regarding economic consequences and associated updates to the Regulatory Analysis and Backfit Analysis guidance.
- f. Activities addressing COMSECY-14-0014, “Cumulative Effects of Regulation and Risk Prioritization Initiative: Update on Recent Activities and Recommendations for Path Forward,” and the SRM-SECY-12-0137, “Implementation of the Cumulative Effects of Regulation Process Changes.”
- g. Activities related to risk-informed rulemakings, such as those related to the risk-informed alternative to address the effects of debris on long term cooling in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.46c, “Performance-Based Emergency Core Cooling Systems Cladding Acceptance Criteria,” 10 CFR 50.46a, “Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements” and the potential rulemaking to decouple the assumption of loss of offsite power from analysis of loss-of-coolant accidents (LOOP-LOCA).
- h. Activities related to updating regulatory guidance documents, such as RG 1.174, “An Approach for Using Probabilistic Risk Assessment In Risk-Informed Decisions on Plant Specific Changes to the Licensing Basis,” RG 1.177, “An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications,” and RG 1.178, “An Approach for Plant-Specific Risk-Informed Decisionmaking for Inservice Inspection of Piping.”
- i. Activities involving broad-scope risk-informed licensing actions, such as 10 CFR 50.69, “Risk-Informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Reactors,” Risk Managed Technical Specifications (Risk-informed Technical Specification Initiative 4B), and Risk-Informed Surveillance Frequencies (Risk-informed Technical Specification Initiative 5B).



- j. Activities of the Risk-Informed Steering Committee working group associated with the acceptance of new PRA methods and close-out of peer review findings.

### Overview of Interrelationships

To illustrate how these activities are interrelated, the staff developed the attached influence diagram (Figure 1) to show the relationships<sup>11</sup> between the activities within the power reactor safety reactor arena.<sup>12</sup> In developing the influence diagram, the staff identified two major types of activities, policy development activities and implementation activities. These two types of activities are being conducted under the oversight of the NRC Risk-Informed Steering Committee (RISC). Some policy development activities will inform other policy development activities as represented by the downward arrow showing how development of objective criteria for defense in depth could potentially inform the regulatory and backfit analysis policy guidance. Policy development activities will also guide various implementation activities as shown by the horizontal and diagonal arrows from certain policy activities to the adjacent implementation activities.

Technical development activities are shown on the right side of the diagram. These activities provide technical input to the RISC working groups on PRA uncertainty and PRA methods. The RISC working groups update the risk-informed guidance documents that facilitate the various types of risk-informed licensing actions and other risk-informed regulations.

### Detailed Description of Interrelationships

More specifically, enhanced guidance on the consideration of qualitative factors resulting from the Economic Consequences SECY paper could be used in regulatory and backfit analysis procedures to inform decisionmaking for ongoing and future risk-informed rulemakings such as the risk-informed alternative to address debris in 10 CFR 50.46c, 10 CFR 50.46a, and LOOP-LOCA. Similarly, regulatory framework recommendations from this RMRF SECY paper (i.e., internal rulemaking guidance) could also affect these future risk-informed rulemakings. Furthermore, it is possible that the NUREG on the history and insights on defense in depth could inform the development of criteria for determining the adequacy of defense in depth<sup>13</sup> and also the regulatory guidance on defense in depth in RG 1.174. The upward and downward arrows emanating from the implementation activity to update RG 1.174 (and other risk-informed guidance) show how the periodically-updated risk-informed review guidance is used to inform both risk-informed rulemaking and risk-informed licensing action initiatives.

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<sup>11</sup> Arrows with solid lines represent actual influences and arrows with dotted lines represent potential influences that may result from ongoing but uncompleted activities.

<sup>12</sup> The influence diagram does not include all the ongoing or recently completed activities, but only some of the major activities. For example, activities related to risk-informing emergency preparedness have recently been completed and received an SRM from the Commission.

<sup>13</sup> Note, however, that this SECY paper recommends against applying resources to develop defense-in-depth criteria at the present time.

At the bottom left of the diagram, insights from the activities related to the Cumulative Effects of Regulation influenced the staff's recommendations<sup>14</sup> for the Risk Prioritization Initiative and associated Tabletop Exercises.

### Management Oversight

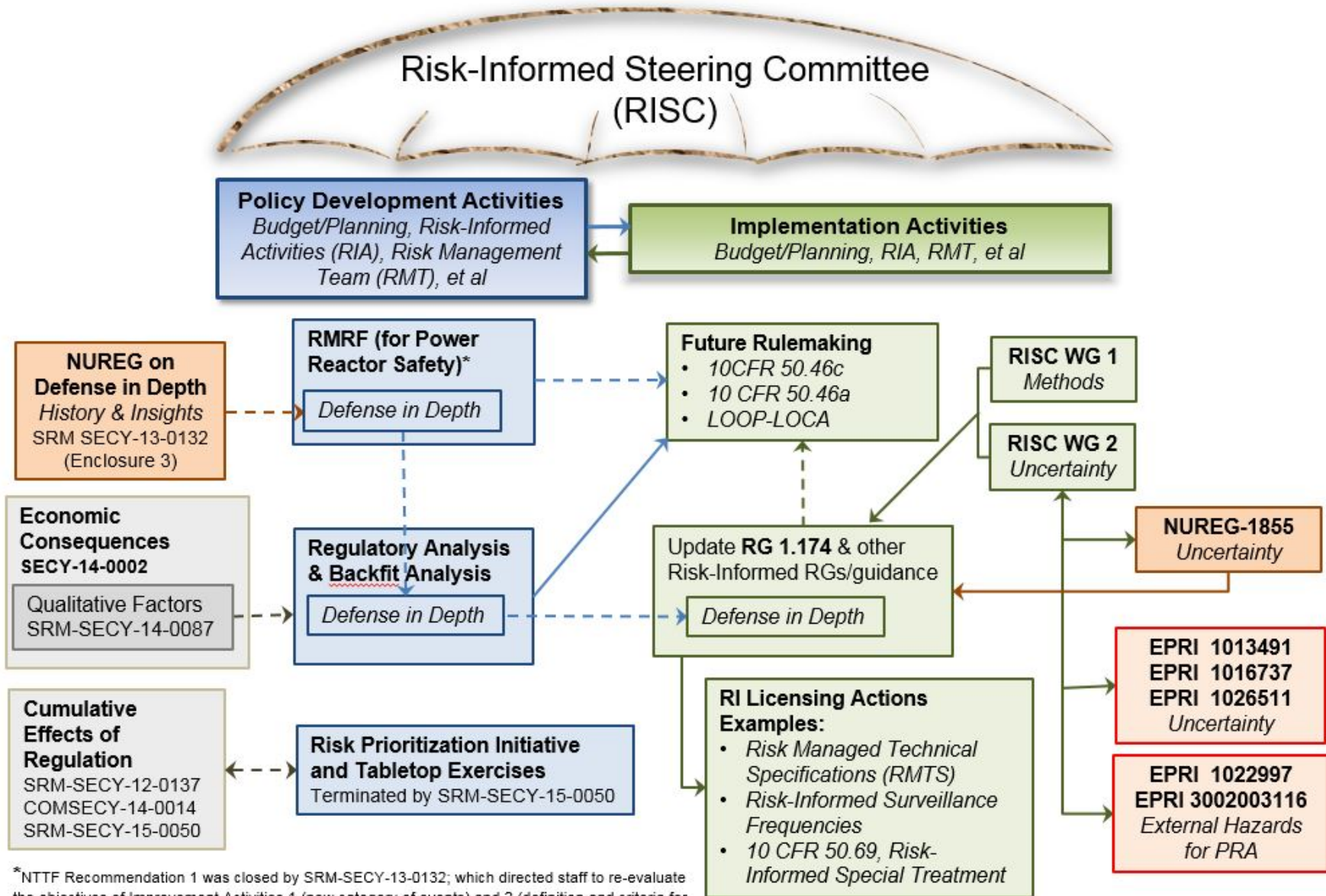
There are numerous management oversight processes and activities utilized by the staff to ensure that risk-informed activities are well planned and effectively coordinated and implemented. These include:

- Division and Office-level steering committees and interactions, such as the regular internal and external RISC meetings, weekly division-level coordination calls between the risk divisions in RES, NRR, and NRO, and the semi-annual User Need meetings between the RES risk division and the risk divisions of NRR and NRO.
- Staff level intra-office coordination and consistency activities, such as the Risk Management Team meetings, which meets the requirements of the NRR/NRO joint procedure on maintaining technical consistency.
- Budget/Planning and tracking activities (e.g., WITS items) also provide opportunities to ensure activities are properly resourced and scheduled reflecting inter-relationships between risk-informed activities and other NRC (and associated industry) activities.
- Risk-Informed Activities website, which provides the latest status on major risk-informed activities across the agency and currently includes an annual status SECY paper.

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<sup>14</sup> The staff's proposed actions related to the Risk Prioritization Initiative and Tabletop Exercises were rejected by the Commission in its SRM on SECY-15-0050 which terminated the effort.

**Figure 1. Interrelationships Between Ongoing Risk-informed Activities**



\*NTTF Recommendation 1 was closed by SRM-SECY-13-0132; which directed staff to re-evaluate the objectives of Improvement Activities 1 (new category of events) and 2 (definition and criteria for defense-in-depth (DID)) as part of RMRF-related implementation activities.