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"

NOTE: *Public availability of this draft document is intended to inform stakeholders of the current status of the NRC staff's evaluation of possible activities related to the recommendations in NUREG-2150, "A Proposed Risk Management Regulatory Framework." The NRC staff is making this information public prior to an NRC public meeting to allow stakeholders to review the material in advance and facilitate discussion during the meeting.*

Overview

In response to Commission direction, the Nuclear Regulatory Commission (NRC) staff expects to provide the Commission with three related items for their consideration or approval:

I. Options for enhancing the risk management approach used to ensure nuclear power reactor safety;

II. Reevaluations of two "improvement activities" from Fukushima Near Term Task Force Recommendation 1 that the Commission deferred, and,

III. Consideration of an over-arching, agency-wide policy statement on using the risk management approach to ensure safety and security.

This white paper discusses these three items in the order shown above. These items are interrelated in many aspects, but may also be considered separately by the Commission.

Item I is discussed in Section I which describes 3 options for enhancing the risk management approach to nuclear power reactor safety: (1) maintain the current regulatory framework; (2) pursue rulemaking to allow licensees to adopt a risk-informed alternative licensing basis for certain aspects of their current licensing basis; or (3) implement a "risk management regulatory framework" (RMRF) for power reactor safety patterned after the approach recommended in NUREG-2150, "A Proposed Risk Management Regulatory Framework," (April 2012; Agencywide Documents Access and Management System (ADAMS) Accession No. ML12109A277).

Item II is discussed in Section II and responds to Commission direction in staff requirements memorandum (SRM)-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), which directs the staff to reevaluate two of its proposed "improvement activities" from SECY-13-0132 in light of the RMRF effort. These two improvement activities involve power reactor safety only (not security). The first improvement activity is to establish a new design-basis extension category of events and associated regulatory requirements. The second improvement activity is to establish Commission

expectations for defense-in-depth, including possible development of a Commission policy statement on defense-in-depth. Accordingly, in Section II of this white paper, the staff describes how it proposes to address these two improvement activities within the context of the RMRF options discussed in Section I.

Item III is discussed in Section III and does not involve options, but rather presents an example risk management policy statement that could apply to all program areas regulated by the NRC. This example policy statement has evolved from the agency-wide RMRF policy statement recommended in NUREG-2150. It would use risk management to ensure both safety and security across the agency. The NRC staff may offer an example to the Commission for its consideration. The staff does not intend to make a recommendation for or against developing this over-arching policy statement.

In summary, there are three major sections in this paper. The first two are focused on power reactor safety. The third would apply to all NRC-regulated program areas.

Section I. Risk Management Regulatory Framework Implementation Options for Nuclear Power Reactors

Background

In a February 11, 2011, memorandum to the Executive Director for Operations (ADAMS Accession No. ML110460611), "Assessment of Options for more Holistic Risk-Informed, Performance-Based Regulatory Approach," the Chairman established a Task Force, referred to as the "Risk Management Task Force" (RMTF), led by Commissioner Apostolakis. The charter for the RMTF specified that the purpose and scope of the effort was to "[d]evelop a strategic vision and options for adopting a more comprehensive and holistic risk-informed, performance-based regulatory approach for reactors, materials, waste, fuel cycle, and transportation that would continue to ensure the safe and secure use of nuclear material. The options may range from a complement to or alternative to [the] current regulatory framework."

In April of 2012, the RMTF published its report as NUREG-2150, "A Proposed Risk Management Regulatory Framework." This report proposes a "risk management regulatory framework" for "… how the agency should be regulating 10 to 15 years in the future." The report recommends that the NRC formally adopt the proposed RMRF by issuing a Commission Policy Statement. As proposed, the RMRF would be applicable to both safety and security and would apply to the activities of the entire agency (i.e., all regulated areas). The RMTF report also provides specific programmatic recommendations for each regulated program area.

On June 14, 2012, the Chairman issued a tasking memorandum, "Evaluating Options Proposed for a More Holistic Risk-Informed, Performance-Based Regulatory Approach" (ADAMS Accession No. ML121660102), directing the NRC staff (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. In developing its options, the staff should consider how modifications to the regulatory framework could be incorporated into important agency policy documents, such as the Strategic Plan. …"

In July 2014, the National Research Council of the National Academy of Sciences published a report entitled, "Lessons Learned from the Fukushima Nuclear Accident for Improving Safety of U.S. Nuclear Plants." This report recommended that 6 actions be taken to improve the resilience of U.S. nuclear power plants and enhance U.S. emergency response. Two of the 6 recommended actions involve risk analysis. They are:

- The U.S. nuclear industry and the U.S. Nuclear Regulatory Commission should strengthen their capabilities for assessing risk from events that could challenge the design of nuclear plant structures and components and lead to a loss of critical safety functions. The U.S. Nuclear Regulatory Commission should support industry's efforts to strengthen its capabilities by providing guidance on approaches and by overseeing rigorous peer review.

- The U.S. Nuclear Regulatory Commission should further incorporate modern risk concepts into its nuclear safety regulations using these strengthened capabilities.

NRC Staff Actions

The staff formed a working group to review NUREG-2150 and make recommendations to the Commission regarding possible implementation of an agency-wide RMRF. For nuclear power reactor safety, the staff's evaluation determined that the existing Policy Statements on "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities" (60 FR 42622) and the "Safety Goals for the Operation of Nuclear Power Plants" (51 FR 30028), in concert with increasing experience with risk-informed regulation and integrated risk-informed decision making processes, have already established a de-facto RMRF[1].

Furthermore, for nuclear power reactor safety, the existing risk-informed regulatory guidance, risk tools, and risk information provide a sufficient foundation to allow the staff to proceed with recommending specific risk management implementation options. Therefore, to obtain Commission direction on whether the current risk-informed regulatory approach for nuclear power reactor safety should be enhanced, the staff intends to provide the Commission with an RMRF SECY paper that includes 3 specific options for increasing the use of risk information.

These options are:

[1] NUREG-2150 identifies four elements as being the components of an RMRF. The existing nuclear power reactor safety regulatory framework includes these 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 (utilizing Commission's Safety Goal Policy Statement and subsidiary risk metrics)
4. Decision making Process that includes monitoring and feedback (e.g., 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.)

1. Maintain the Current Regulatory Framework – There would be no wholesale revision of NRC's regulatory framework, although ongoing and planned risk-informed initiatives would continue.

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. Licensees/applicants of plants with a suitable PRA model would be able to risk inform how they address certain accidents and transients included in their licensing basis. Licensees/applicants that choose to adopt the risk-informed alternative licensing basis would also be required to use their PRAs to search for and mitigate risk-significant events and/or accident sequences on a plant-specific basis in accordance with criteria to be developed and specified in the implementing regulation. This option could result in eliminating or reducing requirements associated with some design-basis accidents included in a plant's licensing basis and adding some currently unregulated events to be mitigated.

3. Implement the NUREG-2150 Plant-Specific RMRF – 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. In addition, the NRC would reevaluate and disposition each of the specific regulatory framework recommendations for nuclear power reactor safety contained in NUREG-2150.

These options are discussed in greater detail In Enclosure 1.

Section II. Staff Reevaluation of NTTF Recommendation 1 Improvement Activities 1 and 2

Background

On March 11, 2011, the Great Tohoku Earthquake off the coast of Japan caused a series of events that led to core damage at three of the six nuclear power reactors at the Fukushima Dai-ichi site. The NRC established a senior level agency task force, referred to as the Near Term Task Force (NTTF), to conduct a systematic and methodical review of NRC processes and regulations to determine whether the agency should make additional improvements to its regulatory system and to make recommendations to the Commission for its policy direction.

The NTTF issued its report on July 12, 2011 (ADAMS Accession No. ML111861807), as an enclosure to SECY-11-0093, "Near-Term Report and Recommendations for Agency Actions Following the Events in Japan" (ADAMS Accession No. ML11186A959). The NTTF developed

12 overarching recommendations[2] for nuclear power reactors. Recommendation 1 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) also 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, "U.S. Nuclear Regulatory Commission Staff Recommendation for the Disposition of Recommendation 1 of the Near-Term Task Force Report," (ADAMS Accession No. ML13277A413). The NRC staff also evaluated the RMTF report's program specific recommendations related to nuclear power reactor safety in Attachment 4 of Enclosure 1 to SECY-13-0132.

In SRM-SECY-13-0132, the Commission closed NTTF Recommendation 1. The Commission directed the staff to reevaluate the objectives of the staff's proposed Improvement Activity 1 (establish 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 reevaluated these activities and provides recommendations below for how Improvement Activities 1 and 2 could be addressed under each of the RMRF nuclear power reactor implementation options discussed in Section I.

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 Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.2. The staff recommended establishing and implementing the new design-basis extension category by revising internal NRC policies, guidance, and procedures. Implementation would include developing a publicly available document (e.g., NUREG) to describe the new category and specify how future design-basis extension requirements should be written in a consistent, logical, and complete manner. The staff also proposed developing a standard set of "attributes" and a standard set of treatment guidelines for each of the attributes which must be addressed for future requirements in the design-basis extension category. Attributes to be addressed when writing a design-basis extension rule would include, but are not necessarily limited to:

- performance goals, including analysis methods and acceptance criteria
- treatment requirements, such as design criteria, level of quality assurance needed, and environmental qualification

[2] These recommendations were all limited to radiological health and safety considerations; common defense and security concerns were not addressed in the NTTF report.

- documentation requirements for information that the NRC has determined needs to be developed and maintained with respect to demonstrating compliance with the design-basis extension requirements
- change processes for licensee-initiated facility changes related to compliance with design-basis extension rules
- reporting requirements

Staff Reevaluation of Improvement Activity 1

Under any of the RMRF implementation options for nuclear power reactor safety discussed in Section I above, the staff would use existing resources to develop clear internal rulemaking guidance to ensure consistency in specifying necessary regulatory "attributes" (performance goals, treatment requirements, documentation requirements, change processes, and reporting requirements) whenever new regulations (both design-basis and beyond design-basis) are developed.

For nuclear power reactor implementation Options 1 and 2, the staff has determined that implementing the internal rulemaking guidance described above would make it unnecessary to apply resources to establish the formal "design-basis extension" category recommended in SECY-13-0132 to define and describe the events and requirements for nuclear power plants that have typically been characterized as "beyond-design-basis" events and accidents.

However, under Option 3, instead of a "design-basis extension" category recommended by SECY-13-0132, the NRC would create a plant-specific "design enhancement" category of events and accidents as recommended in NUREG-2150. The staff would develop risk-informed criteria for determining how individual licensees would determine which events should be placed into the new category for their nuclear power plants. These criteria would also allow the existing set of design-basis events to be modified by re-categorizing events that meet the criteria for "design enhancement." This process would identify regulatory requirements and mitigation criteria on a plant-specific basis and could in effect replace a large portion of the existing generic regulations. The regulations implementing this process would specify documentation requirements, change processes, and reporting requirements. However, because full implementation of Option 3 is expected to take longer than 10 years, the staff would still need to revise internal rulemaking guidance (as recommended above for Options 1 and 2) to ensure that all new regulations issued during this interim implementation period fully address performance goals, treatment requirements, and all other necessary regulatory attributes.

SECY-13-0132 Improvement Activity 2 – Establish Commission Expectations for Defense-in-Depth

Improvement Activity 2 in SECY-13-0132 recommended that the NRC establish the Commission's expectations for defense-in-depth as applied to nuclear power reactor safety, through a Commission policy statement that includes the definition, objectives, and principles of defense-in-depth. The policy statement would have set forth the defense-in-depth approach as a hierarchy that includes specified layers of defense for nuclear power reactor safety. This improvement activity would also have developed implementation guidance that includes details regarding the layers of defense and associated decision criteria to support regulatory decisions regarding the Commission's expectations for defense-in-depth. Revisions to the Regulatory

Analysis Guidelines and substantial conforming changes to several existing regulatory guides would also have been included in this improvement activity.

The policy statement would have reinforced the Commission's expectation that all regulatory decisions be made with appropriate consideration of uncertainties. The strategy and approach in the policy statement for defense-in-depth would have included prevention and mitigation strategies, including consideration of deterministic and probabilistic criteria, and assurance that uncertainties, especially those associated with risk assessments and also those in traditional engineering analyses, are adequately addressed based on clear, objective criteria.

Staff Re-evaluation of Improvement Activity 2

Consistent with the Commission's SRM-SECY-11-0014[3], "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), the staff believes that development of a definition of and decision criteria for determining the adequacy of defense-in-depth[4] for nuclear power reactor safety similar to the approach described in Improvement Activity 2 of SECY-13-0132 should be pursued. The staff would also consider whether a Commission policy statement on defense-in-depth for nuclear power reactors would be appropriate. The staff would develop or revise guidance documents (Regulatory Guide 1.174, etc.) in order to ensure consistent application of defense-in-depth in its regulatory decisions. The staff expects that these guidance documents would be enhanced to better describe and define other key considerations of the risk-informed decision-making process, such as safety margins, cliff-edge effects[5], performance monitoring, treatment of uncertainty, etc. The staff intends to have significant public outreach on this activity, in a manner comparable to the level of outreach undertaken in addressing NTTF Recommendation 1 and culminating in SECY-13-0132. The resources and time frame for implementation of this activity, as well as the scope and level of detail of the guidance, may vary depending upon which of the RMRF power reactor implementation options are pursued.

Under Option 1 (maintain the current regulatory framework) from Section I of this paper, as a minimum, the staff would modify Regulatory Guide 1.174 and other regulatory guidance, as appropriate, to clarify the defense-in-depth guidance and criteria as directed by SRM-SECY-11-0014. However, the staff believes that additional resources should be applied to develop a definition of and decision criteria for the adequacy of defense-in-depth for nuclear

[3] The SRM on SECY-11-0014 directs the staff to revise Regulatory Guide 1.174 to clarify existing language, which is subject to different interpretations, using precise language to assure that defense-in-depth is interpreted and implemented consistently. Other relevant regulatory guidance documents referring to defense-in-depth should also be updated, as appropriate. This effort is currently on hold awaiting a Commission decision on the staff's re-evaluation of the recommendation in SECY-13-0132, Improvement Activity 2 to establish the Commission's expectations on defense-in-depth for nuclear power reactors.

[4] The staff is developing a NUREG report on the history of defense-in-depth, as directed by the Commission in SRM-SECY-13-0132. Potential development of a policy statement, definition of and decision criteria for determining the adequacy of defense-in-depth would consider the observations and insights from this document.

[5] "Cliff-edge" effects were identified as a particular concern by the Fukushima Near-Term Task Force report in SECY-11-0093. They are characterized as situations in which a small decrease in the likelihood of an event will result in a very large increase in its consequences.

power reactor safety as described above. Development and Commission approval of such criteria would improve the efficiency, effectiveness, and predictability of future regulatory decisions that depend on the adequacy of defense-in-depth. Criteria for defense-in-depth would also enhance the NRC's current risk-informed evaluation process under Regulatory Guide 1.174 which considers defense-in-depth, safety margins, and other factors as separate attributes that, together with risk insights, constitute the risk-informed approach to regulation.

Options 2 and 3 from Section I of this paper would provide licensees/applicants with substantial additional opportunities to remove or reduce certain existing regulatory requirements based on a demonstration of their low risk significance as long as sufficient defense-in-depth is maintained. Accordingly, should either of those options be pursued, it is even more important that the staff develop a definition of and decision criteria for determining the adequacy of defense-in-depth.

Section III. Development of an Agency-Wide Risk Management Policy Statement

Background

The staff working group formed to review NUREG-2150 decided to prepare a conceptual example of a risk-informed, performance-based, defense-in-depth RMRF policy statement for Commission consideration. The working group drafted a 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). The staff also met with the Reliability and Probabilistic Risk Assessment subcommittee of the Advisory Committee on Reactor Safeguards on September 4, 2013, and received positive feedback from numerous subcommittee members. Public comments were accepted via the Federal Rulemaking web site (www.regulations.gov) under Docket ID NRC-2013-0254. The public comments received on the draft conceptual agency-wide policy statement varied greatly. The NRC staff's overall assessment is that the comments indicated a need for some revision to the staff's approach. A summary showing the range and variability of public comments is available in ADAMS (see ADAMS Accession No. ML15104A718). Although the staff reviewed and considered all public comments when developing this white paper on a revised approach, the staff did not prepare or publish formal comment responses.

Revised Example of a Draft Policy Statement

After reviewing public comments, the staff has developed a revised example of an over-arching risk management policy statement. The purpose of this example policy statement would be to improve and make more consistent the regulatory framework used for all program areas including reactors, industrial, 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. Such a policy statement could be written at a high level, thereby permitting each program office to implement the agency-wide policy tailored to the specific goals of each regulated activity in a manner commensurate with the hazards and technology of the regulated program area. The risk management policy statement would establish by policy that the NRC uses a risk management approach; as such, the policy statement would establish an aspirational vision for the agency to improve existing agency policies and practices as guided by this vision.

Should the Commission choose to consider and approve further development of an agency-wide policy risk management policy statement, the NRC staff would follow the normal regulatory process to develop the policy statement for Commission approval. This process would involve stakeholder input through public meetings and public review and comments. If the Commission directs the staff to proceed with an agency-wide policy statement, the NRC staff would also evaluate and disposition each of the remaining program-specific RMRF recommendations[6] in NUREG-2150.

Descriptive information and a revised example showing what the agency-wide risk management policy statement might contain are provided in Enclosure 2, along with a possible approach to implementing such a policy statement across the broad range of NRC-regulated activities.

Enclosures:
1. Detailed Discussion of Risk Management Regulatory Framework Implementation Options for Nuclear Power Reactor Safety
2. Example of an Agency-Wide Risk Management Policy Statement

[6] This effort would include the program-specific recommendations for all regulatory program areas other than nuclear power reactor safety. The program-specific recommendations for nuclear power reactor safety were previously evaluated in Attachment 4 to Enclosure 1 of SECY-13-0132.

Should the Commission choose to consider and approve further development of an agency-wide policy risk management policy statement, the NRC staff would follow the normal regulatory process to develop the policy statement for Commission approval. This process would involve stakeholder input through public meetings and public review and comments. If the Commission directs the staff to proceed with an agency-wide policy statement, the NRC staff would also evaluate and disposition each of the remaining program-specific RMRF recommendations[6] in NUREG-2150.

Descriptive information and a revised example showing what the agency-wide risk management policy statement might contain are provided in Enclosure 2, along with a possible approach to implementing such a policy statement across the broad range of NRC-regulated activities.

Enclosures:
1. Detailed Discussion of Risk Management Regulatory Framework Implementation Options for Nuclear Power Reactor Safety
2. Example of an Agency-Wide Risk Management Policy Statement

ADAMS Accession No: PKG: ML15107A192; White Paper: ML15107A402

OFFICE	NRR/DPR/PRMB/PM	NRR/DPR/PRMB/RS	NRR/DPR/PRMB/BC	NRR/DPR/DD	NRR/DPR/D
NAME	RDudley	GLappert	TInverso	AMohseni	LKokajko
DATE	4/27/2015	4/27/2015	4/27/2015	5/1/2015	5/5/2015

OFFICIAL RECORD COPY

[6] This effort would include the program-specific recommendations for all regulatory program areas other than nuclear power reactor safety. The program-specific recommendations for nuclear power reactor safety were previously evaluated in Attachment 4 to Enclosure 1 of SECY-13-0132.

Detailed Discussion of Risk Management Regulatory Framework Implementation Options for Nuclear Power Reactor Safety

Option 1: Maintain the Current Regulatory Framework

This option would maintain the existing regulatory framework of design-basis events and a limited number of beyond design-basis events. Maintaining the existing regulatory framework and processes would maintain the current approach to regulation that has been generally successful and is well-understood. Licensees could continue to request to apply risk-informed approaches for certain applications using existing plant-specific risk information. There would be no requirement to systematically identify plant-specific risk outliers such as might be identified by plant-specific probabilistic risk assessment (PRA) models. Deterministic requirements would continue to be applied to classes of plants without evaluating plant-specific risk insights.

Under Option 1, there would be no wholesale or programmatic changes to existing U.S. Nuclear Regulatory Commission (NRC) policies or processes, but 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 (inspections, audits, research, operating experience program, generic issues program, industry trends program, annual agency action review meeting, annual reactor oversight process self-assessment, communication with international nuclear regulatory bodies, etc.). Emergent issues with potential safety impact, such as the actions stemming from the Fukushima Dai-ichi accident, would continue to be handled by the current regulatory framework and existing regulatory processes. All ongoing and planned risk-informed initiatives would continue. Thus, under Option 1, the NRC would continue to improve its processes and framework in response to operating experience, new information, and new initiatives, just as it has done in the past.

The staff notes that new reactor design certification and licensing processes specified in 10 CFR Part 52 require applicants to have a PRA that must be described in the application along with the PRA results. Furthermore, Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.71(h) requires that Part 52 licensees must develop a level 1 and 2 PRA no later than the scheduled date of initial fuel load, and that this PRA must be maintained and upgraded every 4 years. Thus, the current regulatory framework for new reactors already uses risk insights to a greater extent than they are used for currently operating reactors.

Implementation Issues

There are no unresolved implementation issues associated with Option 1.

Option 2: Establish a Risk-Informed Alternative Licensing Basis

Under Option 2, the staff would issue a "facilitating" regulation that provides a risk-informed alternative approach for compliance with some of the NRC's current requirements (e.g., regulations and/or orders). Licensees and applicants choosing to adopt this approach would submit a request that identifies the requirements for which they propose to implement risk-informed alternatives. The NRC would ensure the licensee/applicant's PRA model is of sufficient scope, level of detail and technical adequacy to support its use in establishing the specific risk-informed alternative compliance approach. Licensees and applicants using this option could address low risk, plant-specific licensing issues using alternative methods, including potentially reducing or removing an existing regulatory requirement from the plant's licensing basis. Exemption requests would not be necessary for licensees/applicants that adopt the alternative approach because the facilitating regulation would specifically allow NRC to approve risk-informed alternatives to certain licensee-selected regulatory requirements.

This option would utilize the current framework for risk-informed licensing basis changes as set forth in Regulatory Guide (RG) 1.174 by codifying specific technical requirements in the facilitating regulation. The regulation would also require licensees to implement a monitoring and feedback process to monitor and periodically reassess facility design changes initially determined to not be risk-significant to ensure that the risk associated with the changes remained acceptably low throughout the facility's lifetime. Licensees and applicants for licenses and other regulatory approvals (e.g., design certifications under Part 52) could request NRC approval to adopt this approach (e.g., as part of an initial application, or as part of a request for license amendment). Licensees could submit such a request any time after the implementing regulation is issued. However, after a licensee or new applicant chooses the alternative approach and the implementing license amendment or license condition is approved; the selected alternative approach becomes a fully enforceable regulatory requirement.

Also, all licensees/applicants that choose to adopt the risk-informed alternative licensing basis would be required to use their PRAs to search for and mitigate risk-significant events and/or accident sequences on a plant-specific basis in accordance with criteria to be developed and specified by the NRC in the implementing regulation.

In order to support fully risk-informed decisions, each licensee that adopts the risk-informed alternative approach would be required to have an upgraded PRA that meets NRC-specified criteria for scope and level of detail and was peer reviewed per RG 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities." The detailed criteria for adequacy of the PRA would need to be developed as an implementation activity associated with this option.

Because this option allows changes to the licensing basis to establish a risk-informed alternative approach for compliance with the existing regulatory requirements, the existing generic regulatory structure would not be changed. However, the implementing regulations would need to specify which regulations, orders, or specific licensing basis topics would be within the scope[1] of this alternative approach.

[1] Not all NRC regulations are amenable to being risk-informed. For example, the occupational radiation exposure requirements in 10 CFR Part 20, the fitness for duty requirements in Part 26 and the emergency

The Backfit Rule, 10 CFR 50.109, would not apply to the regulations issued by the NRC to establish the alternative approach, because licensees have the option to maintain their existing licensing basis. However, after the NRC approves a licensee's request for risk-informing certain aspects of a facility's licensing basis under the new rule, the protections of the Backfit Rule would apply to all future changes to NRC requirements that might affect the NRC-approved risk-informed alternative licensing basis[2].

Possible Incentives

The staff will investigate further incentives that could be provided that might induce current licensees to upgrade their PRA models so they could achieve the benefits of the alternative regulation. In addition, the staff is considering the possibility of requiring adoption of this risk-informed alternative licensing basis as a matter of policy for licensees that continue facility operation for time periods exceeding 60 years[3]. Such licensees would also be required to use their upgraded PRA to identify and mitigate potential significant risk outliers, even if they were not part of the plant's current licensing basis. The NRC staff included this possible additional requirement in this white paper in order to solicit stakeholder feedback on this possibility.

Implementation Issues

The staff has identified several areas of further consideration that would affect how Option 2 would be implemented:

- Time period for development and implementation of this option
- Tools to facilitate implementation
    - criteria for ensuring sufficient quality, scope, level of detail and technical adequacy of PRAs
    - criteria for ensuring continued adequacy of defense-in-depth
- Selection of regulations, orders, or licensing basis topics which would be within the allowable scope of this risk-informed alternative compliance approach

---

preparedness requirements in Section 50.47 and Appendix E would not be subject to alternative risk-informed compliance approaches. Similarly, the 10 CFR Part 50 requirements on deliberate misconduct, completeness and accuracy of information, and reporting, documentation and recordkeeping requirements are other examples of regulations that would not be within the scope of Options 2 and 3. The NRC staff expects that the regulations implementing these options would contain a complete list of requirements that would be amenable to being risk-informed.

[2] The staff needs to further evaluate the Part 52 issue finality provisions applicable to early site permits, design certification rules, and combined licenses, to determine whether conforming changes are needed to implement Option 2.

[3] The staff notes that the issue of requiring PRAs for subsequent license renewals (SLRs; i.e., those exceeding 60 years), was considered in SECY-14-0016, "Ongoing Staff Activities to Assess Regulatory Considerations for Power Reactor Subsequent License Renewal." In its May 22, 2014, letter on SECY-14-0014, the Advisory Committee on Reactor Safeguards stated, "This is a policy issue that should be addressed by the Commission and is not an issue that should be resolved specifically as part of SLR. One appropriate method to resolve this is in the context of either the Risk Management Task Force (RMTF) recommendations or in NTTF Recommendation 1."

- Part 52 issue finality provisions applicable to early site permits, design certification rules, and combined licenses would need to be further evaluated to determine whether conforming changes would to be implemented to allow these applicants and licensees to pursue this option.

Option 3: Implement the NUREG-2150 Plant-Specific RMRF

Under Option 3, the NRC would adopt a risk management regulatory framework for nuclear power reactor safety as described in NUREG-2150. All operating reactor licensees would be required to upgrade their PRAs to meet criteria specified by the NRC.

The NUREG-2150 framework would meet NRC's statutory mission by establishing an objective of managing the risks from the use of byproduct, source and special nuclear materials by issuing regulations and guidance and providing oversight. For nuclear power reactors, the risk management goal of providing sufficient protections to ensure the risks are acceptably low is accomplished by meeting the Commission's Safety Goal Policy Statement. The risk-informed decision-making process with monitoring and feedback is provided by the processes in LIC-504, "Integrated Risk-Informed Decision-Making Process for Emergent Issues," Regulatory Guide 1.174 and other programs (Generic Issues Program; Operating Experience Program; Accident Sequence Precursor Program; Industry Trends Program, etc.). If Option 3 was pursued, the staff would implement the general concepts set forth in NUREG-2150. However, the staff would need to evaluate each specific attribute of the overall risk management regulatory framework to ensure consistency with past advances towards risk-informed regulations.

Option 3 would result in a highly plant-specific licensing basis for nuclear power reactors. After evaluating the plant-specific risk profile determined by the PRA, each licensee would have to describe how the risk objective was met, that the necessary protections were in place to meet the risk management goal, that the risk-informed decision-making process was in place, and that the monitoring/feedback process was in place. Each plant's licensing basis would consist of: (i) "technical requirements" based upon site-specific attributes and applicant-selected design specific elements/constraints; (ii) the rationales (technical bases) why the technical requirements adequately address risk and defense-in-depth in light of the site-specific attributes and applicant-selected design specific elements/constraints; (iii) the FSAR-level description of the site-specific attributes and applicant-selected design specific elements/constraints that are the inputs/assumptions for the rationales (technical bases) which must be developed and maintained as part of Item (ii); and (iv) the process for maintaining the validity of the rationales (technical bases) throughout the operating lifetime of the facility. Licensees would be required to use the structured process with monitoring and feedback to ensure that the licensee's plant-specific licensing basis remained consistent with the risk profile of the plant, which could change over time.

Similar to the approach in Option 2, the implementing regulations for Option 3 would also need to specify which regulations or specific licensing basis topics would be within the scope of this risk-informed approach.

Under Option 3, the structured decision-making process with monitoring and feedback similar to the process described in Chapter 3 of NUREG-2150 would also be mandated for NRC's nuclear

power reactor safety decision-making. In addition, the NRC staff would re-evaluate and disposition each of the specific regulatory framework recommendations for nuclear power reactor safety contained in NUREG-2150.

Implementation Issues

The staff has identified several areas of further consideration that would affect how Option 3 would be implemented:

- Time period for development and implementation of this option
- Tools to facilitate implementation
    - criteria for ensuring sufficient quality, scope, level of detail and technical adequacy of PRAs
    - criteria for ensuring continued adequacy of defense-in-depth
- Selection of regulations, orders, or licensing basis topics which would be within the allowable scope of this risk-informed alternative compliance approach
- Part 52 issue finality provisions applicable to early site permits, design certification rules, and combined licenses would need to be further evaluated to determine whether conforming changes would to be implemented to allow these applicants and licensees to pursue this option.

Table 1: Comparison of the Nuclear Power Reactor Safety Options for Implementing a Risk Management Regulatory Framework

To compare and contrast the various options, the following table has been prepared.

Attribute	Option 1: Maintain the Existing Regulatory Framework	Option 2: Establish a Risk-Informed Alternative Licensing Basis	Option 3: Implement the NUREG-2150 RMRF
Brief Description of option	No wholesale revision of NRC's existing regulatory framework	No wholesale revision of NRC's existing regulatory framework, although a new regulation would be developed to allow the use of the alternative approach Licensees may request NRC approval to comply with certain risk-informed plant-specific licensing basis requirements based on a suitable PRA	Implement plant-specific regulatory framework derived from NUREG-2150, By issuing a new regulation, the NRC would establish criteria for licensees to address events, accidents, design and operational requirements based on plant-specific risk profiles from high quality PRAs
Reduce Unnecessary Regulatory Burden?	No, although ongoing activities to reduce unnecessary burden would continue	Yes, for licensees that choose this option	Yes
Add new requirements?	No, although existing process for identifying new requirements would continue	Yes, if risk vulnerabilities are identified	Yes, if risk vulnerabilities are identified
Generic or Plant-Specific Licensing Basis?	Generic	Generic with certain plant-specific compliance alternatives for licensees who choose this option	Plant-specific

Attribute	Option 1: Maintain the Existing Regulatory Framework	Option 2: Establish a Risk-Informed Alternative Licensing Basis	Option 3: Implement the NUREG-2150 RMRF
New Event Category?	No	No	Yes – design enhancement category
Develop Definition of and Criteria for defense-in-depth	Yes	Yes	Yes
NRC Risk-informed Decision-making Process	RG 1.174 Occasional use of LIC-504	RG 1.174 Occasional use of LIC-504	Mandatory Structured Process
PRA Required for current reactors?	No	Yes for licensees that choose the alternative	Yes
Implementation Time Frame	immediate	5 to 10 years	Beyond 10 years
Backfitting	No changes to regulatory framework or backfitting requirements	Backfitting not applicable to NRC's establishment of voluntary approach After NRC approves licensee entry into alternative approach, backfitting protection would apply	NRC establishment of mandatory new framework must address backfit rule (possible administrative exemption) After NRC approves licensee entry into RMRF, backfitting protection would apply

Example of an Agency-Wide Risk Management Policy Statement

Terminology

To understand the example policy statement, a common understanding of terminology, as it is used in this white paper, is essential. Certain terms that are fundamental to this approach may not be consistently understood. These terms, and the definitions as used in this white paper, include:

- *Risk* is the recognition that there is a threat or danger involved with the use of nuclear material.

- *Risk management* is the recognition of the threat or danger that is involved with the use of nuclear materials and the establishment of controls and oversight to manage the potential threat or danger. That is, it is coordinated activities to direct and control an organization with regard to risk. *[From International Organization for Standardization (ISO) standard ISO 31000, "Risk Management – Principles and Guidelines"]*

- *Risk assessment* is the evaluation (or assessment) of what can go wrong, how likely is it, and what would be the consequences? *[From SRM-SECY-98-144, "White Paper on Risk-Informed and Performance-Based Regulation," March 1999]* This assessment may be addressed either qualitatively or quantitatively. That is, the assessment does not solely imply a probabilistic risk assessment (PRA). These risk assessment methods can include performing a PRA, Integrated Safety Assessments, vulnerability assessments, etc.

- *Risk-informed approach* to regulatory decision-making represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety. A risk-informed approach enhances the deterministic approach which is used to define many of the design and operational requirements for NRC licensees. Risk-informed approaches lie between the risk-based and purely deterministic approaches. *[From SRM-SECY-98-144, "White Paper on Risk-Informed and Performance-Based Regulation," March 1999]*

Overview of Revised Example Policy Statement

The NRC manages risk to ensure public health and safety by establishing requirements, guidance, and other regulatory controls, licensing, and providing for oversight of licensed activities. This approach ensures that licensees appropriately manage risk in a manner that protects public health and safety and the environment, and promotes the common defense and security. The consideration of risk and tailoring regulations and oversight to manage these risks is inherent in current U.S. Nuclear Regulatory Commission (NRC) programs. However, the regulatory approaches for reactors, materials, and other NRC program areas have evolved

separately based on their own individual attributes and characteristics. Thus, the various regulatory approaches are sometimes described using inconsistent terminology.

The field of risk management continues to mature and is increasingly being incorporated into activities of the Federal government and private sector. The NRC has made progress in increasing its use of risk-informed and performance-based regulation. The NRC's Strategic Plan and Principles of Good Regulation state expectations on furthering the use of risk-informed and performance-based insights. The NRC Strategic Plan indicates that the Agency will "Expand [the] use of risk-informed and performance-based insights in NRC decision-making; [and] use state-of-the-art technologies to inform regulatory decisions" to enhance the effectiveness and realism of NRC actions. The Principles of Good Regulation reinforce these points, noting that "Regulatory activities should be consistent with the degree of risk reduction they achieve."

Consistent with these objectives, the staff developed this example of an agency-wide policy statement for Commission consideration. The purpose of this policy statement would be to improve and make more consistent the regulatory framework used for all program areas including reactors, industrial, 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.

If development of an agency-wide risk management policy statement is directed by the Commission, the NRC staff would do so by following the normal regulatory process. This process would involve stakeholder input on a draft policy statement through public meetings and public review and comments. The risk management policy statement would establish by policy that the NRC uses a risk management approach; as such, the policy statement would establish an aspirational vision for the agency to improve existing agency policies and practices as guided by this vision.

Example Policy Statement Concepts:

The policy statement could be applicable to all NRC-regulated program areas (radiological safety and security) and could be composed of the following:

- A risk management approach would be used to ensure adequate protection of public health and safety and promote the common defense and security for all NRC regulatory activities.

- In a risk management approach, safety and security are ensured by (1) understanding the risk associated with NRC-regulated activities and (2) using that risk information to make regulatory decisions.

- The risk management approach would:

    1. Use a structured process to identify issues (including screening of non-risk significant issues), develop and analyze options, make decisions, and monitor the effectiveness of regulatory programs to make improvements as necessary.

2. Ensure appropriate regulatory controls and oversight are in place recognizing the variety of risks associated with different uses of radioactive materials.

3. Employ risk-informed decision-making, in which risk insights are considered together with other factors (e.g., defense-in-depth) commensurate with their importance to public health and safety and common defense and security.

4. Recognize the wide range of risk methods and tools in assessing the risk that would be consistent the complexity, hazard and technology of the regulated activity. These methods and tools would include, for example, the use of PRAs, integrated safety analyses, failure modes and effects analyses, vulnerability assessments, or more qualitative methods and engineering judgment, as appropriate to the regulated activity.

5. Consider input from stakeholders and other interested parties.

- The technical analyses supporting the risk management approach should:

  1. Be based on sound data, information, and methodologies, including consideration of uncertainties,

  2. Use techniques or combinations of techniques appropriate for the hazards and complexity of the issue,

  3. Be realistic commensurate with the need for regulatory decision-making for the program activity, and

  4. Promote and utilize advances in science and technology, as practicable.

- The risk management approach, when implemented (e.g., use of a structured decision process, establishment of risk goals, development of risk analyses), would be tailored to each specific regulated activity, as appropriate.

Implementation

The staff notes that the pros and cons of implementing a risk management approach would vary substantially among the different non-reactor program areas. Therefore, if the Commission directs the staff to develop an agency-wide risk management policy statement, implementation would be done in a deliberate and careful manner, taking into consideration the specific implementation issues within each regulatory area[1]. These issues would include developing or revising existing policy statements and guidance to implement the risk management approach. Communication with both internal and external stakeholders throughout the process would be

[1] A risk management regulatory framework process for structured use of risk-information for non-reactor program areas was developed and approved via the SRM to SECY-04-0182, "Status of Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards," with guidance in "Risk-Informed Decisionmaking for Nuclear Material and Waste Applications, Rev. 1, February 2008 (ADAMS Accession No. ML080720238).

an integral part of developing and implementing the policy. Interactions would include gathering information, deliberating, and soliciting feedback. In addition, appropriate consideration would also need to be given to the roles and responsibilities of Agreement States.

The staff recognizes agency-wide implementation of this vision represents a long-term effort directed toward improving consistency and efficiency in the Agency's regulatory processes. Agency-wide implementation activities for programs other than nuclear power reactors would likely await at least partial completion of the Commission-directed nuclear power reactor implementation option previously discussed in Section I. This stepwise progress would ensure that any lessons learned from the nuclear power reactor implementation activities could be considered in developing implementation activities for other related program areas (e.g., the research and test reactor program area.