FOR: The Commissioners

FROM: Mark A. Satorius
Executive Director
for Operations

SUBJECT: NRC STAFF RECOMMENDATION FOR THE DISPOSITION OF RECOMMENDATION 1 OF THE NEAR-TERM TASK FORCE REPORT

PURPOSE:

The purpose of this paper is to seek Commission approval of the U.S. Nuclear Regulatory Commission (NRC) staff's recommendations for dispositioning Recommendation 1 in the Near-Term Task Force (NTTF) Report, "Recommendations for Enhancing Reactor Safety in the 21st Century," dated July 12, 2011 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML111861807). The staff's recommendations considered, among other things, the nuclear power reactor recommendations presented in the Risk Management Task Force (RMTF) Report, NUREG-2150, "A Proposed Risk Management Regulatory Framework," dated April 2012 (ADAMS Accession No. ML12109A277).

SUMMARY:

The staff working group developed three potential regulatory improvement activities to disposition NTTF Recommendation 1. These potential improvement activities were developed after evaluation of the considerations underlying the NTTF's recommendation and consideration of the RMTF's power reactor recommendations. The staff identified the following recommendations for potential improvement activities:

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(1) Establish a design-basis extension category of events and associated regulatory requirements which would be forward-looking and applied on a generic basis. This would involve developing staff guidance for writing future requirements to ensure consistent performance goals, treatment requirements, documentation requirements, change processes, and reporting requirements.

(2) 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 and associated implementation guidance containing decision criteria for ensuring adequacy of defense-in-depth.

(3) Clarify the role of voluntary industry initiatives in the NRC regulatory process by specifying when these initiatives may be credited and providing guidance regarding what level of NRC oversight is appropriate for future voluntary initiatives.

The staff developed an outline for implementing these three improvement activities, including identification of regulatory products to be developed, key issues that need to be resolved, and cost and schedule estimates. The staff also evaluated the pros and cons for implementing each improvement activity.

The staff recommends that all three of these improvement activities be implemented as set forth in this SECY paper. These activities, if implemented, have the capability to improve the clarity, efficiency, and effectiveness of the current regulatory framework. The improvement activities are not needed to maintain safety of nuclear power reactors. Nonetheless, the staff expects that the improvement activities would result in modest safety enhancements.

BACKGROUND:

Following the accident at the Fukushima Dai-ichi nuclear power plant in Japan in March 2011, the Commission established a senior level agency task force 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, as set forth in Tasking Memorandum COMGBJ-11-0002 and its related staff requirements memorandum (SRM), SRM-COMGBJ-11-0002 (ADAMS Accession Nos. ML110800456 and ML110820875, respectively). 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, limited to radiological health and safety considerations for nuclear power reactors (common defense and security concerns were not directly addressed in the NTTF report). Recommendation 1 consists of an overall recommendation and four sub-recommendations. The overall recommendation is to establish a "logical, systematic, and coherent regulatory framework for adequate protection that appropriately balances defense-in-depth and risk considerations." The four sub-recommendations are:

1.1 Draft a Commission policy statement that articulates a risk-informed, defense-in-depth framework that includes extended design-basis requirements in the NRC's regulations as essential elements for ensuring adequate protection.

1.2 Initiate rulemaking to implement a risk-informed, defense-in-depth framework consistent with the above recommended Commission policy statement.

1.3 Modify the Regulatory Analysis Guidelines to more effectively implement the defense-in-depth philosophy in balance with the current emphasis on risk-based guidelines.

1.4 Evaluate the insights from the IPE and IPEEE efforts as summarized in NUREG-1560, "Individual Plant Examination Program: Perspectives on Reactor Safety and Plant Performance," issued December 1997, and NUREG-1742, "Perspectives Gained from the Individual Plant Examination of External Events (IPEEE) Program," issued April 2002, to identify potential generic regulations or plant-specific regulatory requirements.

In an August 19, 2011, SRM for SECY-11-0093 (ADAMS Accession No. ML112310021), the Commission set forth its direction to the staff with respect to the recommendations in the NTTF report. For Recommendation 1, the Commission stated:

Recommendation 1 should be pursued independent of any activities associated with the review of the other Task Force recommendations. Therefore, the staff should provide the Commission with a separate notation vote paper within 18 months of the issuance of this SRM. This notation vote paper should provide options and a staff recommendation to disposition this Task Force recommendation.

Also, on June 14, 2012, then-Chairman Jaczko 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 to consider, when developing options for the disposition of Recommendation 1, the regulatory framework recommendations for nuclear power reactors in the RMTF report, NUREG-2150. The improvement activities recommended in this SECY reflect staff consideration of the RMTF report for power reactors. A detailed discussion of how each improvement activity addresses each applicable RMTF report recommendation is contained in Enclosure 1.

DISCUSSION:

Staff Approach for Developing Its Recommendation on NTTF Recommendation 1 and RMTF Recommendations for Nuclear Power Reactors

The staff formed a working group consisting of senior staff members from the Office of Nuclear Reactor Regulation, Office of New Reactors, Office of Nuclear Material Safety and Safeguards, Office of Nuclear Security and Incident Response, Office of Federal and State Materials and Environmental Management Programs, Office of Nuclear Regulatory Research, and the Office of the General Counsel. The NTTF Recommendation 1 working group also included members from the original RMTF. A group of senior NRC managers overseeing staff actions associated with the NTTF recommendations, known as the Japan Lessons Learned Project Directorate

(JLD) Steering Committee, was informed of the working group's activities, and provided direction to the working group throughout the development of this SECY paper.

The staff reviewed both the NTTF report and the RMTF report and considered different approaches in developing the improvement activities. During development of its recommendations, the working group held three public meetings, met routinely with the JLD Steering Committee, met six times with the Advisory Committee on Reactor Safeguards (ACRS), solicited and evaluated written public comments, and provided several rounds of briefings to individual Commissioners on the status of the Recommendation 1 effort. Enclosure 2 provides a detailed chronology of the NRC staff's outreach to external stakeholders in the development of these improvement activities for the disposition of NTTF Recommendation 1.

Consistent with the scope of the NTTF report and then-Chairman Jaczko's tasking memorandum, this SECY paper contains recommendations only for light-water nuclear power reactors. It does not contain recommendations for non-power reactors, nuclear materials (e.g., power reactor fuel, including spent fuel) at nuclear power plants, or other nuclear materials regulated by the NRC (such as materials used in medicine and in industrial uses such as well logging); nor does it address security issues.

Identifying the problem that NTTF Recommendation 1 is attempting to resolve

To help the staff identify and assess options for the disposition of NTTF Recommendation 1, the staff developed the following problem statement describing the issues that Recommendation 1 is directed at resolving:

> The existing regulatory framework for power reactors effectively addresses design-basis events, including design-basis accidents. However, for non design-basis accidents, the existing framework could be improved to facilitate more consistent, efficient, timely, and transparent Commission decisions to address new issues and information. These improvements would allow the NRC's regulatory framework to provide:
>
> - An improved structure and set of criteria for identifying and categorizing hazards and events not previously recognized as significant that may require regulatory action (e.g., extended station blackout) (addressed by Improvement Activity 1).
> - A structure and criteria for consistently and predictably evaluating how defense-in-depth should be addressed for an effective NRC regulatory response to new information or events or accidents not previously recognized as significant (e.g., evaluation of a possible requirement for filtered vents) (addressed by Improvement Activity 2).
> - A regulatory process that ensures licensee implementation and consistent long-term maintenance of voluntary industry initiatives (e.g., Severe Accident Management Guidelines (SAMGs)) (addressed by Improvement Activity 3).

The NTTF's concern about a "patchwork" of beyond-design-basis requirements and voluntary initiatives must be understood in context with the NTTF's recommendation for a "framework" in which current design-basis requirements would remain largely unchanged and the current "beyond design-basis" requirements would be complemented with new requirements to establish a more balanced and effective application of defense-in-depth. The NTTF stated that a new framework would establish a more logical, systematic, and coherent set of requirements addressing defense-in-depth. The staff believes that the problem statement presented above effectively captures the NTTF's concern about a "patchwork."

Improvement Activities for the Disposition of NTTF Recommendation 1

The staff developed three improvement activities for the disposition of Recommendation 1. These three improvement activities are summarized below. Enclosure 1 provides the staff's detailed discussion of each improvement activity, including a discussion of how the three activities relate to and address NTTF Recommendation 1 and the RMTF recommendations for nuclear power reactors. Enclosure 1 also explains the NRC staff's rationale for not recommending full implementation of the NTTF or RMTF recommendations.

A viable and acceptable alternative to implementing any or all of these improvement activities would be to maintain the existing regulatory framework of design-basis events augmented with additional regulations as needed. The NRC would continue under its current processes to issue new regulations as needed on a case-by-case basis, as is being done in the NRC's response to the Fukushima Dai-ichi event. Maintaining the existing regulatory framework would maintain nuclear safety while preserving an approach to regulation that has been successful and is well-understood. If the Commission chooses not to adopt these improvement activities at this time, the staff notes that such a decision would not preclude the Commission from pursuing these improvement activities in the future as resources and circumstances permit. A more detailed discussion of maintaining the existing framework is included in Enclosure 1.

The estimates of the costs of each improvement activity provided in Enclosure 1, do *not* reflect possible future savings attributable to the improvement activities, either as benefits or averted costs. The NRC staff's proposed improvement activities have been defined in such a way as to provide increased regulatory efficiency, clarity, and coherence and modest safety benefits without requiring significant resource expenditure or an undue increase in regulatory burden. They build incrementally on the NRC's existing approach to the regulation of nuclear power reactors.

The NRC staff believes that these improvement activities represent real improvements that can be accomplished without undue burden on current nuclear power plant licensees and applicants. Implementation of the improvement activities would confirm the findings of NUREG-1412, "Foundation for the Adequacy of the Licensing Bases," dated December 31, 1991 (ADAMS Accession No. ML080310668), with respect to the evolving nature of the NRC's regulatory process, which the NRC relied upon when adopting the nuclear power plant license renewal requirements in 10 CFR Part 54 (56 FR 64943; December 13, 1991). Although the Commission may adopt none or any one or more of the improvement activities, the staff recommends that all three activities be adopted because implementation of the three activities would be synergistic (e.g., Improvement Activity 2 on defense-in-depth may increase the implementation effectiveness of Improvement Activities 1 and 3). The Commission, should it approve these improvement activities, may also direct their implementation as an “interim” step before the completion of any Commission-directed implementation of the RMRF.

Improvement Activity 1: Establish a Design-Basis Extension Category of Events and Associated Regulatory Requirements

Improvement Activity 1 is intended to address the recommendations of the NTTF and RMTF with respect to establishing a category of beyond-design-basis events and accidents. In the staff’s view, the common concern underlying the NTTF and RMTF recommendations arises from the lack of clarity in the NRC’s regulatory terminology associated with “beyond-design-basis accidents,” which leads to inconsistent approaches for addressing these types of accidents—particularly when years or decades separate the regulatory decisions. The staff believes that the NTTF Recommendation 1 proposal to make extensive changes to the regulations and to develop and implement new processes and criteria to identify new events and accidents will not substantively improve nuclear safety and could divert resources away from other, more effective activities to improve safety. This is especially true given the development and implementation of other post-Fukushima improvements such as providing equipment and mitigating strategies to address conditions such as an extended loss of electrical power, which will serve to reduce the overall risk associated with nuclear power reactors. The RMTF recommended approach would involve even more comprehensive changes than those proposed by the NTTF. This paper presents the staff’s recommendations for a simpler, more cost-effective way to address the NTTF and RMTF common concerns, consistent with the staff's problem statement.

The staff proposes 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.” Design-basis extension events would be those that are not currently considered to be design-basis events or accidents, but that must be regulated because their prevention and/or mitigation is necessary for reasonable assurance of adequate protection or should be regulated because their prevention and/or mitigation would result in a substantial safety improvement at an acceptable burden to licensees. The staff recommends that regulatory requirements in the design-basis extension category include requirements for adequate protection (e.g., recent Order EA-12-049, “Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events,” on mitigating strategies), as well as “cost-justified safety enhancements” (e.g., station blackout; Title 10 of the *Code of Federal Regulations* (10 CFR) 50.63, “Loss of All Alternating Current Power”). The definition of the new term could be accomplished by rulemaking or by revising NRC guidance documents. However, to implement the new design-basis extension category in the regulatory framework for nuclear power plants, the staff recommends 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 process defined in that publicly available document would be implemented by conforming changes to internal NRC policies, guidance, and procedures. Matters to be addressed when writing a design-basis extension rule would include (but are not limited to):

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

- 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

- characterization of each future design-basis extension requirement as a matter of adequate protection or safety enhancement, even if the requirement is not subject to the backfit rule, 10 CFR 50.109, or the issue finality provisions in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants"

The staff recommends that the initial population of events and requirements in this category would be drawn from the existing regulatory requirements addressing what are currently referred to as "beyond-design-basis events," including station blackout; anticipated transients without scram (ATWS—10 CFR 50.62, "Requirements for Reduction of Risk from Anticipated Transients Without Scram (ATWS) Events for Light-Water-Cooled Nuclear Power Plants"); combustible gas control (10 CFR 50.44, "Combustible Gas Control for Nuclear Power Reactors"); loss of large plant areas, (10 CFR 50.54(hh)); and aircraft impact assessment (10 CFR 50.150, "Aircraft Impact Assessment"). Current rulemakings that may be characterized as falling into the new design-basis extension category are the rulemakings on station blackout mitigation strategies, onsite emergency response capability, and containment filtering strategies. The staff recommends that the regulatory requirements for design-basis extension should be applied to both existing and new nuclear power plants, but only on a forward-looking[1] basis when: (1) addressing emergent issues, and (2) the NRC revises existing regulatory requirements due to new information. The staff recommends that the design-basis extension category be applied on a generic basis (i.e., by adoption of generically applicable regulations and issuance of broadly applicable orders), rather than on a plant-specific basis. Hence, a requirement for plant-specific probabilistic risk assessments (PRAs) is not needed to implement this improvement activity. Nonetheless, it is still expected that plant-specific PRAs would continue to be used for regulatory risk-informed activities including the implementation of the improvement activities discussed in this paper even though the staff is not proposing that plant-specific PRAs be required.

The staff will develop a standard set of treatment requirements for future requirements in the design-basis extension category. The development of this standard set will be accomplished via a public process. Because the proposed design-basis extension category would contain both adequate protection and safety enhancement requirements, it may not be possible to determine a standard set of treatment requirements that would be appropriate for all requirements in the proposed category. In the event that a standard set of treatment requirements cannot be defined, the staff would issue guidance to assist rulemaking staff to

[1] Note that under Improvement Activity 3, the staff recommends a retrospective review of certain existing voluntary initiatives which could potentially result in the issuance of new design-basis extension requirements if the staff determines that some safety-significant voluntary initiatives have not been effectively implemented and maintained over time.

determine an appropriate set of requirements to be applied to each individual design-basis extension rule.

As recommended by the staff, the improvement activity would not impose additional incremental costs to the industry over what would otherwise be incurred if the NRC were to adopt new regulatory requirements addressing what are currently regarded as beyond-design-basis events and accidents. The recommended approach's estimated costs for the NRC are expected to be small in that the changes could be incorporated into routine updates of the internal guidance documents. Conforming changes would also be incorporated into the planned update of the Regulatory Analysis Guidelines. Completion of the document to define the category and guidance documents to create and implement the design-basis extension category improvement activity could take 2 to 4 years.

Improvement Activity 1 meets the intent of NTTF Recommendations 1.1 and 1.2, in part, because it clarifies the role of and expectations for regulations that extend the original design basis of nuclear power plants. This activity addresses the NTTF's "patchwork" observation by adding structure to the existing and future regulations intended to extend the plant's design basis. It is a cost-effective way of improving the NRC's regulatory system related to evaluating and establishing regulatory requirements for these events. The design-basis extension category would also increase transparency to the public in that the NRC will regulate all events that are identified as safety issues and clarify the regulatory controls over the systems, structures, and components that mitigate them.

The recommended generic approach can identify and resolve risk outliers associated with design characteristics common to a group of plants (e.g., ice condenser containment systems) but it is not expected to be able to provide additional safety benefits by identifying site-specific vulnerabilities. The staff believes that the possible safety benefits of a site-specific search for vulnerabilities are not justified. Plant-specific vulnerabilities have been searched for and addressed in the past (e.g., Generic Letter 88-20, "Individual Plant Examination for Severe Accident Vulnerabilities") and are now sought routinely as part of the reactor oversight process and the reactor operating experience program. Site-specific vulnerabilities related to seismic and flooding events are being addressed by the post Fukushima actions (e.g., Recommendations 2.1 and 2.3). As a result, it is unlikely that the benefits of plant-specific assessments would justify the costs.

Improvement Activity 2: Establish Commission Expectations for Defense-In-Depth

Improvement Activity 2 would 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 set forth the defense-in-depth approach as a hierarchy that includes specified levels of defense for reactor safety. This hierarchical approach is consistent with the International Atomic Energy Agency's approach to defense-in-depth. This improvement activity would also develop implementation guidance that includes details regarding the levels 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 be part of this improvement activity.

The policy statement would reinforce 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 clearly include prevention and mitigation strategies, include consideration of deterministic and probabilistic criteria, and assure that uncertainties, including those in risk assessments and traditional engineering analyses, are adequately compensated for based on clear deterministic criteria. As currently envisioned, the policy statement would have four major parts:

(1) Statement of Commission Expectations
(2) Definition of Defense-in-Depth
(3) Objective of Defense-in-Depth
(4) Defense-in-Depth Principles

In addition, it is envisioned that the implementation guidance would have two major parts:

(1) Levels of Defense for Nuclear Power Reactor Safety
(2) Decision Criteria

The staff recommends that the new policy statement and associated implementation guidance be applicable to all nuclear power reactors, but that it be applied only to future issues and regulatory and licensing actions (i.e., be forward-looking). The staff does not recommend an associated PRA requirement for currently operating 10 CFR Part 50 ("Domestic Licensing of Production and Utilization Facilities") reactors, for the sole purpose of informing the defense-in-depth policy, because a PRA requirement would not provide safety benefits commensurate with the cost of developing the PRA models.

Improvement Activity 2 directly supports NTTF Recommendation 1, as well as specific sub-recommendations 1.1, 1.2, and 1.3, because defining defense-in-depth and developing decision criteria are necessary to implementing those recommendations. Completion of this improvement activity is expected to take 3 to 4 years.

The major benefit of Improvement Activity 2 is that it provides a uniform, technically justified, documented basis for the defense-in-depth principle of risk-informed decision making. Improvement Activity 2 also directly supports the Commission's PRA Policy Statement. The guidance developed will involve criteria and a process that will provide a structure for decisionmaking on adequacy of defense-in-depth. However, there may be situations where the criteria may not be sufficiently definitive across all foreseeable applications.

Improvement Activity 3: Clarify the Role of Voluntary Industry Initiatives in the NRC Regulatory Process

Improvement Activity 3 does not address an explicit NTTF or RMTF recommendation but rather addresses an apparent NTTF concern as reflected in the NTTF Report discussion preceding Recommendation 1. It would clarify the role of certain industry initiatives in the NRC's regulatory processes by (1) re-affirming the Commission's expectation that initiatives may not be used in lieu of NRC regulatory action on adequate protection issues, (2) specifying when these initiatives may be credited in the baseline case for regulatory analyses, and (3) providing guidance regarding what level of NRC oversight is appropriate for future voluntary initiatives. By "industry initiative," the staff is referring to proposals made by the nuclear power industry (e.g., commitments made by the Nuclear Energy Institute or proposals made by discrete groups of licensees and applicants, such as the Boiling-Water Reactor Owners Group). It does not include an individual plant's voluntary commitments, which are adequately addressed by existing processes[2] and are excluded from Improvement Activity 3. Specifically, the staff's recommendation is focused on those industry initiatives which are developed in response to a potential generic safety concern that the NRC is considering addressing through a rulemaking or broadly-applicable order as a potential cost-beneficial safety enhancement.

In general, this improvement activity would involve revisions to existing guidance, reiterating the current Commission policy that the NRC will not accept industry initiatives in lieu of NRC regulatory action on adequate protection issues (May 27, 1999, Commission SRM (ADAMS Accession No. ML003752062) approving the staff's recommendations in SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," March 2, 1999 (ADAMS Accession No. ML992810068)).

The revised guidance would also direct that an industry initiative is credited in the baseline case as defined in the Regulatory Analysis Guidelines (NUREG/BR 0058, Revision 4) only when there is a high likelihood that the industry will effectively implement and maintain the initiative over time.

As a part of this proposed improvement activity, the staff will develop and implement an integrated program for Type 2[3] voluntary industry initiatives. The program consists of the following two elements. First, the staff intends to evaluate the current status of implementation on those existing Type 2 initiatives that are most risk significant or safety significant. The staff will use risk insights to identify the existing Type 2 initiatives which are the most risk and safety significant and then determine if the effectiveness of licensee implementation of the initiative(s) is already monitored (directly or indirectly) under an existing NRC oversight activity (e.g., inspections, performance indicators, licensee reports). Where an acceptable measure of effectiveness cannot be identified, the staff would verify licensee implementation of the initiatives (e.g., through a one-time audit, change to existing inspection procedure, or request for information). Depending on the results of the verification activity, the staff might take further action. Second, the staff would revise its policies and procedures to ensure that the staff monitors future Type 2 initiatives for continued effective implementation. The staff will ensure that licensee commitments to voluntary initiatives are well-documented and transparent to the public. In the course of revising its policies and procedures, the staff may identify a need for a regulation requiring a licensee to report certain information regarding safety-significant Type 2 voluntary initiatives and/or notify the NRC if it intends to change its decision to implement or maintain any industry initiative that the NRC has publicly identified and relied on as the basis for

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[2] Office of Nuclear Reactor Regulation Licensing Instruction – LIC-105, "Managing Regulatory Commitments Made by Licensees to the NRC," dated September 5, 2013 (ADAMS Accession No. ML13193A358).

[3] The following definition of Type 2 initiatives is from SECY-01-0121: "A Type 2 initiative is developed in response to a potential safety concern that is a potential cost-beneficial safety enhancement outside existing regulatory requirements. Such industry initiatives may be used to provide safety enhancements without the need for regulatory action. However, where it is determined that the proposed industry initiative is not effective in addressing the safety concern, the NRC may pursue rulemaking in accordance with the criteria described in 10 CFR 50.109." See the discussion of Improvement Activity 3 in Enclosure 1 for more details.

not pursuing rulemaking. The staff would follow the routine process to request Commission approval to institute such a rulemaking.

In developing Improvement Activity 3, the staff considered three different approaches for addressing the NTTF concerns regarding voluntary initiatives. These three approaches are described and evaluated in Attachment 3 to Enclosure 1. There were conflicting views within the staff on the best path forward, regarding whether to recommend an approach which reflects the current Commission policy, or to instead recommend that the Commission change its current policy on voluntary initiatives. After consideration, the staff recommends the approach described above, which would improve the NRC's processes for accepting and overseeing voluntary initiatives without reevaluating and revising the existing Commission policy on voluntary initiatives. The staff believes that the recommended approach is preferable because some safety enhancements could be put in place more quickly and efficiently via industry initiatives than by the more resource-intensive and time-consuming rulemaking process.

Improvement Activity 3 partially addresses the NTTF's "patchwork" observation by more clearly stating the NRC's policies regarding industry initiatives and by adding risk-informed regulatory oversight of future and certain existing Type 2 industry initiatives. It also ensures that the safety benefits from industry initiatives are consistently implemented and maintained over time. The staff estimates that Improvement Activity 3 would take 2 years to implement.

Relationship Between NTTF Recommendation 1 and the Risk Management Regulatory Framework (RMRF)

Another interoffice working group (the RMRF working group) is responding to the June 12, 2012, tasking memorandum that stated "…the staff should 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…." The first and second proposed improvement activities in this SECY paper are related to RMRF.

Improvement Activity 1 addresses the recommendations of the NTTF and RMTF with respect to establishing a category of beyond design-basis events/accidents for nuclear power reactors. Staff was mindful of the RMTF proposals as it developed approaches to Recommendation 1.

Improvement Activity 2 recommends that a power reactor safety defense-in-depth policy statement and implementation guidance be developed and identifies possible concepts for such a policy statement and implementation guidance. The RMRF working group is exploring an RMRF policy statement which would be an overall agency policy statement broadly covering a risk management decisionmaking process where defense-in-depth would be a key element. This policy statement would be applicable across the agency, including nuclear power reactors.

Commission direction on NTTF Recommendation 1 will inform the staff's approach for implementation of an RMRF, which will build upon the approach outlined in Recommendation 1.

COMMITMENTS:

Listed below are the actions or activities committed to by the staff in this paper:

The staff will perform verification activities to ensure that certain existing industry initiatives are being consistently maintained, which is within the staff's authority and does not require Commission approval.

RESOURCES:

The resources needed to pursue each of the improvement activities are set forth in Enclosure 1. <INSERT from OCFO>

RECOMMENDATIONS:

The NRC staff recommends that the Commission approve the staff pursing Improvement Activities 1, 2, and 3, as described above and in greater detail in Enclosure 1, to address NTTF Recommendation 1 and certain related RMTF recommendations for nuclear power reactors.

With respect to Improvement Activity 1, the staff specifically recommends adopting the new "design-basis extension" category of events as described above.

With respect to Improvement Activity 2, the staff specifically recommends developing a defense-in-depth policy statement and associated implementation guidance as described above. This activity would also update the Regulatory Analysis Guidelines to appropriately consider defense-in-depth criteria.

With respect to Improvement Activity 3, the staff plans to take the actions that do not require Commission approval set forth under "Commitments," above. In addition, the staff specifically recommends revising the Regulatory Analysis Guidelines to credit only those Type 2 initiatives that are determined to be "highly likely" to be effectively implemented and maintained over time, which could be perceived as a change in Commission policy.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has concurred. Because these recommendations have been reviewed by the JLD Steering Committee, further review by the Committee to Review Generic Requirements was not necessary.

The staff has met five times with the ACRS subcommittee, and once with the ACRS full Committee to discuss Recommendation 1. In a November XX, 2013, letter, the ACRS full Committee provided its views in support of these recommendations. -- OR – [These views have been addressed by the staff in its response to the Committee, which is provided in Enclosure 5 (include this statement only if substantive differing views are expressed by ACRS)].

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Enclosures:
1. Detailed Discussion of Recommended Improvement Activities
2. NRC Staff Responses to Public Comments on White Paper Dated May 14, 2013
3. A History of Defense-in-Depth for Commercial Nuclear Power Plants
4. NRC Staff Outreach on Disposition of NTTF Recommendation 1

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The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has concurred. Because these recommendations have been reviewed by the JLD Steering Committee, further review by the Committee to Review Generic Requirements was not necessary.

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ADAMS Accession No.: Pkg: ML13277A413 Ticket No.

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ENCLOSURE 1: DETAILED DISCUSSION OF RECOMMENDED IMPROVEMENT ACTIVITIES FOR THE DISPOSITION OF NTTF RECOMMENDATION 1

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BACKGROUND

Following the accident at the Fukushima Dai-ichi nuclear power plant in March 2011, the Commission established a senior level agency task force 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, as set forth in Tasking Memorandum COMGBJ-11-0002 and SRM-COMGBJ-11-0002 (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML110800456 and ML110820875, respectively). This task force is referred to as the Near-Term Task Force (NTTF). The NTTF issued its report on July 12, 2011 (ADAMS Accession No. ML111861807), as an enclosure to SECY-11-0093 (ADAMS Accession No. ML11186A959).

The NTTF developed 12 overarching recommendations, limited to radiological health and safety considerations for nuclear power reactors (common defense and security concerns were not directly addressed in the NTTF Report). Recommendation 1 consists of an overall recommendation and four sub-recommendations. The overall recommendation is for the establishment of a "logical, systematic, and coherent regulatory framework for adequate protection that appropriately balances defense-in-depth and risk considerations." (NTTF Report, p. 22). The four sub-recommendations are:

1.1 Draft a Commission policy statement that articulates a risk-informed defense-in-depth framework that includes extended design-basis requirements in the NRC's regulations as essential elements for ensuring adequate protection.

1.2 Initiate rulemaking to implement a risk-informed, defense-in-depth framework consistent with the above recommended Commission policy statement.

1.3 Modify the Regulatory Analysis Guidelines to more effectively implement the defense-in-depth philosophy in balance with the current emphasis on risk-based guidelines.

1.4 Evaluate the insights from the IPE and IPEEE efforts as summarized in NUREG-1560, "Individual Plant Examination Program: Perspectives on Reactor Safety and Plant Performance," issued December 1997, and NUREG-1742, "Perspectives Gained from the Individual Plant Examination of External Events (IPEEE) Program," issued April 2002, to identify potential generic regulations or plant-specific regulatory requirements.

In an August 19, 2011, staff requirements memorandum (SRM) for SECY-11-0093 (ADAMS Accession No. ML112310021), the Commission set forth its direction to the staff with respect to the recommendations in the NTTF Report. For Recommendation 1, the Commission stated:

> *Recommendation 1 should be pursued independent of any activities associated with the review of the other Task Force recommendations. Therefore, the staff should provide the Commission with a separate notation vote paper within 18 months of the issuance of this SRM. This notation vote paper should provide options and a staff recommendation to disposition this Task Force recommendation.*

Also, on June 14, 2012, Chairman Jaczko 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 to consider, when developing options for the disposition of Recommendation 1, the regulatory framework recommendations for power reactors in the Risk Management Task Force (RMTF) report, NUREG-2150, “A Proposed Risk Management Regulatory Framework” (April 2012).

To help the staff identify and assess options for the disposition of NTTF Recommendation 1, the staff developed the following problem statement describing the issues that Recommendation 1 is directed at resolving:

> The existing regulatory framework for power reactors effectively addresses design-basis events, including design-basis accidents. However, for non-design-basis accidents, the existing framework could be improved to facilitate more consistent, efficient, timely, and transparent Commission decisions to address new issues and information. These improvements would allow the NRC’s regulatory framework to provide:
>
> - An improved structure and set of criteria for identifying and categorizing unanticipated hazards and events that may require regulatory action (e.g., extended station blackout). (addressed by Improvement Activity 1)
>
> - A structure and criteria for consistently and predictably evaluating how defense-in-depth should be addressed for an effective NRC regulatory response to new information or unforeseen events or accidents (e.g., evaluation of a possible requirement for filtered vents). (addressed by Improvement Activity 2)
>
> - A regulatory process that ensures licensee implementation and consistent long-term maintenance of voluntary industry initiatives (e.g., Severe Accident Management Guidelines (SAMGs)). (addressed by Improvement Activity 3)

In their report, the NTTF characterized the NRC’s current approach to addressing safety concerns as a “patchwork of beyond-design-basis requirements and voluntary initiatives.” The NTTF’s concern about a “patchwork” of beyond design basis requirements and voluntary initiatives must be understood in context with the NTTF’s recommendation for a “framework” in which current design basis requirements would remain largely unchanged and the current beyond-design-basis requirements would be complemented with new requirements to establish a more balanced and effective application of defense-in-depth. The NTTF stated that a new framework would “establish a more logical, systematic, and coherent set of requirements addressing defense-in-depth” (NTTF Report, p. 21). The staff believes that the problem statement presented above effectively captures the NTTF’s concern about a “patchwork.”

THREE IMPROVEMENT ACTIVITIES FOR THE DISPOSITION OF NTTF RECOMMENDATION 1

The staff recommends that the Commission approve three improvement activities for addressing NTTF Recommendation 1:

- *Improvement Activity 1: Establish a Design-Basis Extension Category of Events and Associated Regulatory Requirements*

- *Improvement Activity 2: Establish Commission Expectations for Defense-In-Depth*

- *Improvement Activity 3: Clarify the Role of Voluntary Industry Initiatives in the NRC Regulatory Process*

Although the Commission may adopt any one or more of the recommended improvement activities, the staff recommends that all three activities be adopted, inasmuch as they are all relatively low-resource intensive with limited impacts on current nuclear power plant licensees and applicants. More importantly, implementation of the three activities would be synergistic (e.g., Improvement Activity 2 on defense-in-depth-may increase the implementation effectiveness of Activities 1 and 3).

The staff intends for these improvement activities to address the underlying intent of the NTTF's recommendations, even if they do not fully implement every aspect of each of the NTTF's recommendations. Based on discussions with the Advisory Committee on Reactor Safeguards (ACRS) and public comments, the NTTF report appears to have given some stakeholders the impression that the current NRC process to develop new regulations is purely reactive in the sense that an accident must occur before actions are taken. Recommendation 1 is viewed by some stakeholders as being intended to change this reactive process into a proactive process. Most new regulations are reactive in the sense that new information is obtained which is evaluated and a determination made that changes to the regulations are needed. The staff may obtain new information from a variety of sources, including accidents and near accidents, after the occurrence of which the NRC's response is observed by the public. In addition, the NRC obtains new information from its oversight activities, which include inspections, audits, and review of reports from monitoring systems it has required licensees to implement, which are capable of identifying performance degradation before an accident occurs (e.g., unexpected performance deficiencies). Information from these sources may also lead to new regulatory requirements, but these requirements are not as visible to the public as actions taken following an accident. Even a probabilistic risk assessment (PRA) is reactive (after the initial IPE and IPEEE vulnerability issues from Generic Letter 88-20 were identified), in the sense that either an un-modeled event must occur or an indication that a previous model is incorrect must be obtained before any new risk insights could be developed. Therefore it is the staff's position that the extent to which the regulatory process/framework is reactive or proactive is independent of how aggressively a new regulatory framework is developed and implemented. The potential concern is in instances in which the regulator's reaction to unexpected events is narrow-scoped and does not involve determination of root causes and broad corrective action to address the full implications of the event. The staff believes that the NRC's response to the Fukushima Dai-ichi accident in general, as well as the staff's recommendations for the disposition of Recommendation 1 in this SECY Paper, belies such a regulatory philosophy at the NRC.

The staff recognizes that, as an abstract matter, more action could be taken to reduce uncertainties. However, the need for such action must be judged against the fact that the NRC has many ongoing regulatory activities to both identify and address new issues and reduce uncertainties. Some activities are long standing, as first comprehensively chronicled in NUREG-1412, "Foundation for the Adequacy of the Licensing Basis." Other activities have been instituted through the routine evolution of the regulatory process, including all the post-Fukushima actions that the NRC has undertaken (e.g., seismic and flooding hazard reviews). After surveying past and current NRC regulatory actions, the staff does not believe it to be prudent at this time to redirect limited resources and regulatory attention away from known safety and risk issues, in order to search to identify unknown (speculative) risk and safety vulnerabilities.

Each of the three improvement activities are discussed in the next section, "DISCUSSION OF EACH IMPROVEMENT ACTIVITY." First, a summary of the improvement activity is provided, followed by the relevant history or background of the underlying issue. Background information, including the relationship of the improvement activity to NTTF Recommendation 1 and related RMTF recommendations, is provided next. Following that is a detailed description of the improvement activity in sufficient depth to facilitate understanding of how the NRC staff would proceed if the improvement activity is approved by the Commission. This section includes a description of the proposed approach, key issues, expected products, estimated resources, length of time to implement, and pros and cons (both from the perspective of the industry and the NRC). Next, the staff discusses how the proposed improvement activity would resolve NTTF Recommendation 1, and concludes with an example scenario illustrating the possible outcome of implementing the proposed improvement activity.

Commission decision not to adopt any of the three recommended improvement activities

Consistent with the NRC's Regulatory Analysis Guidelines, NUREG/BR-0058, Revision 4, the staff evaluated the possible effects of a Commission decision not to adopt any of the three staff-recommended improvement activities. The staff believes that the public would continue to be adequately protected if the Commission took no action at this time on these recommendations. These activities, if implemented, have the capability to improve the clarity, efficiency, and effectiveness of the current regulatory framework. The improvement activities are not needed to maintain safety of nuclear power reactors. Nonetheless, the staff expects that the improvement activities would result in modest safety enhancements.

Moreover, the staff believes that a decision not to take specific action on any of the three improvement activities at this time neither precludes the Commission from deciding to adopt one or more of these activities in the future, when circumstances permit, nor the NRC from adopting some aspects of the improvement activities in the course of the ongoing evolution of the NRC's regulatory framework for nuclear power plants.

If the Commission decides not to pursue any of these improvement activities, there would be no changes to existing NRC policies or processes initiated by the Commission in response to NTTF Recommendation 1. Instead, the NRC would continue under its current process to make improvements as needed on a case-by-case basis, when identified in the course of existing regulatory processes, e.g., inspections, audits, new research, generic issues program, communications with international nuclear regulatory bodies. Emergent issues with potential safety impact would continue to be handled as they currently are, as is the case for the actions now underway as a result of the Fukushima Dai-ichi accident. In addition, the staff notes that existing new reactor certification and licensing processes specified in 10 CFR Part 52 require licensees to perform PRAs and use them to address beyond design basis events, including severe accidents.

Thus, a Commission decision not to implement any of these improvement activities is *not* a "do nothing" approach. Under the existing regulatory processes and framework, the NRC would continue to improve portions of its processes and framework in response to operating experience, new information, or emergent issues, just as it has done in the past. For example, the NRC began to update its Regulatory Analysis Guidelines prior to the Fukushima Dai-ichi event. As another example, post-Fukushima Orders and other related regulatory actions will ensure NRC oversight of SAMGs, enhance the ability of licensees to mitigate severe accidents, improve emergency planning, and realize other safety improvements. These activities are being accomplished under the current NRC regulatory framework.

Maintaining the existing regulatory processes, policy, and framework would cause no additional incremental costs to be incurred by either the NRC or the nuclear power industry. However, the NRC and industry would incur costs when the agency decides to undertake future framework improvement activities on an *ad hoc* basis, and may forego possible reductions in costs resulting from efficiencies that might be realized if regulatory process and framework improvement activities were accomplished in an integrated fashion under the three framework improvement activities recommended in the SECY paper and described in detail below.

The major benefit of maintaining the existing regulatory processes and framework is that it would maintain nuclear safety while preserving an approach to regulation that has been successfully implemented by the NRC and industry for many years and is well understood by both. The existing framework allows for incremental improvements of the regulatory approach with full stakeholder engagement. However, it does not clearly address the apparent "patchwork" remarked upon by the NTTF and therefore does not aid in improving the understanding of NRC's regulatory structure. It does not provide a systematic method for assuring appropriate treatment criteria, change processes, reporting requirements, etc. are put into place for all new requirements developed in the future. It may also not be as efficient at effecting identified improvements as a framework that has been augmented by the three framework improvement activities described below.

DISCUSSION OF EACH IMPROVEMENT ACTIVITY

Improvement Activity 1: Establish a Design-Basis Extension Category of Events and Associated Regulatory Requirements

I. Summary of Improvement Activity

This improvement activity would adopt a new term – "design-basis extension" -- to define and describe the events and requirements which have typically been characterized as "beyond design-basis:"

> "Design-basis extension" conditions are those conditions (including hazards and events) posing a significant safety concern at nuclear power plants for which accident prevention and/or mitigation capability must be provided, but are neither postulated accidents (anticipated operational occurrences or design basis accidents) evaluated in a nuclear power plant's final safety analysis report, nor the external hazards for which a nuclear power plant was designed and licensed.

This terminology is deliberate and is intended to convey that these conditions are not treated as design basis accidents but they are included in the design basis. This improvement activity would result in revision of NRC's internal policies, guidance and procedures to define this new term and to ensure that future design-basis extension requirements (both rules and orders) are written in a consistent, logical, and complete manner.

II. Background

A. The Concept of Design Basis and Design Basis Events

The Commission has historically relied upon a set of design-basis events and accidents to demonstrate that a nuclear plant design is robust. Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants.", provides a list of potential accident initiating events (initiators) that applicants are requested to address in Chapter 15 of the Safety Analysis Report. The loss of coolant accident (LOCA) is specified in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50 as the design-basis for the light water reactor (LWR) emergency core cooling system and containment, and the performance of these systems, structures, and components (SSCs) is evaluated and reported in Chapter 6 of the FSAR. The term “design-basis accident” (DBA) is defined as a postulated set of failure events that a facility is designed and built to withstand without exceeding the offsite exposure guidelines in 10 CFR 50.34(a)(1) or 10 CFR 100.11 of the Commission’s regulations.

NUREG/CR-6042, "Perspectives on Reactor Safety," provides the long history of the concept of design-basis for nuclear power plants. Yet, despite the long history of this regulatory concept, important “design-basis” terms have not been consistently defined or clearly distinguished from other regulatory requirements in 10 CFR Part 50. Although “design bases” is defined in 10 CFR 50.2, “design-basis event”[1] (DBE) and “design-basis accident” are not, even though both terms are used in many places in Part 50.

B. Events outside the Set of Design Basis Accidents/Events

Chapter 3, “Regulatory Framework for the 21st Century,” of the NTTF report provides a discussion of the historical development of requirements to address issues beyond the design-basis which will not be repeated here. In summary, the NRC has adopted requirements addressing new events based on new information (e.g., risk insights from IPE/IPEEE and other probabilistic risk analyses, plant events, operating experience) without a common set of criteria for characterizing these events using the DBA/DBE nomenclature. Some examples include the Station Blackout (SBO) Rule, 10 CFR 50.63, and the Aircraft Impact Assessment Rule, 10 CFR 50.150. In addition, the NRC has relied upon industry or individual licensee voluntary actions to address some issues identified as the result of new information, but without characterizing these issues using the DBA/DBE nomenclature. For example, programs for management of severe accident conditions have been instituted at licensed facilities on a voluntary basis. They are not required by the NRC.

As noted below, both the NTTF and the RMTF have recommended that the Commission consider establishing a category of extended or enhanced design-basis accidents or events to augment the existing NRC regulatory framework for power reactors. Additionally, several international industry and regulatory organizations have already published requirements to consider beyond-design-basis events explicitly. The Western European Nuclear Regulators Association (WENRA) now recommends[2] a “design-extension” analysis and the International Atomic Energy Agency (IAEA) has included a requirement in a draft safety requirements document[3] for identification of “design-extension conditions”. In both cases events are selected based on deterministic insights, probabilistic assessments, and engineering judgment. Power plants are expected to have measures for prevention or mitigation of the events.

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[1] Although "design basis event" is defined in 10 CFR 50.49, "Environmental qualification of electric equipment important to safety for nuclear power plants."
[2] See Appendix F of WENRA Reactor Harmonization Working Group, “WENRA Reactor Safety Reference Levels,” (January 2008)
[3] DS414, “Safety of Nuclear Power Plants”

C. Relationship to NTTF Recommendation 1

The NTTF considered the current NRC regulatory framework as one that "… has come to rely on design-basis requirements and a patchwork of beyond-design-basis requirements and voluntary initiatives for maintaining safety." The NTTF observed that "… for new reactor designs, the Commission's expectations that beyond-design-basis and severe accident concerns be addressed and resolved at the design stage are largely expressed in policy statements and staff requirements memoranda, only reaching the level of rulemaking when each design is codified through design certification rulemaking." The NTTF supported a more formal approach that would include "extended design-basis events" in a new regulatory framework:

> The Task Force envisions a framework in which the current design-basis requirements (i.e., for anticipated operational occurrences and postulated accidents) would remain largely unchanged and the current beyond-design-basis requirements (e.g., for Anticipated Transients Without SCRAM (ATWS) and SBO) would be complemented with new requirements to establish a more balanced and effective application of defense-in-depth.

The NTTF report goes on to say:

> This framework, by itself, would not create new requirements nor eliminate any current requirements. It would provide a more coherent structure within the regulations to facilitate Commission decisions relating to what issues should be subject to NRC requirements and what those requirements ought to be. … Such changes would establish a more logical, systematic, and coherent set of requirements addressing defense-in-depth.

D. Relationship to RMTF Report

The RMTF explicitly recommends the creation of a special category of events that are beyond the current design-basis events, called "design-enhancement events:"

> The purpose of the design-enhancement category is to address gaps that exist between the regulatory controls that are appropriate to address the risk management goal (e.g., risk-informed, performance-based defense-in-depth) and current controls involving a combination of design-basis events and ad hoc requirements added in reaction to specific events or other concerns. The goal would be to define a consistent approach for such events in terms of analysis techniques, safety classification, change control, reporting, and other regulatory requirements that have been defined previously on a case-specific basis. … [The RMTF] envisions that the combination of design-basis events, design-enhancement events, and various programs such as emergency preparedness collectively define the risk-informed and performance-based defense-in-depth protections that are the centerpiece of the proposed Risk Management Regulatory Framework.

III. Detailed Description of Improvement Activity 1

Improvement Activity 1 is intended to address the recommendations of the NTTF and RMTF with respect to establishing a category of beyond design-basis events/accidents. In the staff's view, the common concern underlying the NTTF and RMTF recommendations is with the NRC's inconsistent approach for dealing with hazards and events which are typically characterized as "beyond design-basis accidents." The staff believes that neither the NTTF Recommendation 1 approach nor the RMTF approach is a cost-effective approach for addressing the common concerns of the NTTF and RMTF. Therefore, the staff is proposing a simpler way to address the common concern which appears to underlie the categorization recommendations of the NTTF and RMTF.

A. Proposed Approach

The staff proposes that the NRC adopt a new term – "design-basis extension" – to define and describe the events and requirements which have typically been characterized as "beyond design-basis."

The proposed terminology should avoid confusion between a plant's design basis, as defined in 10 CFR 50.2; and the various events, accidents, occurrences, hazards, and conditions that comprise the plant's design and licensing basis[4]. It makes it clear that there are regulations regarding hazards and events that are not included in the set of design-basis accidents (but may still be part of the plant's design bases) and for which, therefore, the regulatory treatment of associated systems, structures, and components (SSCs) may be different than that prescribed for safety-related SSCs.

After reviewing the current NRC regulations that address so-called[5] beyond design-basis events (SBO, ATWS, 10 CFR 50.44, 10 CFR 50.54(hh), etc.), the NRC staff determined that a de-facto "category" of requirements to address what would be termed "design-basis extension events" already exists. This de-facto category includes NRC requirements that address events or conditions that do not meet NRC criteria in either regulations or guidance for inclusion in the plant safety analysis. Thus, it is unnecessary for the NRC to undertake rulemaking to establish such a category[6]. The proposed approach increases the coherency and clarity of the NRC's regulatory framework while providing regulatory stability and efficiency and requires fewer resources than any of the other three approaches the NRC staff considered.

As part of Improvement Activity 1, the NRC would revise its internal policies, guidance and procedures to ensure that future design-basis extension requirements (both rules and orders) are written in a consistent, logical, and complete manner. To ensure consistency, rationality, and completeness, the guidance would specify a core set of attributes that every new requirement in this category would address. These attributes to be addressed would include (but are not limited to):

[4] An individual plant's licensing basis includes a plant's design, operation, or other activities that require NRC approval.

[5] These events are part of the design basis of currently operating plants, but they are not part of the design-basis accidents analyzed for a given plant. They are, therefore, not "beyond" the design basis; rather, they are additions as a result of regulations after initial plant licensing that *extend* its design basis.

[6] However, there may be value to including a "definition" of this new category in Part 50 for clarity.

- Performance goals, including analysis methods and acceptance criteria
- Treatment requirements, such as design criteria, level of quality assurance needed, and environmental qualification
- Documentation requirements for information which the NRC 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
- Characterization of each future design-basis extension requirement as a matter of adequate protection or safety enhancement, even if the requirement is not a backfit or inconsistent with Part 52 issue finality provisions

The staff notes that a standard set of guidelines for all requirements would be ideal from many perspectives, but that it may be necessary to have a process that allows for a graded approach to addressing matters above based on whether or not the requirement at hand is being promulgated to maintain adequate protection of the public or is a cost-justified safety enhancement.

The staff's simplified approach for implementing Improvement Activity 1 would use existing NRC programs (e.g., reactor operating experience program, generic issues program, industry trends program, etc.) for the identification of new regulatory issues and would use existing guidelines (e.g., regulatory analysis guidelines, safety goals, etc.) for determining which regulatory requirements would be imposed to address matters of design-basis extension. The staff plans, however, to update the criteria for both identification and promulgation of new regulations in conjunction with routine updates of internal guidance documents and other Commission-directed activities now underway[7]. Also, in Improvement Activity 2 on defense-in-depth, the staff proposes to make other changes to the regulatory analysis guidelines to include consideration of defense-in-depth. These proposed improvements to the regulatory analysis guidelines could, in certain cases, simplify the staff's decisionmaking process for when new design-basis extension regulations should be issued. But the staff's proposal to continue to determine the need for rulemaking by using existing programs and processes will not result in explicit new criteria for identifying when additional design-basis extension rules should be promulgated. (Development of such criteria was recommended explicitly in the RMTF report and implicitly by the description of the new regulatory framework envisioned by the NTTF.)

The initial population of requirements in this category would be drawn from the existing regulatory requirements addressing what are currently referred to as beyond design-basis events. These existing regulations include station blackout (10 CFR 50.63), anticipated transients without scram (10 CFR 50.62), combustible gas control (10 CFR 50.44), loss of large plant areas (10 CFR 50.54(hh)), and aircraft impact assessment (10 CFR 50.150). In-process rulemakings which could be characterized as design-basis extension rules under this proposal

[7] In response to the SRM on SECY-12-0110 on Economic Consequences, the staff is updating guidance documents integral to performing cost-benefit analyses in support of regulatory, backfit, and environmental analyses. These revisions include an update to NRC's dollar per person-rem conversion factor policy, an update to replacement energy costs, and non-policy changes to the Regulatory Analysis Guidelines and the Regulatory Analysis Technical Evaluation Handbook to ensure consistent use of terminology. Any additional potential policy issues regarding these guidance documents would be provided for Commission review and approval. Information on the staff's plans to update cost-benefit guidance will be provided in an upcoming SECY paper.

include the risk-informed emergency core cooling system rule (proposed 10 CFR 50.46a) and the station blackout mitigation strategies rulemaking that address NTTF Recommendations 4.1 and 4.2 respectively.

The internal staff guidance to establish the design-basis extension category could be provided in a number of different ways. This guidance would address the best regulatory practices identified by the staff (i.e., inclusion of requirements for performance goals, documentation, reporting, change control, and special treatment) for regulatory requirements (both rules and orders) in the design-basis extension category.

The NRC staff's recommended approach to this improvement activity is expected to achieve a small level of future safety improvement for currently operating plants at the lowest cost of any alternative that was considered. This approach should improve consistency, transparency, coherency and efficiency when requirements are developed as new issues are identified.

Limited Scope of Proposed Approach

The staff notes that this improvement activity is limited to establishing the new category of design-basis extension conditions. It does *not* involve re-evaluating the existing regulatory construct for design-basis accidents and events, including formally defining the characteristics, elements, and/or risk thresholds for both design-basis accidents and events and for the new design-basis extension category. The staff acknowledges that the portion of the NRC's existing regulatory framework addressing design-basis events and accidents for nuclear power plants, as well as its de facto practice of addressing matters which would fall into the proposed new design-basis extension category is complex. This regulatory framework has evolved over time and may not be as logical, consistent, or coherent[8] as might be a framework developed all at once. Nonetheless, the existing framework for design-basis events and accidents is reasonably well understood by NRC and licensees. Developing characteristics, elements, and risk thresholds would be complex, and the benefits of this developmental effort would be directed, for the most part, at NRC decisionmakers in determining the categorization of future regulatory requirements. Applicants and licensees, for the most part, would not directly benefit from the developmental effort, except as potential commenters on NRC-proposed categorization criteria for new or amended regulatory requirements. The staff believes that it would not be cost-justified to use additional NRC resources to re-visit the existing framework for design-basis events and accidents, and define the characteristics, elements, and/or risk thresholds for either design-basis accidents or the new design-basis extension category. Given these considerations, the staff did not include a proposed action for developing the characteristics, elements, or risk thresholds for design basis accidents and events or for the new design-basis extension category as part of Improvement Activity 1.

Improvement Activity 1 also does not involve developing a formal definition of "adequate protection," nor would the improvement activity include developing a discussion which relates the adequate protection concept to either the design basis accident and event category, or to the design-basis extension category. Developing a definition of adequate protection is not needed because the adequate protection concept does not directly control the characteristics, elements, or risk thresholds for either the design-basis accidents and events, or the new design-basis extension category. The concepts of design-basis and design-basis extension are largely technically-driven, whereas the adequate protection concept is more philosophical or normative

[8] For example, the initiating event frequencies of the external hazards that nuclear power plants are designed to withstand are not consistent and, in certain cases, vary by several orders of magnitude.

in character. Defining adequate protection, by itself, does not determine the elements, characteristics, or thresholds of the design-basis extension category. Thus, the NRC may establish the design-basis extension category, populate that category in a forward-looking[9] manner (and in a retrospective manner as well, should the Commission so elect), and establish consistent treatment for regulations in this category, all without defining adequate protection. Finally, it is not clear that developing a definition of adequate protection, in a manner that results in consistent NRC decisionmaking, would be achievable. Given these considerations, the staff did not include a proposed action for developing a definition of adequate protection as part of Improvement Activity 1.

B. Key Issues

There are several issues which the NRC staff considered in developing this improvement activity:

1. Would the approach be generic, plant-specific, or a hybrid?
2. Would the category be for adequate protection, safety enhancement, or both?
3. Would a plant-specific PRA be required?
4. Would the new category be applicable to new reactors only, or also to operating plants?
5. Would the category be populated on a forward-looking or retrospective basis?

Each of these issues is discussed in turn.

1. Would the approach be generic, plant-specific, or a hybrid? The NRC staff believes that the regulatory requirements for design-basis extension conditions should be applied on a generic basis, meaning that NRC would determine when orders or regulations would be promulgated and licensees would be required to comply with the generic requirements applicable to classes or groups of licensees.

2. Would the category be for adequate protection, safety enhancement, or both? The staff believes that regulatory requirements for beyond design-basis events could be for either adequate protection (e.g., recent Order EA-12-049 on mitigation strategies) or for safety enhancement[10], or both. Regulations developed under either rationale would require the NRC to define appropriate performance goals, treatment requirements, documentation and reporting requirements, and change processes; although the specific requirements might be more stringent for regulations deemed necessary to provide reasonable

[9] By "forward-looking," the staff means that the activity would apply to future NRC regulatory actions. For rulemakings, this would include both new regulations addressing events and accidents, as well as future amendments of existing regulations to address new information. For licensing actions, this would include only new license applications and new licenses issued after the improvement activity is completed and first implemented. By "retrospective" or "backwards-looking," the staff means that the improvement activity, once completed and implemented, would be applied to existing NRC regulations and existing licenses. For existing regulations, retrospective implementation would require amendment of those regulations that did not conform to the improvement activity and possible imposition of backfits on existing license holders.

[10] Safety enhancements include backfits meeting the criteria for cost-justified significant safety enhancement (e.g., 10 CFR 50.63 SBO rule) and forward-fit safety enhancements determined to be cost-effective (e.g., 10 CFR 50.150 Aircraft Impact Assessment rule).

assurance of adequate protection of public health and safety. The NRC will develop a standard set of treatment requirements for design-basis extension category requirements. The staff recommends that the development of this standard set of requirements be accomplished via a public process. Because the proposed design basis extension category would contain both adequate protection and safety enhancement requirements, it may not be possible to determine a standard set of treatment requirements that would be appropriate for all requirements in the proposed category. In the event that a standard set of treatment requirements cannot be defined, the staff would issue guidance to assist rulemaking staff to determine an appropriate set of requirements to be applied to each individual design-basis extension rule.

3. Would a plant-specific PRA be required for facilities licensed under 10 CFR Part 50? PRAs are useful tools for maintaining and operating plants safely and may also be used to assess the site-specific risk-significance of emergent issues. All operating reactors have PRA's of varying quality and have used these PRAs to search for site-specific vulnerabilities (i.e., Generic Letter 88-20), to support risk-informed regulatory activities (e.g., 10 CFR 50.65 risk assessments and the Significance Determination Process of the Reactor Oversight Program), and to support risk-informed alternatives to regulatory requirements (e.g., changes to Technical Specifications and Inspection programs). However, the NRC staff believes that a regulatory requirement for a site-specific PRA for currently operating reactors, for the sole purpose of searching for as yet unrealized cost-beneficial risk-reduction activities, would not provide benefits commensurate with the substantial costs[11] of developing such regulatory compliant PRA models. Nuclear power plants licensed under Part 52 are already required to have plant-specific PRA models and include features in their design for mitigation of severe accidents. These new reactor designs have already benefited from risk insights.

4. Would the new category be applicable to new reactors only, or also to operating plants? The staff believes that the regulations developed for design-basis extension events should be applicable to all nuclear power reactors affected by the hazard or event that a new requirement is intended to address unless found unnecessary due to plant-specific design features as demonstrated by a request for exemption.

5. Would the category be populated on a forward-looking or retrospective basis? A retrospective approach would generally reassess currently operating plants to determine whether there are additional risk-reduction measures that should be imposed to address design-basis extension conditions. A forward-looking approach would not involve a new assessment of currently operating plants unless new information arose that indicated a reassessment would potentially lead to new requirements. The NRC staff believes that the forward-looking is the more effective approach especially given that, under the staff's proposed approach, the processes for identifying and making decisions on regulatory requirements are unchanged.

[11] The NRC staff estimated industry costs to upgrade and maintain PRAs at current operating plants to be $702 to $865 million. The staff qualitatively estimated only the safety benefits that could result from requiring PRAs. The staff did not attempt to estimate the potential non-safety benefits (e.g., potential increases in operational flexibility, etc.) that could result from having PRAs. For more information about PRA cost estimates, please see Attachment 1 to this Enclosure.

C. Expected Products

Expected products resulting from this activity would include a publicly available document (e.g., a NUREG) to define the new category and specify how future design-basis extension requirement should be written in a consistent, logical, and complete manner. The process defined in that publicly available document would be implemented by conforming changes to internal NRC policies, guidance, and procedures. The Commission could also direct rulemaking to establish a "definition" of the new category in Part 50.

D. Estimated Resources and Schedule

<u>Industry Resources</u>

Because the design-basis extension category can be implemented by NRC action alone, no incremental licensee resource expenditures are needed. Even though individuals from industry, licensees, non-governmental organizations, and the general public will be invited to participate in developing the new design-basis extension approach, such voluntary expenditures are not considered when estimating costs and preparing regulatory analyses for an NRC activity.

<u>NRC Resources</u>

NRC resource estimates for developing the publicly-available document describing and defining the design-basis extension category were based on historical resource usage data for rulemaking activities. Average total resource usage (both project management and technical staff) for each phase of a typical rulemaking is shown below:

Rulemaking phase	Regulatory Basis	Proposed Rule	Final Rule
FTE required	1.2	1.5	1.2
Time required	13 months	1 year	1 year

The staff believes that detailed development activities for the design-basis extension category will involve a process similar to developing the regulatory basis for a rulemaking but will take significantly more resources than for an average rule. Thus the staff doubled the time and resources needed for developing a regulatory basis (2.4 FTE and 26 months). This effort will also involve more extensive public outreach than is typically done when developing a regulatory basis. This outreach involves activities similar to those conducted during both the proposed and final rule stages but was estimated to involve only about 25% of typical rulemaking resources for those stages (1.5 + 1.2 = 2.7 FTE X 25% = 0.625 FTE). Thus the total estimated resources and the duration of the activity are 2.4 + 0.625 = 3.025 FTE and 26 + (12 + 12) X 25% = 26 + 6 = 32 months, respectively; which were rounded off to an estimate of 3.0 FTE over approximately 3 years.

Then internal staff guidance must be developed to implement the design-extension category as described in the public document. Because the staff routinely updates all key internal guidance documents, resource needs for the incremental changes associated with updating internal staff guidance are typically assumed to be negligible when performing regulatory and cost analyses. However, because numerous different guidance documents are expected to need substantial revision, the staff has estimated an additional 0.5 FTE to update internal guidance which could take an additional year.

Thus the staff's estimate for total NRC resources needed for Improvement Activity 1 is 3.5 FTE over a time period of 3 to 4 years.

Resource Estimate for Optional NRC Rulemaking

If desired by the Commission, after the public document and the internal guidance have been issued establishing the definition and implementation process for the design basis extension category, the definition of "design-basis extension" could be added to 10 CFR 50.2, "Definitions." The staff believes that this effort could be combined with another Part 50 rulemaking activity and that the additional resource expenditures would be approximately 10 percent of a typical rulemaking (10 percent of 1.2 + 1.5 + 1.2 = 0.1 X 3.9 = 0.39 FTE) which was rounded off to an estimate of 0.4 FTE.

E. Pros and Cons

Pros:

The NRC staff believes that Improvement Activity 1 supports the NRC strategic plan and the principles of good regulation in the following ways:

- Promotes openness and clarity
    - Provides clarity and a common terminology for describing these events (now characterized inconsistently in various ways including "beyond design-basis").
    - Provides a consistent, clear, and efficient approach to developing future requirements for addressing design-basis extension conditions
    - Aids the public's understanding of NRC regulations that address events that are not design-basis accidents, including the regulatory controls over the SSCs that mitigate these events
    - Provides for consistently addressing performance goals, treatment requirements, documentation and reporting requirements, and change processes for all design-basis extension requirements

- Improves efficiency
    - This approach represents a cost-effective way to improve NRC's regulatory system related to evaluating and establishing regulatory requirements for these events.

- Increases alignment between the NRC and its counterpart foreign regulatory bodies and international organizations, such as the IAEA, which have adopted the concept of a design-extension event category for addressing certain beyond-design-basis events.

<u>Cons</u>:

- While it maintains safety, this generic approach is not expected to be able to provide safety benefits by identifying potential site-specific risk outliers

- Because this approach does not provide explicit criteria for identifying design-basis extension requirements, the current uncertainties over which events and accidents should be included in the category will remain.

F. How the NRC Staff's Proposal Resolves NTTF Recommendation 1

Proposed Improvement Activity 1 would not establish by rule a design extension category of events exactly as recommended by the NTTF. However, the proposed activity would meet the intent of NTTF Recommendation 1 in part. Table 1-1 shows the extent to which Improvement Activity 1 relates to each part of NTTF Recommendation 1:

Table 1-1: Comparison of Improvement Activity 1 to NTTF Recommendation 1	
NTTF Recommendation	Activity 1
1. [Establish] a logical, systematic, and coherent regulatory framework for adequate protection that appropriately balances defense-in-depth and risk considerations.	Increased coherence and stakeholder understanding by defining and using a common term. Increased clarity going forward as new requirements consistently include treatment, reporting, and QA requirements as well as explicit change control provisions.
1.1 Draft a Commission policy statement that articulates a risk-informed defense-in-depth framework that includes extended design-basis requirements in the NRC's regulations as essential elements for ensuring adequate protection.	Both adequate protection and safety enhancement requirements would be covered (refer to Improvement Activity 2 for discussion of defense-in-depth).
1.2 Initiate rulemaking to implement a risk-informed, defense-in-depth framework consistent with the above recommended Commission policy statement.	The intent of this sub-recommendation would be accomplished without promulgating a rule.
1.3 Modify the Regulatory Analysis Guidelines to more effectively implement the defense-in-depth philosophy in balance with the current emphasis on risk-based guidelines.	Not covered by this activity.
1.4 Evaluate the insights from the IPE and IPEEE efforts … to identify potential generic regulations or plant-specific regulatory requirements.	Not covered by this activity. The basis for the staff's decision not to pursue this recommendation is provided in the section below.
Voluntary safety initiatives by licensees should not take the place of needed regulatory requirements. (NTTF Report, pp 19, 21)	Not covered by this activity (refer to Improvement Activity 3).
The current NRC regulatory approach (requirements for design-basis events, beyond design-basis events, and voluntary initiatives) has resulted in a "patchwork" of regulatory requirements and other safety initiatives.	This activity partially addresses the NTTF's "patchwork" observation by adding structure to the existing and future regulations intended to extend the plant's design basis.

Table 2 at the end of Enclosure 1 presents summary information on each improvement activity for easy comparison showing the extent to which each improvement activity addresses NTTF Recommendation 1.

The NRC staff working group was questioned by internal stakeholders (the ACRS and the Japan Lessons Learned Directorate (JLD) Steering Committee) regarding why it is not proposing to evaluate IPE and IPEEE insights as set forth in NTTF recommendation 1.4. The staff considered NTTF recommendation 1.4 in detail and concluded that there is a low likelihood of identifying plant-specific design or operational safety concerns, and therefore expending the resources (staff and industry) to pursue this activity would not be justified.

Specifically, the NRC staff notes the following regarding the IPE and IPEEE studies and present risk assessments:

- The IPE/IPEEE are dated and were performed before applicable industry consensus standards existed.
- All plants have updated their IPE studies and have subjected them to industry peer reviews. These internal events, at-power PRA models are routinely used for:
    - Requesting risk-informed license amendments
    - Assessing the risk of performance deficiencies under the significance determination part of the ROP
- The NRC built simplified plant analysis risk (SPAR) models for every site. These models were benchmarked against plant-specific internal events PRA models by NRR with contract support from Idaho National Laboratory (INL). While the SPAR models themselves may not be developed to a level of detail that might identify all potentially risk-significant issues, the process of comparing them to licensee models made NRC aware of plant-specific features modeled in the licensee's updated IPE models.
- NTTF Recommendation 2.1 is re-evaluating seismic and flooding hazards at all operating reactors to the latest methods applied to new reactors.
- Section 402 of Public Law 112-074, "Consolidated Appropriations Act," requires NRC to require reactor licensees to reevaluate the seismic, tsunami, flooding, and other external hazards at their sites against current applicable Commission requirements and guidance for such licenses as expeditiously as possible, and thereafter when appropriate.
- The SBO/mitigation strategies orders and associated rulemaking will provide a flexible means of mitigating a range of events and conditions that one might identify from a review of IPE/IPEEE. Thus, the motivation for searching for such events through IPE/IPEEE review is lessened because many would be addressed by the flexible mitigation strategies.

The staff concluded that there is a low likelihood of finding a safety-significant issue as a result of reviewing the outdated IPE/IPEEE results that would not either have already been identified from existing risk-informed activities or that would be identified as a result of the activities already planned or underway post-Fukushima. The resources required to review the IPE/IPEEE summary documents would be better employed in the review of the external hazard re-assessments referred to above.

The staff did consider several alternatives to address the concern raised by NTTF Recommendation 1.4 before reaching its conclusion that no action was necessary.

First, under Improvement Activity 1, the NRC staff realized that a review of IPE/IPEEE insights could result in new design-basis extension events. However, as documented elsewhere in this enclosure, the staff concluded that the new category of events should be implemented in a forward-looking, and not retrospective, fashion. The staff also noted that any regulatory action taken as a result of the NTTF 2.1 or Public Law 112-074 hazard reassessments would benefit from implementation of Improvement Activity 1, in that a standard set of treatment requirements, reporting requirements, quality assurance requirements, and change control processes would be specified.

Second, under Improvement Activity 3, the NRC staff considered whether to recommend an effort to confirm that safety-significant licensee commitments made under the IPE/IPEEE program had been implemented and were still in effect. However, after considering the length of time that has elapsed since the IPEs were performed (over 20 years) and the scope of safety improvements that have been made in the past and are being implemented now in response to Fukushima, the staff did not believe that the safety benefits of such an effort would be substantial. Therefore, the staff concluded that it would not be prudent to expend resources to confirm these commitments had been implemented and maintained.

Finally, the staff also considered whether updated risk information should be requested from licensees. (The question of whether an improved regulatory framework should include a plant-specific PRA requirement for operating reactors is discussed in Attachment 2 to this Enclosure.) The staff concluded that, as a result of risk-informed submittals and licensee analyses as part of significance determination process discussions, there would be few additional insights from having licensees submit at-power, internal events PRA results. As stated above, external hazards re-assessments are underway or planned that will provide such insights for those hazards. Therefore, the staff did not recommend that updated risk information be sought from licensees under NTTF Recommendation 1.

G. Example of a Possible Outcome of Implementing Improvement Activity 1

To provide an example of the possible outcome of implementing Improvement Activity 1, the staff believes that portions of 10 CFR 50.54(hh)(2) on loss of large areas of the plant would have been designated as a design-basis extension rule. Having staff guidance for promulgating such rules would have provided a more complete basis for specifying appropriate treatment requirements for SSCs required to meet 10 CFR 50.54(hh)(2) and could have led to more timely, clear, and consistent implementation of the rule.

H. Staff Evaluation of Alternative Approaches to Establish a New Event Category

Both the NTTF and the RMTF reports discuss options for creating a single new event category but offer differing insights as to what this new category may look like and how it would be populated with events and associated requirements. The extent to which the implementation of Improvement Activity 1 conforms with either NTTF or RMTF recommendations depends upon how the five key issues discussed above are resolved. The various combinations of possible answers to the five key issues could result in significantly different approaches to establishing the new category of accidents or events. The NRC staff considered three specific approaches in detail before finalizing its recommended approach for this proposed improvement activity:

- A plant-specific approach using NRC-required plant-specific PRA models
- A plant-specific approach using generic risk information and plant-specific risk insights developed by an expert panel established by the licensee
- A generic approach without a PRA requirement, which would use available risk insights from licensee PRAs, NRC risk studies (e.g., SOARCA; Level 3 PRA Project), and SPAR models

The staff ultimately adopted a simplified version of the third approach as presented above. Attachment 2 to this Enclosure provides a detailed discussion of the NRC staff's evaluation of the three approaches and its rationale for not recommending them.

Improvement Activity 2: Establish Commission Expectations for Defense-In-Depth

I. Summary of Improvement Activity

This improvement activity would establish the Commission's expectations for defense-in-depth as applied to nuclear power reactor safety. A Commission policy statement would be developed that would include the definition, objectives, and principles of defense-in-depth. This improvement activity would also develop implementation guidance that would specify the needed levels of defense for reactor safety along with associated decision criteria to support regulatory decisions regarding whether the Commission's expectations for defense-in-depth have been addressed in the design and operation of a nuclear power plant.

II. Background

A. History

Defense-in-depth is a major aspect of the NRC's regulatory framework. It is embodied in the requirements, and an important element of NRC's regulatory decision-making process. It is addressed in numerous regulatory guides, NUREGs, Commission papers, etc. However, it is described differently in the various sources. Because of this, it would be useful to formalize the defense-in-depth philosophy as it applies to nuclear power reactors and provide a common terminology to foster understanding and consistent application of this concept.

The NRC has made progress towards implementing risk-informed regulation. Although initial successes have indicated the usefulness and importance of using risk insights to inform regulatory decisions, principles of risk-informed regulation have not been incorporated into the overall regulatory framework for power reactors in a comprehensive manner. Two examples serve to illustrate this point.

Five key principles of risk-informed regulation have been specified in Regulatory Guide 1.174, which provides guidance for licensees to voluntarily request risk-informed license amendments. One of these principles, that any proposed change be consistent with the defense-in-depth philosophy, is difficult to implement, both in a relative sense (e.g., whether a proposed change maintains adequate defenses) and in an absolute sense (that is, not only for changes), absent a well-defined policy that includes an objective definition and associated decision criteria. Such a policy would facilitate regulatory decision-making. As a second example, NRR Office Instruction LIC-504, "Integrated Risk-Informed Decision-Making Process for Emergent Issues," uses these same five key principles in a decision process for emergent issues where no other NRC process exists to resolve the issue. Again, assessing whether the proposed resolution of an emergent issue is consistent with the defense-in-depth philosophy is problematic without a common definition and associated decision criteria.

A brief history of the defense-in-depth philosophy is presented below to provide a starting point for characterizing this improvement activity.

Since the beginning of licensing nuclear facilities, the concept of defense-in-depth has been an integral part of the regulatory framework regardless whether the term defense-in-depth was used. Starting with WASH-740 in March 1957, "Theoretical Possibilities and Consequences of Major Accidents in Large Nuclear Power Plants," the concept of multiple lines of defense was introduced, as shown in this sample excerpt from that document: "Looking to the future, the principle on which we have based our criteria for licensing nuclear power reactors is that we will require multiple lines of defense against accidents which might release fission products from the facility." This concept of multiple lines of defense over time has evolved into what is consistently referred to as "defense-in-depth" today. It has been generally characterized in terms of multiple barriers, levels of defense, levels of protection, successive compensatory measures, lines of protection, multiple measures, protective barriers, echelons of defense, etc. Moreover, levels of defense have been viewed as an approach to address accident prevention and mitigation. This consistency can be seen in two examples regarding the different, but similar, explanations for levels of defense:

- preventing accidents from occurring, having safety systems in place should an accident occur, having mitigation capabilities in place should the safety systems not function, having emergency plans in place if mitigation does not work

- employing successive barriers between the radiological source term and the public, such as fuel cladding, RCS boundary, containment, and siting in remote areas

In further reviewing the history, the NRC staff found that there has been a consensus in that defense-in-depth is needed to provide a robust plant design that will be tolerant of anticipated challenges and to compensate for the recognized lack of knowledge (i.e., uncertainties) regarding nuclear reactor operations and the consequences of potential accidents. That is, defense-in-depth is needed to deliver a design that is tolerant of uncertainties in our knowledge regarding plant behavior, component reliability, or operator performance that might compromise safety. Moreover, given the uncertainties, when failures occur they would be compensated for or corrected without causing harm to individuals or the public at large. In summary, there has been a common theme with regard to defense-in-depth which is to prevent and mitigate accidents via multiple levels of defense in light of uncertainties to keep the risk to an acceptable level. Although the levels of defense address accident prevention and mitigation, how to implement a level of defense has not been viewed consistently. Implementation of the various levels of defense has included for example:

- reactor core, reactor vessel, reactor container

- quality in design, safety systems, consequence-limiting systems

- quality assurance, protective systems, engineered safety features

- safety margins, high quality, redundancy, containment structure and safety features, emergency plans

The above discussion presents a deterministic approach to defense-in-depth. The deterministic model to defense-in-depth is embodied in the structure of the regulations and in the design of the facilities that are built in accordance with those regulations. The potential requirements for defense-in-depth result from repeatedly asking the question, "What if this barrier or safety feature fails?" without assigning a likelihood of such a failure. Therefore, a characteristic of this approach is that there is reliance on each line of defense to protect against the unknown and unpredictable; e.g., assuming the other defenses have not succeeded.

Use of probabilistic insights to complement traditional engineering analyses, including application of the defense-in-depth philosophy, came into the history in the mid-1990s. At that time, it was generally acknowledged that PRA can be a powerful tool in pointing out areas where "deterministic defense-in-depth" needs enhancement.

The NRC has moved towards a risk-informed regulatory framework. In the risk-informed approach to regulation, PRA could be used to inform regulatory decisions regarding whether there is sufficient defense-in-depth for a given situation. The discussion in the *Federal Register* Notice (FRN) that promulgated the Commission PRA Policy Statement (1995) notes that "PRA technology will continue to support the NRC's defense-in-depth philosophy by allowing quantification of the levels of protection and by helping to identify and address weaknesses or overly conservative regulatory requirements." The FRN discussion also notes that defense-in-depth is used by the NRC to provide redundancy as well as a multiple-barrier approach. Risk insights could be used to move to a more structured, formal process in implementing and evaluating the adequacy of defense-in-depth.

Several proposals to use risk insights to help assess whether adequate defense-in-depth has been achieved were proposed in the 2000–2012 time frame. IAEA and INL, in particular, have proposed risk as one of the measures to assist in determining adequacy of defense-in-depth. For example:

- quantitative safety goal targets are established for each level of defense using a frequency consequence curve; plant design and operation is evaluated against each level to determine if the quantitative target goal has been met

- decision process with criteria is established that evaluates whether quantitative criteria (using a frequency consequence curve) have been met while also determining whether there are adequate safety margins and if the known uncertainties have been adequately addressed

B. Relationship to NTTF Recommendation 1

This improvement activity directly supports NTTF Recommendation 1, which states: "The Task Force recommends establishing a logical, systematic, and coherent regulatory framework for adequate protection that appropriately balances defense-in-depth and risk considerations." Implementing this improvement activity accomplishes this by defining defense-in-depth for nuclear power reactors and developing decision criteria for assessing when defense-in-depth has been adequately addressed in the design or operation of a nuclear power plant.

In Recommendation 1 of the NTTF report, that task force provided its definition of defense-in-depth:

> The key to a defense-in-depth approach is creating multiple independent and redundant layers of defense to compensate for potential failures and external hazards so that no single layer is exclusively relied on to protect the public and the environment. In its application of the defense-in-depth philosophy, the Task Force has addressed protection from design-basis natural phenomena, mitigation of the consequences of accidents, and EP.

The NTTF concluded that a more balanced application of the Commission's defense-in-depth philosophy using risk insights would provide an enhanced regulatory framework that is more logical, systematic, coherent, and better understood. Such a framework would support appropriate requirements for increased capability to address events of low likelihood and high consequence, thus enhancing safety. The NTTF described a new regulatory framework where risk assessment and defense-in-depth would be combined more formally. It should be noted that the NTTF concluded that the new framework could be implemented on the basis of full-scope Level 1 core damage assessment PRAs and Level 2 containment performance assessment PRAs; the NRC staff's recommendation for Improvement Activity 2 does not include a PRA requirement, as discussed in further detail below.

Table 2 at the end of Enclosure 1 presents summary information on each improvement activity for easy comparison of the activities by showing the extent to which each improvement activity addresses NTTF Recommendation 1.

C. Relationship to RMTF Report

The RMTF notes in NUREG-2150 that "After decades of use, there is no clear definition or criteria on how to define adequate defense-in-depth protections." The RMTF further notes that "the concept of defense-in-depth has served the NRC and the regulated industries well and continues to be valuable today. However, it is not used consistently, and there is no guidance on how much defense-in-depth is sufficient." The RMTF concluded that "clarifying what the U.S. Nuclear Regulatory Commission (NRC) means by defense-in-depth is a necessary part of the development of a holistic strategic vision."

This improvement activity supports the RMTF overall recommendations (R2.1-2.4) and those for power reactors (PR-R-5, OR-R-5, and NR-R-5). Table 3 at the end of Enclosure 1 presents summary information on each improvement activity for easy comparison of the activities by showing the extent to which each improvement activity addresses the power reactor recommendations of the RMTF report.

III. Detailed Description of Improvement Activity 2

If this improvement activity were implemented, the Commission would issue a policy statement that would articulate the Commission's expectations for defense-in-depth as applied to nuclear power reactor safety.

The policy for defense-in-depth as applied to nuclear power reactor safety would define what is meant by defense-in-depth and set forth the objectives of this strategy. It would define the fundamental levels of defense that comprise the top level in a hierarchical approach to applying defense-in-depth to nuclear power reactors.

The NRC staff would also prepare guidance documents to implement the policy statement. The implementation guidance would articulate the decision criteria to support regulatory decisions regarding whether the Commission's expectations for defense-in-depth have been addressed in the design and operation of a nuclear power plant. If necessary, and in accordance with the forward-looking implementation of Improvement Activity 1, the rulemaking process would be used to impose any new requirements necessary to implement the Commission's expectations regarding nuclear power reactor defense-in-depth.

A. Proposed Approach

If the Commission directs the NRC staff to proceed with Improvement Activity 2, the staff would develop the policy statement and implementation guidance as described above. However, as noted in the *Background* above, there has been a great deal of thought already given to this topic over many years. Therefore, in order to help inform the Commission's decision, the major elements of the proposed policy statement and implementation guidance are provided below, along with examples for each element of the policy. These are examples because the specific elements may change as the staff works to develop the specific details and evaluates inputs from various stakeholders.

Policy Statement

The staff envisions four major parts to the Commission Policy Statement on Defense-in-Depth for Nuclear Power Reactor Safety:

- Statement of Commission Expectations
- Definition of Defense-in-Depth
- Objective of Defense-in-Depth
- Defense-in-Depth Principles

Example Commission Expectations: A defense-in-depth approach is used to provide reasonable assurance of public health and safety from the operation of the reactor of a nuclear power plant.

Example Definition: Defense-in-depth is a strategy that employs successive levels of defense and safety measures in the design, construction and operation of the nuclear power plant to ensure appropriate barriers, controls, and personnel are in place to prevent, contain, and mitigate exposure to radioactive material.

Example Objectives: The purpose of employing a defense-in-depth strategy is to keep the risk to the public and environment from the operation of the reactor of a nuclear power plant acceptably low by:

- Compensating for uncertainties, including events and event sequences which are unexpected
- Making the nuclear power plant more tolerant of failures and external challenges; for example, by:
  - compensating for potential adverse equipment performance, as well as human actions of commission (including intentional adverse acts) as well as omission
  - maintaining the effectiveness of barriers and protective systems by ensuring multiple, generally independent and separate, means of accomplishing their functions
- Protecting the health and safety of the public even assuming a severe accident and radiological release

Example Principles: The objectives of defense-in-depth are achieved by implementing the following **example** principles:

- Key safety functions are not dependent upon a single element of design, construction, maintenance or operation
- Uncertainties in SSCs and human performance are accounted for in the safety analysis and appropriate safety margins are provided
- Application of conservative codes and standards
- High quality in the design, construction, and operation of the nuclear power plant
- System redundancy, independence, and diversity are part of the design and operation
- Defenses against potential common-cause failures are part of the design and operation

The policy statement would reinforce 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 likely include both deterministic and probabilistic decision criteria. The policy statement would clearly state that the deterministic criteria for defense-in-depth must, at the most fundamental level, compensate for uncertainties, including those in the PRA models or other risk assessments.

Implementation Guidance

The staff envisions two major parts to the associated implementation guidance:

- Levels of Defense for Nuclear Power Reactor Safety
- Decision Criteria

Example Levels of Defense: For ensuring nuclear power reactor safety, defense-in-depth is comprised of four successive levels of defense where each level's defense measures are applied if the previous level fails:

- Event preclusion – safety measures that can preclude events that could challenge safety
- Accident prevention – safety measures that can prevent events from progressing to core damage
- Source term containment– safety measures that can prevent radioactive release from the containment
- Release mitigation – safety measures that can protect the public from the effects of radioactive releases

Example Decision Criteria: Decision criteria would be developed to determine whether a given plant design had sufficient depth, that is, an appropriate number of each of the four levels of defense, as well as to judge whether the defenses within a level had an appropriate reliability and availability in view of uncertainties. Such decision criteria could involve:

- Extent to which the objectives of defense-in-depth are met
- Extent to which the principles of defense-in-depth are employed
- How well each level of defense provides protections from a given hazard or scenario

- Extent to which each level of defense is independent from the other levels
- Amount of safety margin available
- Effectiveness of performance measurement or monitoring strategies
- Significance of uncertainties
- Comparison to quantitative acceptance guidelines (e.g., CDF, LERF)

The information contained in the policy statement and implementation guidance would use the information provided in Enclosure 3, which documents a comprehensive review of the history of defense-in-depth.

B. Key Issues

There are several issues which the NRC staff considered in developing this improvement activity:

1. Would a plant-specific PRA be required?
2. Would the policy be applicable to new reactors only, or also to operating plants?
3. Would the policy be implemented on a forward-looking or retrospective basis?

Each of these issues is discussed in turn.

1. Would a plant-specific PRA be required? The staff considered whether a regulatory requirement for a plant-specific PRA would be necessary in order to make decisions regarding adequacy of defense-in-depth. The NRC staff believes that a requirement for a site-specific PRA for currently operating reactors, for the sole purpose of informing the defense-in-depth policy, would not provide benefits commensurate with the cost of developing such PRA models. Nuclear power plants licensed under Part 52 are required to have a plant-specific PRA.

   In development of the policy statement (e.g., defining defense-in-depth), a PRA is not needed. However, it is likely that the criteria for determining whether a given nuclear power plant has sufficient defense-in-depth will include quantitative risk criteria. A PRA rule is not needed to develop this criteria; however, a PRA may be beneficial to the licensee in demonstrating that the risk criteria have been met.

2. Would the policy be applicable to new reactors only, or also to operating plants? The staff considered whether the new policy and any related requirements would be applicable to currently operating reactors, reactors licensed in the future, or both. The staff believes that the new policy should be applicable to all light water nuclear power reactors.

3. Would the policy be implemented on a forward-looking or retrospective basis? The staff considered whether the new policy and promulgation of any associated regulatory requirements upon implementing the new policy, would be forward-looking or retrospective. A retrospective approach would assess currently licensed plants to determine whether the Commission's expectations regarding defense-in-depth were met. In cases where the expectations were not met, the NRC staff would pursue imposition of

backfits to the extent allowed by 10 CFR 50.109. A forward-looking approach would not assess currently licensed plants, but would apply the Commission's expectations for defense-in-depth to new issues as they arise. This could still lead to the imposition of backfits on plants, but these would be the result of the new information. The NRC staff believes that the forward-looking approach would be more consistent with the NRC's principles of good regulation, given that there is reasonable assurance of adequate protection for currently licensed plants.

C. Expected Products

If this improvement activity is approved by the Commission, the staff would develop the following:

- Commission policy statement that includes:
  - The Commission's expectations on defense-in-depth for nuclear power reactor safety
  - Definition, objective and principles of defense-in-depth
  - Identification of the levels of defense-in-depth for nuclear power reactors.
  - Identification of the types of decision criteria for assessing adequacy of defense-in-depth

  The development of this policy statement would be accomplished by the NRC staff with input from interested stakeholders.

- Implementing guidance that includes:
  - Detailed discussion describing the levels of defense-in-depth and their associated safety measures
  - Decision criteria for implementing the strategy for achieving defense-in-depth and associated decision criteria for determining whether sufficient defense-in-depth has been achieved
  - Revision to the Regulatory Analysis Guidelines to include defense-in-depth as a fundamental decision criterion and to reference the policy statement and the staff's guidance on determining adequacy of defense-in-depth
  - Conforming changes to existing regulatory guides including Regulatory Guide 1.174
  - Conforming changes to Management Directives and Office procedures, as appropriate

  The development of the implementation guidance may be internal NRC documents (e.g., Management Directive, Office Instruction, Standard Review Plan, Regulatory Analysis Guidelines) or external documents (e.g., Regulatory Guide, generic communication).

D. Estimated Resources and Schedule

Industry Resources

Because the defense-in-depth improvement activity can be implemented by NRC action alone, no incremental licensee resource expenditures are needed. Even though individuals from industry, licensees, non-governmental organizations, and the general public will be invited to participate in developing the new design-basis extension approach, such voluntary expenditures are not considered when estimating costs and preparing regulatory analyses for an NRC activity.

NRC Resources

NRC resource estimates for developing the defense-in-depth conceptual approach and criteria for determining adequacy and for and issuing the policy statement were estimated by assuming that 5 persons would be necessary working for 15% of their time for a period of 2 years (5 persons X 2 years X 15% = 1.5 FTE).

Internal staff guidance must then be developed to implement the process and criteria in the policy statement. The estimated resources for this are 4.8 FTE assuming that 6 persons would be necessary working for 40% of their time for a period of 2 years (6 persons X 2 years X 40% = 4.8 FTE).

Implementation of the new criteria will also require that they be incorporated into the existing Regulatory Analysis Guidelines (NUREG/BR-0058, Rev. 4). In response to the SRM on SECY-12-0110 on Economic Consequences, the staff is now working to update guidance documents integral to performing cost-benefit analyses in support of regulatory, backfit, and environmental analyses, including NUREG/BR-0058, Rev. 4. Necessary resources are being budgeted separately in conjunction with this effort. Incremental resources needed to incorporate defense-in-depth criteria into this update are negligible. This update activity is expected to take an additional 1 to 2 years.

Thus the staff's estimate for total NRC resources needed for Improvement Activity 2 is 6.3 FTE over a time period of 3 to 4 years.

E. Pros and Cons

Pros:

Improvement Activity 2 supports the NRC strategic plan and the principles of good regulation in the following ways:

- Promotes efforts that help ensure that licensees perform at acceptable safety levels.
    - Provides a uniform and technically-justified concept of defense-in-depth for nuclear power reactors
    - Supports risk-informed regulation by more clearly defining one of the five key principles: defense-in-depth
- Supports the NRC strategic plan effectiveness objective that NRC actions are high quality, efficient, timely, and realistic.

  - Formalizes the defense-in-depth philosophy into a defined strategy for addressing uncertainty
  - With a common understanding of defense-in-depth, enables more efficient, effective, consistent and timely decisions on safety issues
  - Provides clear and timely guidance to applicants and licensees for submittal of high-quality and timely license applications and risk-informed license amendment requests
  - Facilitates high quality implementation of Improvement Activity 1, if it is selected

- Promotes openness, clarity, and reliability: criteria for adequacy of defense-in-depth for regulatory actions are specified, resulting in a more predictable and stable regulatory process
- Supports the PRA policy statement for increased use of PRA technology to the extent supported by the state-of-the-art that complements the NRC's deterministic approach and supports defense-in-depth.
- Improves consistency with the international community on the concept of defense-in-depth and provides international leadership on defining defense-in-depth and associated decision criteria

Cons:

- It will be challenging to develop decision criteria with sufficient detail to achieve consistency in applying those criteria to regulatory decisions regarding defense-in-depth.
- The magnitude of any improvements in the overall level of safety for power reactors under this improvement activity is uncertain.

F. How the NRC Staff's Proposal Resolves NTTF Recommendation 1

As stated in the introduction to this Enclosure, the NRC staff developed a problem statement describing the issue that Recommendation 1 is directed at resolving. Implementation of Improvement Activity 2 addresses the aspect of the problem statement involving how risk and defense-in-depth should be addressed for an effective NRC regulatory response to new information or unforeseen events or accidents. Improvement Activity 2 would define defense-in-depth and develop decision criteria to support risk-informed regulatory decisions.

Table 1-2: Comparison of Improvement Activity 2 to NTTF Recommendation 1

NTTF Recommendation	Activity 2
1. [Establish] a logical, systematic, and coherent regulatory framework for adequate protection that appropriately balances defense-in-depth and risk considerations.	Activity 2 would develop a policy statement defining defense-in-depth and develop decision criteria to support risk-informed decisions

Table 1-2: Comparison of Improvement Activity 2 to NTTF Recommendation 1	
NTTF Recommendation	Activity 2
1.1 Draft a Commission policy statement that articulates a risk-informed defense-in-depth framework that includes extended design-basis requirements in the NRC's regulations as essential elements for ensuring adequate protection.	Activity 2 would support development of extended design-basis requirements (which are addressed as Improvement Activity 1) to the extent that these requirements were needed to provide adequate defense-in-depth.
1.2 Initiate rulemaking to implement a risk-informed, defense-in-depth framework consistent with the above recommended Commission policy statement.	Activity 2 of itself would not include any new rules. However, the need for additional rules to implement the Commission's policy would be evaluated as part of Improvement Activity 1 and Activity 2.
1.3 Modify the Regulatory Analysis Guidelines to more effectively implement the defense-in-depth philosophy in balance with the current emphasis on risk-based guidelines.	Conforming changes would be made to the Regulatory Analysis Guidelines as appropriate.
1.4 Evaluate the insights from the IPE and IPEEE efforts … to identify potential generic regulations or plant-specific regulatory requirements.	Activity 2 does not address this sub-recommendation.
Voluntary safety initiatives by licensees should not take the place of needed regulatory requirements. (NTTF Report, pp. 19, 21)	Activity 2 does not address this sub-recommendation.
The current NRC regulatory approach (requirements for design-basis events, beyond design-basis events, and voluntary initiatives) has resulted in a "patchwork" of regulatory requirements and other safety initiatives.	Activity 2 does not address this sub-recommendation.

Table 2 at the end of Enclosure 1 presents summary information on each improvement activity for easy comparison showing the extent to which each improvement activity addresses NTTF Recommendation 1.

G. Example of a Possible Outcome of Implementing Improvement Activity 2

To provide an example of the possible outcome of implementing Improvement Activity 2, the staff describes how the NRC's recent deliberations on filtered vents in Mark I and II containments might have proceeded if this activity had been implemented and in effect during those deliberations. The containment designs would have been evaluated for defense-in-depth considerations. If the NRC had well-defined criteria for evaluating the adequacy of defense-in-depth, the NRC may have been able to more efficiently come to a decision on this issue. Such decision criteria would improve the transparency and predictability of the NRC's regulatory process.

Improvement Activity 3: Clarify the Role of Voluntary Industry Initiatives in the NRC Regulatory Process

I. Summary of Improvement Activity

This improvement activity would clarify the role of industry initiatives in the NRC's regulatory processes by (1) re-affirming the Commission's expectation that industry initiatives may not be used in lieu of NRC regulatory action where a question of adequate protection of public health and safety exists; (2) specifying when industry initiatives may be credited in the baseline case for regulatory analyses; and (3) providing guidance regarding what level of NRC oversight is appropriate for future voluntary initiatives. Specifically, this improvement activity would yield:

- Revisions to existing guidance to clarify the role of Type 2 industry initiatives
- Guidance for NRC oversight of certain types of industry initiatives (defined later in this enclosure) determined to be risk or safety significant
- A staff evaluation of whether the most risk/safety significant existing industry initiatives of this type are being adequately maintained

II. Background

A. History

The NRC has a long history of encouraging licensees and the nuclear industry as a whole to take the initiative to address safety or other issues related to nuclear plant design and operation.

The NRC has on several previous occasions considered policy issues related to voluntary commitments or initiatives. The decision to develop guidelines for using industry initiatives in the regulatory process was an outgrowth of the Commission's Direction Setting Initiative (DSI) 13, which was published as part of SECY-97-303, "The Role of Industry (DSI-13) and Use of Industry Initiatives," dated December 31, 1997 (ADAMS Accession No. ML992950105), and the associated April 16, 1998, staff requirements memorandum (SRM) (ADAMS Accession No. ML003753845). The staff proposed in SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," on March 2, 1999 (ADAMS Accession No. ML992810068), to develop NRC guidelines for crediting industry initiatives in lieu of taking regulatory action.

On May 27, 1999, the Commission issued an SRM (ADAMS Accession No. ML003752062) approving the staff's recommendations in SECY-99-063. In this SRM, the Commission agreed that the current regulatory framework does not preclude voluntary industry initiatives and that existing regulatory processes can be used to support implementation of voluntary initiatives as long as such initiatives will not be used in lieu of regulatory action where a question of adequate protection of public health and safety exists. The SRM directed the staff to work with the industry and other stakeholders in developing the guidelines for using industry initiatives. These guidelines were developed and provided to the Commission in SECY-00-0116, "Industry Initiatives in the Regulatory Process," on May 30, 2000 (ADAMS Accession No. ML003718488). In response to the June 28, 2000, SRM on SECY-00-0116 (ADAMS Accession No. ML003727346), the staff revised the proposed guidelines as directed by the Commission and published them for public comment on August 31, 2000 (65 FR 53050).

After reviewing the public comments, the staff found that some industry stakeholders perceived the proposed guidelines on industry initiatives as imposing a burdensome obstacle to open and candid interactions between the regulator and the industry. A public interest group stated that it is "…categorically opposed to the regulatory retreat under way at the U.S. Nuclear Regulatory Commission (NRC) under the guise of voluntary industry initiatives (in lieu of regulation)...The NRC plans to supplant regulation with voluntary initiatives that are non-enforceable, remove the public from the process, and fail to address significant safety issues....Proposed guidelines will limit the ability of the public to meaningfully participate in the decisions that affect the health and safety of our families, homes, and communities...." In view of the stakeholders' reluctance to embrace the proposed guidelines, the staff concluded that implementing this largely voluntary process would be ineffective. Thus, in SECY-01-0121, "Industry Initiatives in the Regulatory Process," on July 5, 2001 (ADAMS Accession No. ML011630126), the staff requested Commission approval to notify all stakeholders that the proposal to implement a new industry initiative program and related guidelines would be withdrawn. The Commission approved, in an SRM on August 2, 2001, (ADAMS Accession No. ML012140398). The program was withdrawn by an August 20, 2001 notice in the *Federal Register* (66 FR 43597).

SECY-01-0121 defines three types of industry initiatives:

> Type 1: A Type 1 initiative is developed in response to an issue of potential safety concern that would complement regulatory actions within existing regulatory requirements. However, when it is determined that the safety concern involves the assurance of adequate protection, or other criteria described in Title 10, Section 50.109, of the *Code of Federal Regulations* (10 CFR 50.109), the NRC shall pursue rulemaking. In such a case, the Type 1 industry initiative may form the basis for an acceptable method of meeting the new regulation through endorsement in a regulatory guide.
>
> Type 2: A Type 2 initiative is developed in response to a potential safety concern that is a potential cost-beneficial safety enhancement outside existing regulatory requirements. Such industry initiatives may be used to provide safety enhancements without the need for regulatory action. However, where it is determined that the proposed industry initiative is not effective in addressing the safety concern, the NRC may pursue rulemaking in accordance with the criteria described in 10 CFR 50.109.
>
> Type 3: A Type 3 initiative is developed as an information-gathering mechanism, or a means to address issues of concern to the applicable industry group that are not potential safety concerns, do not involve adequate protection issues, are outside existing regulatory requirements, and are not likely to yield cost-beneficial safety enhancements. These voluntary industry initiatives may be used by the applicable industry group to address economic or efficiency issues.

NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 4, provides the most current descriptions of these three types of industry initiatives:

> Industry initiatives can generally be put into one of the following categories:
>
> (1) those put in place in lieu of, or to complement, a regulatory action to ensure that existing requirements are met,

(2) those used in lieu of, or to complement, a regulatory action in which a substantial increase in overall protection could be achieved with costs of implementation justifying the increased protection, and

(3) those that were initiated to address an issue of concern to the industry but that may or may not be of regulatory concern.

Issues related to adequate protection of public health and safety are deemed the responsibility of the NRC and should not be addressed through industry initiatives.

The Fukushima Dai-ichi event highlighted that some measures previously put in place as voluntary initiatives in the U.S. to deal with severe accidents (e.g., severe accident management guidelines (SAMGs) and hardened vents), could have played a significant role in preventing or mitigating the accident. However, NRC assessments performed after the Fukushima event revealed that these specific examples were not subject to NRC inspection or enforcement activities, ostensibly because they were not implemented by a legally-binding requirement. These assessments found that the implementation and maintenance of these industry initiatives did not, in some cases, provide the desired degree of confidence that the equipment or procedures would have worked as the NRC had intended when an industry initiative was accepted in lieu of taking a regulatory action. As discussed below, both the NTTF and the RMTF expressed concerns that in some cases use of licensee voluntary initiatives has led to inefficiencies and potentially less robust resolution of issues. The lack of oversight of such initiatives, which has been NRC's practice, has resulted in the NRC not knowing the extent to which voluntary industry initiatives have been implemented or maintained over time.

The NRC's ability to enforce industry initiatives is limited. An industry initiative is not directly enforceable, but a licensee's failure to meet a formal commitment could be the basis for a notice of deviation and any associated finding would be captured by the Reactor Oversight Process. Actions taken to address Type 2 industry initiatives are developed and implemented by licensees outside the scope of existing regulatory requirements, and they can be documented in written commitments. Traditional enforcement would not be possible, although an inspector could write a notice of deviation from the licensee's commitments. While a deviation is within the enforcement guidance, it is not captured by the Reactor Oversight Process unless there is an associated finding. A finding can be associated with a regulatory requirement or a licensee's self-imposed standard. In the case of deviations, a finding exists if the licensee failed to implement a self-imposed standard, the issue was within the licensee's ability to foresee and correct and therefore should have been prevented, and the issue is more than minor in accordance with Reactor Oversight Process program guidance. If the Reactor Oversight Process inspection program issues a finding, the significance of the finding would be determined in the significance determination process and it would be assigned a color. This finding will be an input into the overall inspection level for the plant. Licensees could respond by putting the finding into their corrective action program and by making changes to conform to the regulatory commitment or by revising the regulatory commitment. One of the goals of Improvement Activity 3 is to providing guidance regarding what level of NRC oversight is appropriate for future Type 2 industry initiatives. If NRC oversight activities determine that multiple licensees are failing to implement or maintain a particular voluntary initiative, the NRC may conclude that the industry initiative was ineffective, and that there may be a need for regulatory action (e.g., order, rulemaking) to address the safety concern or substantial safety enhancement issue. Also, if a licensee failed to take timely action to correct a deviation found to be of substantial safety significance for the facility (e.g., a significance determination process rating of RED or YELLOW), the NRC could conclude that the industry initiative was ineffective at the particular facility and that there may be a need for regulatory action (e.g., plant-specific backfit).

B. Relationship to NTTF Recommendation 1

The NTTF stated that the current NRC regulatory approach includes the following:

- requirements for design-basis events with protection and mitigation features controlled through specific regulations or the general design criteria 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” Appendix A, “General Design Criteria for Nuclear Power Plants”)
- requirements for some “beyond-design-basis” events through specific regulations (e.g., station blackout, large fires, and explosions)
- voluntary industry initiatives to address severe accident features, strategies, and guidelines for operating reactors"

The NTTF provided examples of voluntary industry initiatives:

- containment hardened vents for BWR Mark I designs
- some severe accident considerations (through the IPE and IPEEE programs)
- shutdown risk issues
- SAMGs
- Groundwater Protection Initiative

In several places in the NTTF report, the Task Force notes that voluntary initiatives have a place in NRC's regulatory framework, but states that voluntary industry initiatives should not serve as a substitute for regulatory requirements but as a mechanism for facilitating and standardizing implementation of such requirements. The NTTF further notes that NRC inspection and licensing programs give little attention to industry voluntary initiatives since there are no requirements to inspect against.

The NTTF noted that voluntary industry initiatives had been valuable and useful in the past as a mechanism for facilitating and standardizing implementation of ... [NRC] requirements. The NTTF report cited the development of symptom-based emergency operating procedures (EOPs) in the 1980s and development of the EDMGs following the events of September 11, 2001 as just two examples of notable industry contributions to effective implementation of regulatory initiatives.

However, the NTTF noted potential problems with some voluntary industry initiatives – specifically, those initiatives that were used to address safety concerns in lieu of the NRC developing and issuing regulatory requirements. To demonstrate this point, the NTTF requested that NRC inspectors collect information (TI 2515/184) on how each licensee had implemented SAMGs, a voluntary initiative. It also considered the results of an inspection

(TI 2515/183) of required activities related to mitigation strategies codified in 10 CFR 50.54(hh). The NTTF wrote:

> Through these two inspection activities, the Task Force also had the opportunity to compare industry activities under a required program and a similar voluntary initiative (i.e., EDMGs and SAMGs). Both programs had been effectively implemented, including initial program formulation and licensee staff training. Those programs are now 10 to 20 years old, and some licensees have maintained both programs in a manner expected for an important safety activity, including in terms of maintenance, configuration control, training, and retraining. However, some licensees have treated the industry voluntary initiative (the SAMG program) in a significantly less rigorous and formal manner, so much so that the SAMG inspection would have resulted in multiple violations had it been associated with a required program. The results of the SAMG inspection do not indicate, nor does the Task Force conclude that, the SAMGs would not have been effective if needed. However, indications of programmatic weaknesses in the maintenance of the SAMGs are sufficient to recommend strengthening this important activity.

In summary, the NTTF expressed its belief that voluntary industry initiatives could play a useful and valuable role in the suggested framework. These voluntary industry initiatives should not serve as a substitute for regulatory requirements but as a mechanism for facilitating and standardizing implementation of such requirements. Although the topic of voluntary industry initiatives is not specifically included in the NTTF Recommendation 1 or the related sub-recommendations, the staff included the topic in this paper because it does generally relate to improving the regulatory framework and it was not being addressed by other post-Fukushima activities.

Table 2 at the end of Enclosure 1 presents summary information on each improvement activity for easy comparison of the activities by showing the extent to which each improvement activity addresses NTTF Recommendation 1.

C. Relationship to RMTF Report

The RMTF report also expressed a concern regarding NRC's handling of industry voluntary initiatives in Finding PR-F-3: "The extent to which licensee activities undertaken as part of voluntary industry initiatives can be credited has been a source of contention in the Reactor Oversight Process and has reduced the efficiency of that process."

Table 3 at the end of Enclosure 1 presents summary information on each improvement activity for easy comparison of the activities by showing the extent to which each improvement activity addresses the power reactor recommendations of the RMTF report.

III. Detailed Description of Improvement Activity 3

A. Proposed Approach

Improvement Activity 3 would clarify the role of Type 2 industry initiatives in NRC's regulatory processes by (1) re-affirming the Commission's expectation that industry initiatives may not be used in lieu of NRC regulatory action where a question of adequate protection of public health and safety exists; (2) specifying when industry initiatives may be credited in the baseline case for regulatory analyses; and (3) providing guidance regarding what level of NRC oversight is appropriate for future voluntary initiatives. By "industry initiative," the staff is referring to proposals made by the nuclear power industry, e.g., commitments made by the Nuclear Energy Institute (NEI) on behalf of all licensees, or proposals made by discrete groups of licensees and applicants, e.g., the BWR Owners Group.

As stated in the *Background* section above, industry initiatives can generally be classified as one of three types. Improvement Activity 3 focuses on how Type 2 industry initiatives should be considered in the NRC regulatory process. It does not address Type 1[12] or Type 3[13] initiatives. Some examples of existing Type 2 industry initiatives include:

- Low power/shutdown risk
- Severe accident management guidelines
- Heavy load lifts
- Hydrogen igniter backup power for BWR Mark III and ice condenser containments

The scope of this proposed improvement activity is limited to voluntary initiatives proposed at a high level during rulemaking activities and for application to all or a class of licensed facilities in lieu of a generic regulatory requirement under consideration by the NRC. It does not address implementation of plant-specific voluntary commitments made by licensees of individual facilities.

In general, this activity would involve revisions to existing guidance. The revised guidance would reiterate the current Commission policy that industry initiatives may not be used in lieu of NRC regulatory action where a question of adequate protection of public health and safety exists (May 27, 1999, Commission SRM (ADAMS Accession No. ML003752062), approving the staff's recommendations in SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," March 2, 1999 (ADAMS Accession No. ML992810068)). The revisions to existing guidance would also direct that industry initiatives may not be credited in the baseline case as defined in the Regulatory Analysis Guidelines (NUREG/BR 0058, Rev. 4) unless there is a high likelihood that the industry will effectively implement and maintain the initiative over time.

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[12] Activity 3 does not address Type 1 industry initiatives even though some of those initiatives address NRC requirements involving adequate protection. Additional NRC action on Type 1 industry initiatives is unnecessary, because the NRC already has the regulatory tools to address a licensee's failure to comply with the underlying NRC regulatory requirement (regulation, license condition, order, technical specification) to which the Type 1 industry initiative is directed. The NRC may inspect/audit a licensee to determine if the licensee is complying with the underlying NRC requirement and may take enforcement action if the NRC determines that the licensee is not complying with the underlying NRC requirement.

[13] Activity 3 does not address Type 3 industry initiatives because those initiatives address issues that are not potential safety concerns.

As a part of this proposed improvement activity, the staff will develop and implement an integrated program for Type 2 voluntary industry initiatives. The program consists of the following two elements. First, the staff intends to evaluate the current status of implementation on those existing Type 2 initiatives which the staff believes are most risk significant or safety significant. The staff will use risk insights to identify the existing Type 2 initiatives which are the most risk and safety significant and then determine if the effectiveness of licensee implementation of the initiative(s) is already monitored (directly or indirectly) under an existing NRC oversight activity (e.g., inspections, performance indicators, reports). The staff would verify those initiatives where an acceptable measure of effectiveness cannot be identified (e.g., one-time audit, inspection, or request for information). Depending on the results of the verification activity, the staff might take further action, including pursuing a regulatory requirement. The verification activities to ensure that certain existing industry initiatives are being consistently maintained are within the staff's authority and do not require Commission approval. Second, the staff would revise its policies and procedures to ensure that the staff monitors future Type 2 initiatives for continued effective implementation. The staff will ensure that licensee commitments to voluntary initiatives are well-documented and transparent to the public. In the course of revising its policies and procedures, the staff may identify a need for a regulation requiring a licensee to report certain information regarding voluntary initiatives and/or notify the NRC if it intends to change its decision to implement or maintain any industry initiative that the NRC has publicly identified and relied on as the basis for not pursuing rulemaking.

Table 4 at the end of this enclosure provides a partial listing of voluntary industry initiatives identified by the staff.

B. Key Issues

There are several issues which the NRC staff considered in developing this improvement activity:

1. Should a Commission policy statement be developed?
2. Should the existing approach be modified to allow less reliance on Type 2 voluntary industry initiatives; for example by requiring a legally binding requirement once such initiatives have been implemented?
3. Should the NRC staff perform a detailed assessment of Type 1 and/or Type 2 initiatives to ensure they have been implemented and are being maintained?

Each of these issues is discussed in turn.

1. Should a Commission policy statement be developed? The NRC staff believes that the Commission policy, as set forth in SRM/SECY-99-063, is clear and will be made more readily accessible by including the policy in NRC internal guidance documents. Therefore, the staff does not believe that a Commission policy statement is necessary.

2. Should the existing approach be modified to allow less reliance on Type 2 voluntary industry initiatives; for example by requiring a legally binding requirement (e.g., rule or order) once such initiatives have been implemented? The staff believes that the proposed approach, which provides oversight for significant Type 2 initiatives and guidance on crediting such initiative in regulatory analyses, is sufficient to ensure that

these initiatives are implemented and maintained. Therefore, the staff does not recommend a change in policy that would require legally binding requirements for all Type 2 industry initiatives.

3. Should the NRC staff perform a detailed assessment of Type 1 and/or Type 2 initiatives to ensure they have been implemented and are being maintained? The NRC staff believes that its proposed activity to use a risk-informed approach to evaluate significant Type 2 industry initiatives is a cost-effective way of providing reasonable assurance that the most important industry initiatives are in place and being maintained. The two inspection activities initiated after the Fukushima accident (SAMGs and hardened vents) have already evaluated two very key industry initiatives and the staff is currently developing proposed requirements to assure that these activities are implemented properly. The staff reviewed existing Type 1 initiatives and concluded that sufficient oversight and performance monitoring activities are in place. Therefore, the NRC staff does not recommend a detailed assessment of Type 1 and non-significant Type 2 industry initiatives.

C. Expected Products

This improvement activity would result in the following:

- Revisions to existing guidance documents (e.g., Management Directives, Office Instructions, and other guidance documents) to implement the current Commission direction regarding voluntary industry initiatives

- Revision to the Regulatory Analysis Guidelines and procedures for preparing both plant-specific and generic backfit analyses, specifying when Type 2 industry initiatives may be credited in the baseline case.

- Revisions to inspection manual to better address industry initiatives

D. Estimated Resources and Schedule

<u>Industry Resources</u>

Industry resources are estimated to support the planned NRC audits of certain facilities to evaluate the implementation effectiveness of certain existing safety-significant initiatives. For the purposes of a resource estimate, it is assumed that the NRC would send 3 inspectors to perform audits at six sites. Licensee support for an entrance meeting (6 person-hours), daily support (48 person-hours), an exit meeting (6 person-hours), and responding to a follow-up request for additional information (200 person-hours) plus administrative and management support would cost approximately $180,000. This figure was rounded up to $200,000 for conservatism.

<u>NRC Resources</u>

NRC resource estimates for developing the conceptual approach, criteria, and revising a significant amount of internal staff guidance (Office Instructions, changes and additions to Inspection Manual chapters, etc.) addressing how the NRC will address future voluntary industry initiatives were made by assuming that 4 persons would be necessary working for 25% of their time for a period of 1 year (4 persons X 40% X 1 year = 1.0 FTE).

Implementation of the new criteria for crediting of voluntary initiatives will also require that they be incorporated into the existing Regulatory Analysis Guidelines (NUREG/BR-0058, Rev. 4). In response to the SRM on SECY-12-0110 on Economic Consequences, the staff is now working to update guidance documents integral to performing cost-benefit analyses in support of regulatory, backfit, and environmental analyses, including NUREG/BR-0058, Rev. 4. Necessary resources are being budgeted separately in conjunction with this effort. Incremental resources needed to incorporate new criteria for voluntary initiatives into this update activity are negligible.

Also, a screening review of existing voluntary initiatives to determine which initiatives would be audited by the NRC would be done in parallel with the above activity and is estimated to require 4 persons working for 25% of their time for a period of 1 year (4 persons X 40% X 1 year = 1.0 FTE).

Additional audit/inspection resources to conduct the audits are not included as these resources would be diverted from existing budgeted inspection activities. Completion of the audit activity is expected to take an additional year.

Thus the staff's estimate for total NRC resources needed for Improvement Activity 3 is 2.0 FTE over a time period of 2 years.

Resource Estimate for Possible NRC Rulemaking

In the course of revising its policies and procedures, the staff may identify a need for a regulation requiring a licensee to report certain information regarding voluntary initiatives and/or notify the NRC if it intends to change its decision to implement or maintain any industry initiative that the NRC has publicly identified and relied on as the basis for not pursuing rulemaking. The staff estimates that such a rulemaking would be of average scope and complexity and would require approximately 3.9 FTE over a time period of 3 years. Should this occur, the staff would follow the routine process to request Commission approval to institute the rulemaking.

E. Pros and Cons

Pros:

Improvement Activity 3 supports the NRC strategic plan and the principles of good regulation in the following ways:

- Ensures that that the safety benefits from voluntary industry initiatives would be consistently maintained over time by providing risk-informed regulatory oversight
- Facilitates monitoring and feedback to ensure that voluntary initiatives (whether used in lieu of or to support implementation of regulatory requirements) are improved as needed
- Improves the clarity of NRC regulatory processes by providing guidance on the handling of industry initiatives
    - Sets clear criteria for determining when and how voluntary industry initiatives would be integrated into regulatory processes

  - Clarifies and makes visible to all stakeholders how voluntary initiatives fit into the NRC's regulatory framework
  - Defines how industry initiatives should be addressed within NRC inspection and oversight processes.

<u>Cons</u>:

- Improvement Activity 3 may not support efficiency
  - Licensees may be less likely to interact with the NRC on safety issues
  - Licensees may be less likely to develop industry initiatives for Type 2 issues.
- Could result in industry backing away from initiatives if they are not given credit for their implementation
- This approach may not be seen as going far enough to address voluntary initiatives

F. How the NRC Staff's Proposal Resolves NTTF Recommendation 1

Table 1-3 below presents summary information on Improvement Activity 3 showing the extent to which it addresses NTTF Recommendation 1.

Table 1-3: Comparison of Improvement Activity 3 to NTTF Recommendation 1

NTTF Recommendation	Activity 3
1. [Establish] a logical, systematic, and coherent regulatory framework for adequate protection that appropriately balances defense-in-depth and risk considerations.	Adds clarity by reaffirming existing Commission policy regarding Type 1 initiatives and provides guidance and oversight for Type 2 initiatives, contributing to a systematic and coherent approach to regulation.
1.1 Draft a Commission policy statement that articulates a risk-informed defense-in-depth framework that includes extended design-basis requirements in the NRC's regulations as essential elements for ensuring adequate protection.	Does not address.
1.2 Initiate rulemaking to implement a risk-informed, defense-in-depth framework consistent with the above recommended Commission policy statement.	Does not address.
1.3 Modify the Regulatory Analysis Guidelines to more effectively implement the defense-in-depth philosophy in balance with the current emphasis on risk-based guidelines.	Does not address, although Regulatory Analysis Guidelines would be revised regarding when to credit voluntary industry initiatives in the baseline case.

Table 1-3: Comparison of Improvement Activity 3 to NTTF Recommendation 1	
NTTF Recommendation	Activity 3
1.4 Evaluate the insights from the IPE and IPEEE efforts … to identify potential generic regulations or plant-specific regulatory requirements.	Does not address.
Voluntary safety initiatives by licensees should not take the place of needed regulatory requirements. (NTTF Report, pp 19, 21)	Addresses by re-affirming Commission's expectation that industry initiatives may not be used in lieu of NRC regulatory action where a question of adequate protection of public health and safety exists. Strengthens expectations beyond the status quo for use of voluntary initiatives in cost-justified substantial safety enhancements.
The current NRC regulatory approach (requirements for design-basis events, beyond design-basis events, and voluntary initiatives) has resulted in a "patchwork" of regulatory requirements and other safety initiatives.	Improvement Activity 3 adds formal structure and NRC oversight to address the concerns identified by the NTTF with voluntary industry initiatives.

Table 2 at the end of Enclosure 1 presents summary information on each improvement activity for easy comparison showing the extent to which each improvement activity addresses NTTF Recommendation 1.

G. Example of a Possible Outcome of Implementing Improvement Activity 3

To provide an example of the possible outcome of implementing this option, the staff has reviewed the history of its efforts in 2004–2005 to promulgate a rule requiring Mark III and ice condenser containments to provide backup power to hydrogen igniters. As the staff was performing the backfit analysis and regulatory analysis, industry representatives voluntarily proposed to install a rudimentary backup power system that relied substantially on operator manual actions. As a result of crediting this proposed initiative in the baseline case of the value-impact analysis, the benefits of the staff's proposed rule for ice condensers were reduced and the staff could not find that there was a “substantial increase” in protection to public health and safety, or that the proposed rule was cost-effective under the regulatory analysis. The staff believes that, had Improvement Activity 3 been implemented at the time of the proposed rulemaking, the industry initiative would have been credited only if verification activities (e.g., NRC inspections, reporting requirements, etc.) had been put in place.

H. Staff Evaluation of Alternative Approaches to Address Voluntary Industry Initiatives

The Recommendation 1 Working Group and the Steering Committee conducted a detailed evaluation of three different approaches for addressing the concerns on voluntary industry initiatives identified by the both the NTTF and the RMTF. They include:

Approach #1 - Credit initiatives in regulatory analyses only if highly likely to be implemented and maintained in the future; increase NRC oversight of significant voluntary industry initiatives

Approach #2 - Explore change in current Commission policy

Approach #3 – Maintain Status Quo on Voluntary Industry Initiatives

Additional details on the development of the NRC's current policy on voluntary initiatives and the specific considerations addressed by the staff in its evaluation of these different approaches are provided in Attachment 3 to this Enclosure.

HOW THE STAFF'S REGULATORY FRAMEWORK RECOMMENDATIONS WOULD ADDRESS THE RMTF RECOMMENDATIONS FOR POWER REACTORS

The Chairman's Tasking Memorandum on June 14, 2012, (ADAMS Accession No. ML121660102) directed the staff to "consider the regulatory framework recommendations for power reactors provided in the RMTF report [NUREG-2150] in its development of options for implementing NTTF Recommendation 1." The Chairman's memorandum also directed the staff to "review NUREG-2150 and provide a paper to the Commission that would identify options and make recommendations [responding to the RMTF recommendations]." This separate effort is now being performed by the Risk Management Regulatory Framework (RMRF) working group, which has been coordinating closely with the NTTF Recommendation 1 working group. Commission direction on Recommendation 1 will inform future actions taken regarding the RMRF. Accordingly, Table 3 of Attachment 4 shows how the proposed Recommendation 1 improvement activities would address the RMTF recommendations for power reactors in NUREG-2150. The staff believes that the new design-basis extension category proposed under Improvement Activity 1 would be a logical first step towards to longer term regulatory framework envisioned by the RMTF. Similarly, the proposed establishment of a definition and criteria for adequacy of defense-in-depth under Improvement Activity 2 will be a key component of the risk-informed and performance-based defense-in-depth approach proposed by the RMTF under the Risk Management Regulatory Framework.

Staff Estimate of the Costs of Upgrading Existing PRAs to Meet Phase 4 of the Commission's Graded Quality Initiative

Purpose

The purpose of this attachment is to explain how the staff developed its estimate of the costs of requiring nuclear power plant licensees to upgrade their existing PRAs to an acceptable level of scope and quality sufficient to support making fundamental plant-specific changes to the current licensing basis of individual plants. Such licensing basis changes could include: (i) the addition of some currently unregulated events or accidents to the new design-basis extension category of regulatory requirements that are now considered to be beyond design-basis requirements; (ii) re-designation of existing design-basis requirements with low risk significance as "design-basis extension" requirements where less stringent levels of mitigation would be allowed; and (iii) elimination of certain non-risk-significant existing design-basis requirements. A PRA of Phase 4 scope and quality would be also adequate to inform the defense-in-depth decision criteria associated with Improvement Activity 2, although a PRA of lesser scope and quality would also be sufficient. However, the NRC staff did not recommend a PRA requirement in either of these improvement activities because the significant PRA upgrade and maintenance costs estimated in this attachment were not deemed to be justified for these purposes.

Background

In the SECY paper, the staff noted that a plant-specific PRA requirement to support Improvement Activity 1 and Improvement Activity 2 was not justified due to (1) the high cost of such a requirement and (2) the low anticipated level of safety benefits. On November 2, 2012, the NRC staff provided to interested stakeholders its initial cost estimate of a PRA that would be sufficient to make fundamental changes to a plant's licensing basis. Both NEI and the PWROG provided information indicating that the staff's estimates were substantially low. This section provides the staff's detailed estimate for a PRA that would meet Phase 4 of the Commission's graded quality initiative, which is what the staff believes would be necessary to support the establishment of a plant-specific licensing basis.

The staff evaluated whether the NRC should amend its regulations to require current nuclear power plant licensees to upgrade their existing PRAs to a level of PRA quality sufficient to support a regulatory framework embodying plant-specific licensing basis based upon risk-informed considerations. Because such a regulatory framework approach would allow both the NRC and licensees to reduce certain existing regulatory requirements, the staff believes it essential that existing plant PRAs used to determine the plant-specific risk profiles of these facilities be upgraded to have acceptable scope, technical adequacy, and quality.

Because this regulatory framework approach would require rulemaking, it must be evaluated by performing both a regulatory analysis and a backfit analysis.[14] Thus, it is important to know the

[14] A backfit analysis would be required, in addition to a regulatory analysis, because the contemplation of both the NTTF and the RMTF is to conduct rulemaking to apply the new regulatory framework to existing nuclear power plants. Such an imposition would constitute backfitting. Plants licensed under 10 CFR Part 52, and design certifications under Part 52 already have PRAs as required by regulation. Therefore, it would be unnecessary to backfit those plants and designs and the issue finality provisions of Part 52 need not be addressed.

cost of requiring licensees to upgrade their existing PRAs to a level that would support establishing and maintaining site-specific licensing bases for each reactor facility.

Initial Staff Estimate of PRA Cost

The NRC staff's first estimate of the cost of upgrading PRAs to support a site-specific licensing approach was described in an option summary document made public on November 2, 2012 (ADAMS Accession No. ML12296A096). Among other alternatives, this document analyzed an Option 4b which was patterned after the design-enhancement category approach recommended by the RMTF. The staff's original estimate for the one-time costs of upgrading licensee PRAs is shown in Table 1. below.

Table 1. Original Staff Cost Estimate of Industry Cost for Upgrading PRA to All Mode, All Initiating Events

Industry Costs	Hours per action	No. of actions	Labor rate	Implementation cost
Upgrade plant-specific PRA Peer review plant specific PRAs	3120 624	68 68	$105 $105	$22,276,800 $4,455,360
			Total	$26,732,000*
Average licensee cost per unit				$393,000*

*Numbers rounded to the nearest thousand dollars

The staff then estimated the present value of the annual cost to maintain those PRAs throughout the average remaining estimated lifetime (27 years) of the operating reactor fleet ($21,000 per unit for 104 plants for a total of $2,184,000 per year for 27 years) resulting in $42,000,000 at 3% discount and $28,000,000 at 7% discount rate. Thus, the total costs of the PRA requirement were initially estimated to be $68.7 million (@ 3% discount rate) or $54.7 million (@ 7% discount rate).

Stakeholder Comments on the Initial Staff Estimates

The staff requested public comments on its November 2012 option summary document in late 2012. The staff received comments from the Pressurized Water Reactors Owners Group (PWROG) and the Nuclear Energy Institute (NEI). Among other comments provided, both commenters stated that the NRC's initial PRA cost estimates were substantially underestimated. The comments of the PWROG and NEI are presented separately below.

Pressurized Water Reactors Owners Group Comments

In its December 12, 2012, comment submission letter, the PRWOG provided the following detailed cost estimates for upgrading existing licensee PRAs:

Table 2. PWROG Cost Estimates for Upgrading Various Types of PRAs

Scope	Low Estimate	High Estimate
Internal Events (including Internal flooding)	$500,000	$1,500,000
Fire	$1,500,000	$3,000,000

Seismic	$1,500,000	$3,000,000
Other External Events	$250,000	$500,000
LPSD/SFP	$200,000	$300,000
Other	$100,000	$200,000

Based on the above estimates, the total industry cost of model upgrades would range from $168,700,000 to $339,200,000 if it is assumed that only 17 of the 68 sites require significant upgrades to their internal events PRA and an upgraded fire PRA. This PWROG estimate indicates that the initial NRC estimates of the required resources for development of full-scope, all-modes PRA models sufficient to support the proposed regulatory framework are underestimated by up to a factor of 12.

The PWROG stated that peer review costs were also underestimated by the NRC. Estimates provided by the PWROG for each peer review, excluding utility support, are as follows:

Table 3. PWROG Cost Estimates for Peer Reviews

Scope	Partial Review	Full Review
Internal Events, Other External Events, and LPSD	$60,000	$90,000
Fire and Seismic	$70,000	$124,000

As discussed above, if it is assumed that 17 of the 68 sites require fire and internal events PRA peer reviews, the total industry cost of required PRA peer reviews, including approximately 160 hours of utility labor per review, is $26,282,000 to $37,364,000. Thus, the PWROG estimated that PRA upgrade costs would range from $195 million to $377 million. The PWROG did not provide estimates of the annual costs for licensees to maintain their upgraded PRAs.

Nuclear Energy Institute Comments

In its December 13, 2012, comment submission letter, the Nuclear Energy Institute provided the following cost estimates for upgrading existing licensee PRAs:

Table 4. NEI PRA Cost Estimates

Scope	Development Cost Range	Peer Review Cost Range	Peer Review Finding Resolution Cost Range	Annual Maintenance Cost Range
Internal Events	$600,000 - $4,000,000 (Note 1)	$90,000 - $150,000	$75,000 - $250,000	$125,000 - $150,000
Fire	$1,500,000 - $4,000,000 (Note 2)	$350,000 - $625,000 (Note 3)	$130,000 - $500,000	$50,000 - $250,000
Seismic	$1,500,000 - $3,500,000	$150,000 - $250,000	$200,000 - $250,000 (Note 4)	$100,000 - $150,000

Notes:

(1) The majority of the fleet upgraded existing internal events PRAs to meet the ASME/ANS PRA Standard; the lower end of this range reflects plants that used this approach while the upper end represents those plants that undertook a substantial model reconstruction.

(2) The lower end of this range reflects the fact that not all plants include fire modeling and circuit analysis in their Fire PRA development costs.

(3) The upper end of this range reflects the fact that some plants had to do substantial documentation work to support their Fire PRA peer reviews.

(4) As no final Seismic PRA Peer Review report has been issued, these are estimates.

NRC Staff Cost Estimate

After reviewing the cost estimates provided by the PWROG and NEI, the NRC staff made its own estimate using the more detailed incremental PRA upgrade costs provided by the PWROG, added annual PRA maintenance costs similar to those provided by NEI, and applied them to the staff's estimate of the overall scope and quality of PRAs across the current operating reactor fleet.

As can be seen from Table 5 below, the staff's estimate of the present value of the total costs of a PRA requirement range from $607 million (@ 3% discount rate) to $727 million (@ 7% discount rate).

Table 5. Cost Estimates for Existing Plants to Upgrade PRAs to Achieve Phase 4 of the Graded Quality Initiative[15]

Type of PRA activity	Number of Sites (1)	Cost of Upgrade (2)	Cost of Peer Review (3)	Cost of Peer Review Comment Resolution (3)	Implementation Cost
Internal PRA Major upgrade	30	$1,500,000*	$150,000*	$250,000*	$57.0M
Internal PRA Minor upgrade	31	$500,000*	$90,000*	$75,000*	$20.6M
Fire PRA Major upgrade (4)	30	$4,000,000	$625,000*	$500,000*	$153.8M
Fire PRA Minor upgrade (4)	31	$200,000	$90,000(7)	$75,000(7)	$11.3M
Seismic PRA Major upgrade (8)	30	$3,000,000*	$250,000*	$250,000	$105.0M
Seismic PRA Minor upgrade (8)	31	$200,000 (9)	$90,000 (9)	$75,000 (10)	$11.3M
Other PRA Upgrades		(6)	(6)	(6)	(6)
				Total	$359.0M
				Annual Maintenance	$342.8M – $506.2M(5)

(1) This table uses 61 sites for the purpose of developing the estimate. The NRC 2013-2014 Information Digest (NUREG-1350, Volume 25, dated August 2013 (ADAMS Accession No. ML13241A207)), states that as of June 30, 2013, there were 62 commercial reactor sites including Vermont Yankee Nuclear Power Station. However, the operator of Vermont Yankee Nuclear Power Station announced plans to permanently cease operations, so that site was removed and a total of 61 sites was used in the table.
(2) All sites will require at least minor upgrades to appropriately clean up and develop final documentation of the technical adequacy of their PRAs.
(3) All sites will require a new Peer Review (perhaps 3 or 4 sites have a new, post-2009 peer review, but that fact is not reflected in this table). This is not currently required but experience with NFPA-805 indicates that uncertainties arising from (sometimes 14 year old) peer reviews supported by a series of “focused scope” reviews are a major obstacle to swift and efficient NRC PRA quality determination.
(4) PWROG estimated $1,500,000 to $3,000,000 for fire PRAs. This has been changed to $200,000 for plants with recent fire PRAs, and $4,000,000 to perform a fire PRA.
(5) This cost range represents the 7% and 3% net present values of annual maintenance at 61 sites by 2 additional full time employees at each site over an average remaining number of life-years per site of 24 years. Maintenance includes PRA analysts to review new information and all plant changes and incorporate changes in PRA as needed.

[15] Phase 4 is described in Staff Requirements Memorandum – COMNJD-03-0002 – Stabilizing the PRA Quality Expectations and Requirements.

(6) Insufficient information was available to estimate costs associated with upgrading PRAs to include "other initiating events."
(7) Industry low peer review was 350,000 for review, 130,000 for resolution but low values for internal events peer reviews seem more applicable.
(8) Industry is currently reevaluating their expected ground motion hazards to determine whether a Seismic risk assessment will be required. These reevaluation will be completed by the second quarter of 2014. For planning purposes, a reasonable estimate assumes that ½ of the facilities will need to perform a risk assessment to fulfill the 50.54f letter requirements.
(9) Values estimated to be the same as a fire PRA minor upgrade.
* Estimate taken for PWROG Cost estimate report – high estimates used for Major updates, low estimates used for Minor updates.

Staff Evaluation of Alternative Approaches to Develop a New Category for Beyond Design-Basis Events and Associated Requirements

Both the NTTF and the RMTF reports discuss options for creating a single new event category but offer differing insights as to what this new category may look like and how it would be populated with events and associated requirements. The extent to which the implementation of Improvement Activity 1 conforms with either NTTF or RMTF recommendations depends upon how five key issues are resolved. These key issues are presented below:

1. Would the approach be generic, plant-specific, or a hybrid?
2. Would the category be for adequate protection, safety enhancement, or both?
3. Would a plant-specific PRA be required?
4. Would the new category be applicable to new reactors only, or also to operating plants?
5. Would the category be populated on a forward-looking or retrospective basis?

The various combinations of possible answers to the five questions could result in substantially different approaches to develop a new category of accidents or events. The NRC staff considered the various combinations of answers to these questions and selected the following three approaches for establishing a new category to analyze in detail before making a recommendation on this proposed improvement activity.

- A plant-specific approach using NRC-required plant-specific PRA models
- A plant-specific approach using generic risk information and plant-specific risk insights developed by an expert panel established by the licensee
- A generic approach without a PRA requirement, which would use available risk insights from licensee PRAs, NRC risk studies (e.g., SOARCA; Level 3 PRA Project), and SPAR models

The WG believes there are three reasons why the NTTF and RMTF recommended creating and populating a new category of events and accidents:

- To increase **safety**,
- To increase **coherency** of how our regulations address safety issues, and
- To reduce unnecessary licensee **burden**.

The WG evaluated the three different approaches for establishing a new category against these criteria to develop its recommended approach.

Approach #1: Plant-Specific Approach Using NRC-Required Plant-Specific PRA Models

This approach is modeled after the approach recommended by the RMTF as described in NUREG-2150, Appendix H, Alternatives 2 and 3. Licensees would be required to perform plant-specific PRAs meeting standards specified by the NRC. The PRA results would be analyzed to identify plant-specific event sequences which exceeded threshold criteria also specified by the NRC. The threshold criteria could be risk-informed or could be augmented to consider cost effectiveness. Event sequences exceeding the thresholds would be required to be mitigated by licensees to reduce risk to meet acceptance criteria established by the NRC.

The WG's evaluation of Approach #1 concluded that it would be the most thorough and systematic approach. It would be consistent with current Commission policy to increase the use of PRAs and to increase safety of new reactors by using PRAs to perform severe accident evaluations. The WG agrees that the PRAs utilized by this approach could identify some plant-specific risk outliers that could not be identified by generic approaches. Thus, Approach #1 could **increase safety** by identifying and requiring licensees to mitigate plant-specific risk outliers. However, the WG believes there is substantial uncertainty regarding the magnitude of such safety increases. The capability of PRAs to identify unforeseen safety issues is limited because PRAs cannot identify unknown phenomena or scenarios not already incorporated into the PRA models. The NRC staff believes that Approach #1 is not likely to result in major safety benefits because all operating reactors have PRAs (of varying quality) and have used them to search for site-specific vulnerabilities (i.e., Generic Letter 88-20). Licensees also use PRAs to support risk-informed regulatory activities (e.g., 10 CFR 50.65 risk assessments and the Significance Determination Process of the Reactor Oversight Program), and to propose risk-informed alternatives to regulatory requirements (e.g., changes to Technical Specifications and in-service inspection programs). Therefore, it is likely that some potential vulnerabilities and some opportunities to reduce unnecessary burden that might be identified by a PRA have already been identified. Also, ongoing post-Fukushima actions and other external hazards reviews are addressing site-specific vulnerabilities related to seismic and flooding events (e.g., Recommendations 2.1 and 2.3). And finally, the other post-Fukushima activities, including the station-blackout/mitigation strategies Orders and rulemaking, are addressing a wide range of potential safety issues which will result in further reductions in overall risk.

Approach #1 may **reduce stakeholders'** (both internal and external) **perception of** the overall **coherency** of NRC's regulatory framework. The overall coherence of NRC's regulatory framework for power reactors has depended, from a historical perspective, on a comprehensive set of generic safety requirements addressing a complete set of external events, physical phenomena, and plant conditions and accidents that determined the fundamental basis for radiological health and safety. The staff recognizes that some NRC regulations for power reactors are written to take into account plant-specific (and site-specific) information, primarily in the area of consideration of natural phenomena. Nonetheless, most NRC technical requirements for power reactors are written to apply "generically" (if not to all plants, to all plants of a class or design as specified in the regulation, e.g., all boiling water reactors). These "generic" regulations are applied (absent an NRC exemption) uniformly to all plants within the class. Approach #1 differs significantly from this existing regulatory framework paradigm, by allowing a *plant-specific* determination of the technical requirements based upon *plant-specific risk information*. Mandating the use (as opposed to allowing the voluntary use) of a plant-specific approach for determining the technical requirements may result in the growing irrelevance of NRC generic technical requirements to the new plant-specific regulatory framework inasmuch as the technically-relevant requirements would be reflected in each plant's licensing basis/design basis. Consequently, industry stakeholders may seek to remove the "generic" technical requirements from the NRC's generic regulatory framework on the basis that they are no longer necessary to safety. While the staff believes that the generic technical issues must be retained in the NRC's regulations if only to specify the technical matters which applicants and licensees must address, the staff also believes that much of the "prescriptive" and perhaps even some aspects of the current performance-based requirements would not be needed under Approach 1 and could result in significant rewriting of the full set of technical regulations. The rewriting activity, as well as each licensee's actions to demonstrate compliance under a plant-specific approach, would require significant resource expenditures by both the NRC and licensees. Moreover, there may be reductions in NRC's regulatory efficiency as individual plants' licensing bases diverge, making it more difficult for the NRC to identify evolving trends and problems. Divergence of licensing bases may also make it more difficult for the industry (or discrete segments, such as owners groups) to effectively develop common approaches for resolving emerging issues.

On the other hand, if the NRC adopts a new regulatory paradigm of implementing risk-informed regulation on a *plant-specific basis* under Approach #1, and on that basis removes or rewrites unnecessary generic requirements, then the result would be **greater** overall **coherence between the regulatory framework** and both the plant-specific licensing bases **and the risk profiles across the entire fleet of plants**.

Approach #1 may reduce public confidence in NRC's regulatory processes, not only because of the possible perceived lack of coherence, but also because PRA results and supporting information/analyses are not transparent to and easily understood by many members of the public. During public meetings related to Recommendation 1, some stakeholders have expressed a lack of confidence in PRA results and urged the NRC not to implement a new regulatory framework based on PRA.

Approach #1 could **reduce unnecessary** licensee **burden** because the plant-specific PRAs could also be used to identify existing NRC requirements that are not risk-significant at certain plants and thus could be reduced without significantly affecting overall facility risk. However, there are significant costs associated with upgrading existing PRA models[16], maintaining the models, and inspecting the plant-specific licensing bases.

Therefore, the WG did not further consider Approach #1 because it is costly for existing Part 50 licensees and has uncertain safety benefits.

Approach #2: Plant-Specific Approach Using Generic Risk Information and Plant-Specific Risk Insights Developed by an Expert Panel Established by the Licensee

Instead of requiring licensees to perform plant-specific PRAs, Approach #2 would require licensees to use expert panels to evaluate generic risk information and develop plant-specific risk insights to identify risk outliers for further mitigation and to identify existing, non-risk-significant requirements which could be reduced to eliminate unnecessary licensee burden.

The WG believes that expert panels (without having the benefit of an up-to-date plant-specific PRA) might not be able to identify plant-specific risk outliers. Thus, there is uncertainty over whether this approach could increase **safety**.

The WG also believes that without the benefit of a plant-specific PRA, expert panels might have trouble identifying existing, non-risk-significant requirements which could be reduced. Thus the WG believes that recommendations on how to reduce existing requirements to eliminate **burden** might be subjective and inconsistent from plant to plant.

Because Approach #2 would be based upon the same plant-specific regulatory framework paradigm as Approach 1, Approach #2 may also **reduce stakeholders'** (both internal and external) **perception** of the overall **coherency** of NRC's regulatory framework. Similarly, successful implementation of Approach 2 could **increase** overall **coherence between the regulatory framework and** the plant-specific **risk profiles across the entire fleet of plants**.

[16] Costs for existing Part 50 licensees to perform and maintain PRAs consistent with the NRC-endorsed industry consensus standards have been estimated by the NRC and industry to be in the range of several hundred million dollars. The staff qualitatively estimated only the safety benefits that could result from requiring PRAs. The staff did not attempt to estimate the potential non-safety benefits that could result from having PRAs.

Approach #2, like Approach #1, may reduce public confidence in NRC's regulatory processes because of the perceived lack of coherence and because risk information and supporting information/analyses are not transparent to and easily understood by many members of the public. Additionally, because Approach #2 uses expert panels instead of quantitative PRAs to consider risk information, some stakeholders might not be convinced that licensee expert panel reviews could be conducted in an objective and unbiased manner. Thus, Approach #2 has an additional factor which may result in reduced public confidence in the NRC's regulatory oversight which is not present under Approach #1.

Furthermore, this approach would be very difficult for the NRC staff to implement. The NRC would have to specify criteria and thresholds for licensees to use to identify which risk outliers to mitigate and which non-risk significant existing requirements could be reduced. Without having a PRA updated to comply with NRC-endorsed industry standards, the WG believes it would be difficult to implement consistent regulatory oversight of applicants and licensees. It may also result in inconsistency in the level of safety achieved by different licensees.

Therefore, the WG does not recommend Approach #2 because of concerns about its overall effectiveness and consistency and the difficulty of NRC implementation.

Approach #3 - Generic Approach without a PRA Requirement Which Would Use Available Risk Insights from Licensee PRAs, NRC Risk Studies (e.g., SOARCA; Level 3 PRA Project) and SPAR Models

Under a generic approach the NRC would search for and identify any risk-significant new events and/or accidents, and would promulgate generic requirements for all licensees (or groups or classes of licensees) to reduce the risk posed by these new events. These new requirements (and certain existing requirements) would be grouped together in a new category established for "design-basis extension" requirements. Rulemaking would be conducted to define the new category and describe the types of requirements that it would include.

The WG's evaluation of this approach concluded that it is unlikely to directly increase **safety** beyond that already achieved by the current framework because its generic structure closely resembles and would rely on many of the same processes used under the existing generic regulatory framework. The NRC already has an extensive set of processes and programs in place to search for and evaluate new potential safety issues. Such programs include but are not limited to public petition processes for rulemaking and enforcement actions, the Accident Sequence Precursor program, the Reactor Operating Experience Program, the Generic Issues program, the Reactor Oversight (Inspection) program, the Industry Trends program, and the Agency Action Review Meeting to review ROP effectiveness and trends in industry and licensee performance. The WG does not believe that a comprehensive re-evaluation of existing generic regulatory requirements using available risk insights under Approach #3 is likely to result in increased safety by identifying additional necessary requirements not already identified by the existing processes described above. Furthermore, the NRC's mitigation strategies order (EA-12-049), the ongoing industry FLEX program, and the SBO mitigation strategies rule are being implemented to provide additional protection for existing plants against a wide range of unspecified beyond design basis accident conditions. If new or unforeseen events or conditions are identified, it is likely that the new systems and equipment being installed under these activities would provide at least partial mitigating capability for the adverse conditions. In addition to the SBO mitigation strategies rule, other ongoing efforts in response to the other Fukushima NTTF recommendations are also investigating a wide range of safety potential concerns for possible additional requirements. Additionally, existing plants have all performed IPE and IPEEE studies to identify and mitigate certain plant-specific risk outliers associated with severe accident vulnerabilities. New reactors are required to have plant-specific PRA models which are used to identify plant-specific risk outliers and to analyze design features to prevent and mitigate severe accidents. Therefore, in light of these activities, Approach #3 would be unlikely to identify new generic requirements that would result in an increase in safety.

The WG determined that Approach #3 could reduce unnecessary regulatory **burden** from generic requirements which are found to be non-risk significant based upon an integrated consideration of available risk information. However, a generic approach would not facilitate removal or reduction of generic requirements which are not risk-significant at a particular facility because of unique plant-specific or site-specific considerations.

The WG determined that Approach #3 would increase **coherency** because the establishment of the new “design-basis extension” category of requirements would make it clear to both internal and external stakeholders that the NRC regulations may go beyond the existing “design basis” in certain instances and would not always require “safety-grade” regulatory treatment requirements for the equipment required by the regulations in the new category. The WG notes that the new category would be consistent with IAEA and other international standards and recommendations.

However, because the new “design-basis extension” category established under Approach #3 is not expected to significantly enhance safety, the WG concluded that it was of primary importance to minimize the implementation cost and burden of the approach to both licensees and to the NRC. By minimizing costs, resources to establish the new category would not be diverted from other ongoing NRC and licensee efforts to enhance nuclear power reactor safety. For these reasons, the WG proposes the simplified generic approach for establishing the new design-basis extension category described in Enclosure 1.

Staff Evaluation of Alternative Approaches to Address Voluntary Industry Initiatives

A Brief History of Crediting Industry Initiatives in NRC's Regulatory Analyses

Prior to Revision 2 of the Regulatory Analysis Guidelines (NUREG/BR-0058), there was no formal NRC guidance on how to treat voluntary industry initiatives in Regulatory Analyses.[17]

The NRC issued Revision 2 of the Regulatory Analysis Guidelines in November 1995.

- For base case calculations, "no credit" was to be given for voluntary actions taken by licensees.
- However, for sensitivity analysis purposes, costs and benefits were displayed with "full" credit for voluntary activities.
- In addition, the guidelines specified that if voluntary programs are effective, such that there are no problems, there is no need to codify them in the regulations.
- There was no formal program for reviewing and accepting voluntary industry initiatives.

The following quote from the Regulatory Analysis Guidelines reflects the NRC's concerns with voluntary industry initiatives at that time:

> Most voluntary actions are discretionary, and their impacts are primarily ongoing and future-oriented. Voluntary programs might be characterized as adopting vague requirements, lacking in NRC enforceability, and resulting in nonuniform programs across all licensees. The NRC intends to be able to impose regulatory requirements in lieu of voluntary programs that, for any number of reasons, are not providing the level of safety assurance the NRC deems necessary. This would be the case, for example, when voluntary programs are nonuniform across all licensees. As a result, some licensees may not have a program, or established programs could easily dissipate by licensee action alone, perhaps without NRC's knowledge. Furthermore, if credit is provided for voluntary initiatives and values and impacts associated with the proposed regulatory action are reduced, meaningful health and safety improvements could not be assumed in the future because they would remain uncodified and voluntary in nature, not subject to enforcement on the part of the NRC.[18]

The staff noted that this practice of reviewing initiatives is informal and relies on judgments that are not explicitly acknowledged or systematically documented. There is no formal NRC definition of an industry initiative or formal NRC approval of criteria to use in evaluating them. There is no tracking or repository of industry initiatives, and there is no program in place to verify that licensees follow through on proposed initiatives.[19]

In 1996, the Commission expressed concern regarding the NRC's monitoring of voluntary programs or activities initiated by the industry in lieu of the imposition of regulatory

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[17] SECY-99-178, "Treatment of Voluntary Initiatives in Regulatory Analyses," dated July 9, 1999 (ADAMS Accession No. ML992370072), page 2

[18] NUREG/BR-0058, Revision 2, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," dated November 1995 (ADAMS Accession No. ML111180434), page 19

[19] SECY-97-303, "'The Role of Industry (DSI-13)' and Use of Industry Initiatives," dated December 31, 1997 (ADAMS Accession No. ML12263A785)

requirements.[20] The Commission directed the staff to develop and activate a procedure to verify that such voluntary industry programs are, in fact, being carried out. The Commission also requested the staff to inform the Commission of possible methods for determining the effectiveness of these programs.

In 1997, the Commission appeared to change its view on voluntary industry actions when it disapproved a proposed rule on shutdown operations and directed the staff to review current regulatory analysis methodology in light of the ongoing evaluation of a proposal, known as Direction Setting Issue (DSI) 13, to increase NRC reliance on industry activities as an alternative for NRC regulatory activities. The Commission directed the staff to submit, for Commission review, options that would address possible revisions to the regulatory analysis methodology, particularly with regard to recognition of existing initiatives and voluntary actions in the cost-benefit analyses.[21]

In 1999, the staff submitted its proposed revisions to the regulatory analysis methodology regarding treatment of voluntary initiatives in regulatory analyses.[22] The Commission approved the staff's recommended approach.[23] The NRC issued Revision 3 to the Regulatory Analysis Guidelines incorporated the revised methodology in July 2000.[24] This approach remains the NRC's current position with respect to the treatment of voluntary initiatives in regulatory analyses.

- Develop two sets of value-impact estimates: one based on "no credit" and the other based on "full credit" for industry initiatives. These results will have equal weight and will be presented for sensitivity analysis purposes. If the overall value-impact result does not tilt from an overall net cost to an overall net benefit (or vice versa), there is no need to proceed further.
- If the results are highly sensitive to that level of variation, such that the overall value-impact conclusion shifts or the final recommendation changes, the analyst would proceed to develop a "best estimate" base case.

At the time this approach was developed, the staff and the Commission expected that a formal process for reviewing and accepting voluntary industry initiatives would be developed (as a result of DSI-13) and that this would increase NRC's assurance that industry initiatives will be effective long-term alternatives to regulatory actions.[25]

However, the NRC withdrew the proposed voluntary industry initiative program in 2001 after overwhelmingly negative feedback from stakeholders.[26,27] Some industry stakeholders

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[20] "Staff Requirements – Briefing on NRC Inspection Activities, 10:00 a.m., Friday, May 31, 1996, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to Public Attendance)," dated July 30, 1996 (ADAMS Accession No. ML003754984)
[21] SRM-SECY-97-168, "Issuance for Public Comment of Proposed Rulemaking Package for Shutdown and Fuel Storage Pool Operation," dated December 11, 1997 (ADAMS Accession No. ML003752569)
[22] SECY-99-178, "Treatment of Voluntary Initiatives in Regulatory Analyses," dated July 9, 1999 (ADAMS Accession No. ML992370072)
[23] SRM-SECY-99-178, "Treatment of Voluntary Initiatives in Regulatory Analyses," dated August 26, 1999 (ADAMS Accession No. ML003752222)
[24] NUREG/BR-0058, Revision 3, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," dated July 2000 (ADAMS Accession No. ML023290519)
[25] Regulatory Analysis Guidelines, Revision 3, page 23
[26] 65 FR 53050, "Proposed Guidelines for Including Industry Initiatives in the Regulatory Process," dated August 31, 2000

perceived the proposed guidelines on industry initiatives as imposing a burdensome obstacle to open and candid interactions between the regulator and the industry. A public interest group stated that it is "…categorically opposed to the regulatory retreat under way at the U.S. Nuclear Regulatory Commission (NRC) under the guise of voluntary industry initiatives (in lieu of regulation)...The NRC plans to supplant regulation with voluntary initiatives that are non-enforceable, remove the public from the process, and fail to address significant safety issues....Proposed guidelines will limit the ability of the public to meaningfully participate in the decisions that affect the health and safety of our families, homes, and communities...." In view of the stakeholders' reluctance to embrace the proposed guidelines, the staff concluded that implementing this largely voluntary process would be ineffective.

In summary, the current NRC policy is that the current regulatory framework does not preclude voluntary initiatives serving as substitutes for NRC regulatory action for safety enhancements. Issues related to adequate protection of public health and safety are deemed the responsibility of the NRC and should not be addressed through industry initiatives. The current Regulatory Analysis Guidelines state that the NRC encourages voluntary initiatives and credits them in regulatory analyses supporting regulatory decisionmaking. However, there is no formal NRC process for reviewing and accepting voluntary industry initiatives and there is no formal NRC program in place for verifying that voluntary initiatives have been effectively implemented or maintained over time.

Relying on Industry Initiatives

This background discussion has focused on the history of crediting industry initiatives in NRC's regulatory analyses. A separate and more fundamental policy issue is whether it is appropriate to allow an industry initiative to serve as a substitute for NRC regulatory action. The following paragraphs provide more background on the history of that policy issue.

In 1996, the staff identified "the role of industry" as an issue (DSI-13) that affects the basic nature of NRC activities and the means by which this work is accomplished.[28] In its description of this issue, the staff noted that the existing interaction had evolved absent an overall explicit policy statement. Prior to this date, the NRC had allowed voluntary industry actions to serve as a substitute for NRC regulatory actions on several occasions. One example is when the Commission directed the staff to approve the installation of hardened vents for Mark I containments under 10 CFR 50.59.[29]

In 1997, the Commission directed the staff to evaluate further reliance on industry activities as an alternative to NRC regulatory activities and to develop guidance to describe the process and the general decision criteria the NRC would use for evaluating proposals. The staff provided the results of its evaluation to the Commission in 1999. The Commission responded with the statement below which is still the NRC's current policy:

> The Commission has approved the staff's recommendation that voluntary industry initiatives will not be used in lieu of regulatory action where a question of

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[27] 66 FR 43597, "Notice of Withdrawal of Proposed Voluntary Industry Initiative Program," dated August 20, 2001
[28] "Strategic Assessment Issue Paper, Direction Setting Issue 13 (DSI) 13 - The Role of Industry," dated September 13, 1996 (ADAMS Accession No. ML051590494)
[29] SRM-SECY-89-017, "Mark I Containment Performance Improvement Program," dated July 11, 1989 (ADAMS Accession No. ML12291B088)

> adequate protection of public health and safety exists. Voluntary industry initiatives are approved as an appropriate substitute for NRC regulatory action where the action to be taken is needed to meet existing requirements or for cases where substantial increase in overall protection can be achieved with costs of implementation justifying the increased protection. The Commission has agreed that the current regulatory framework does not preclude voluntary industry initiatives and existing regulatory processes can be used to support implementation of voluntary initiatives. The staff should move forward, working with industry and other stakeholders, in the development of the process and guidelines for use of industry initiatives in the regulatory process. The guidelines should be provided to the Commission for review prior to their implementation.[30]

In 2000, the Regulatory Analysis Guidelines were revised to include a statement implying that it is the agency's policy to encourage voluntary initiatives.[31]

In summary, the current policy is that voluntary initiatives may serve as a substitute for regulatory action where the action to be taken is needed to meet existing requirements or for cases where a substantial increase in overall protection can be achieved with costs of implementation justifying the increased protection but not for issues of adequate protection. However, there is no process in place for reviewing and overseeing voluntary initiatives. Again, it should be noted that the guidelines for use of industry initiatives in the regulatory process mentioned in the previous quote were developed and issued for public comment but were later withdrawn.

Three Types of Industry Initiatives

The current version of the Regulatory Analysis Guidelines provides the following description of three types of industry initiatives:

Industry initiatives can generally be put into one of the following categories:

(1) those put in place in lieu of, or to complement, a regulatory action to ensure that existing requirements are met,

(2) those used in lieu of, or to complement, a regulatory action in which a substantial increase in overall protection could be achieved with costs of implementation justifying the increased protection, and

(3) those that were initiated to address an issue of concern to the industry but that may or may not be of regulatory concern.

Fukushima

The Fukushima Dai-ichi event highlighted that some measures previously put in place as voluntary initiatives in the United States to deal with severe accidents (e.g., severe accident management guidelines (SAMGs) and hardened vents), could have played a significant role in

[30] SRM-SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," dated May 27, 1999 (ADAMS Accession No. ML003752062)
[31] The footnote on page 5 includes the following statement: "The Commission also believes that this approach…is consistent with the agency's policy of encouraging voluntary initiatives."

preventing or mitigating the accident. However, NRC assessments performed after the Fukushima event reinforced that these specific examples were not subject to NRC inspection or enforcement activities. In addition, the implementation and maintenance of the industry initiatives did not, in some cases, provide the desired degree of confidence that equipment or procedures would have worked as the NRC had intended when an industry initiative was accepted in lieu of taking a regulatory action. As discussed below, both the Near-Term Task Force and the Risk Management Task Force expressed concerns that in some cases use of licensee voluntary initiatives has led to inefficiencies and potentially less robust resolutions of issues. The lack of inspection and enforcement for such initiatives, which has been NRC's practice, may have contributed to some measures implemented as part of voluntary initiatives to degrade over time.

Enforceability

The NRC's ability to enforce industry initiatives is limited. An industry initiative is not directly enforceable, but a licensee's failure to meet a formal commitment could be the basis for a notice of deviation and any associated finding would be captured by the Reactor Oversight Process. Actions taken to address Type 2 industry initiatives are developed and implemented by licensees outside the scope of existing regulatory requirements, and they can be documented in written commitments. Traditional enforcement would not be possible, although an inspector could write a notice of deviation from the licensee's commitments. While a deviation is within the enforcement guidance, it is not captured by the Reactor Oversight Process unless there is an associated finding. A finding can be associated with a regulatory requirement or a licensee's self-imposed standard. In the case of deviations, a finding exists if the licensee failed to implement a self-imposed standard, the issue was within the licensee's ability to foresee and correct and therefore should have been prevented, and the issue is more than minor in accordance with Reactor Oversight Process program guidance. If the Reactor Oversight Process inspection program issues a finding, the significance of the finding would be determined in the significance determination process and it would be assigned a color. This finding will be an input into the overall inspection level for the plant. Licensees could respond by putting the finding into their corrective action program and by making changes to conform to the regulatory commitment or by revising the regulatory commitment. One of the goals of the current working group recommendation for Improvement Activity 3 is to providing guidance regarding what level of NRC oversight is appropriate for future Type 2 industry initiatives. If NRC oversight activities determine that multiple licensees are failing to implement or maintain a particular voluntary initiative, the NRC may conclude that the industry initiative was ineffective, and that there may be a need for regulatory action (e.g., order, rulemaking) to address the safety concern or substantial safety enhancement issue.

Alternative Approaches for Addressing Voluntary Initiatives

Approach #1 - Credit initiatives in regulatory analyses only if highly likely to be implemented and maintained in the future; increase NRC oversight of significant voluntary industry initiatives

Under this approach the NRC would clarify the role of Type 2 industry initiatives in NRC's regulatory processes by (1) re-affirming the Commission's expectation that industry initiatives may not be used in lieu of NRC regulatory action where a question of adequate protection of public health and safety exists; (2) specifying when industry initiatives may be credited in the baseline case for regulatory analyses; and (3) providing guidance regarding what level of NRC oversight is appropriate for future voluntary initiatives. Additionally, the staff would re-evaluate whether the most risk/safety significant existing Type 2 industry initiatives are being adequately maintained. The staff would verify those initiatives where an acceptable measure of effectiveness cannot be identified (one time audit, inspection, or request for information). Depending on the results of the verification activity, the staff might take further action, including pursuing a regulatory requirement.

The bases for selecting this alternative are:

- May result in safety enhancements being installed more quickly than if implemented via rulemaking (for some issues not related to adequate protection)
- Ensures that that the safety benefits from voluntary industry initiatives would be consistently maintained over time by providing risk-informed regulatory oversight
- Provides for monitoring and feedback to ensure that voluntary initiatives (whether used in lieu of or to support implementation of regulatory requirements) are improved as needed
- Maintains the incentive for licensees to take action in advance of establishment of requirements and recognizes the effects of actions taken
- Improves the clarity of NRC regulatory processes by providing guidance on the handling of industry initiatives
    - Sets clear criteria for determining when and how voluntary industry initiatives would be integrated into regulatory processes
    - Clarifies to all stakeholders how voluntary initiatives fit into the NRC's regulatory framework
    - Defines how industry initiatives should be addressed within NRC inspection and oversight processes.

Countervailing considerations that should be evaluated are:

- Improvement Activity 3 may not support efficiency
    - Licensees may be less likely to interact with the NRC on safety issues
    - Licensees may be less likely to develop industry initiatives for Type 2 issues.
    - NRC regulatory oversight activities for voluntary initiatives may be less efficient and effective than oversight of enforceable regulatory requirements.

Approach #2 - Explore change in current Commission policy

Under this approach, the SECY paper on NTTF Recommendation 1 would recommend that the Commission direct the staff to explore changing the current Commission policy on treatment of Type 2 industry initiatives,[32] by adopting a new policy of not providing any credit to such industry initiatives in NRC decisionmaking including, but not limited to, regulatory analysis, backfit analysis and/or Part 52 issue finality discussions supporting a new or changed generic regulatory requirement (*i.e.*, a regulation, or orders issued to multiple addressees). The new policy would explicitly direct the removal of all guidance to the staff in the current NRC Regulatory Analysis Guidelines associated with crediting industry initiatives in determining the baseline for performing the regulatory analysis and backfit analysis. The new policy would state that voluntary industry initiatives are not an appropriate substitute for NRC regulatory action in cases where a substantial increase in overall protection can be achieved with costs of implementation justifying the increased protection. Voluntary industry initiatives could still serve

[32] The NRC's current policy is that "[v]oluntary industry initiatives are approved as an appropriate substitute for NRC regulatory action where the action to be taken is needed to meet existing requirements or for cases where substantial increase in overall protection can be achieved with costs of implementation justifying the increased protection." See SRM-SECY-99-063 (May 27, 1999).

as a mechanism for facilitating and standardizing implementation of regulatory requirements (Type 1 initiatives).

The SECY paper would recommend a process—similar to what was used by the NTTF Recommendation 1 working group—to explore a change to the current Commission Policy in this regard. The staff would develop a proposed change in policy, the proposed bases for the change, the likely effect on future NRC regulatory actions when confronting new regulatory issues, and a discussion of additional considerations associated with such a policy change. Stakeholder input would be obtained, and then the staff would develop a preliminary draft policy statement that would address industry initiatives with respect to at least the following two matters:

- Reiterating the current Commission direction that industry initiatives may not be relied upon to address matters of adequate protection
- Adoption of a new Commission policy of not providing any credit to such industry initiatives in NRC decisionmaking including, but not limited to, regulatory analysis, backfit analysis and/or Part 52 issue finality discussions supporting a new or changed generic regulatory requirement

The Commission would follow its routine process of issuing the proposed policy statement for public comment (perhaps with a public meeting to allow the public to obtain clarification on any aspects of the proposed policy statement which have changed from that presented in the preliminary draft policy statement).

The bases for selecting this alternative are:

- The new policy avoids the complexities associated with the current Recommendation 1 working group proposal to increase oversight of certain voluntary initiatives that are not requirements. Those complexities include development of criteria for determining if there is a “high likelihood” that an industry alternative will be maintained and development of guidance for determining when and what manner of oversight would be appropriate for future industry initiatives.
- The new policy would likely reduce the time for NRC determination as to whether a regulatory action is justified, because the regulatory analysis and backfitting determination will be less complex. The reduced complexity would be due to the removal of the NRC Regulatory Analysis Guidelines requirements associated with when the NRC would consider industry initiatives in determining baselines for regulatory analyses.
- The new policy would likely make it easier for NRC decision makers to decide whether or not to proceed with generic regulatory action.
- The new policy would likely increase public confidence in the NRC’s regulatory process.
- The NTTF Report’s discussion supports the proposed policy change: “[V]oluntary industry initiatives should not serve as a substitute for regulatory requirements but as a mechanism for facilitating and standardizing implementation of such requirements.” (NTTF Report, page viii).
- A letter from NEI dated August 15, 2013, appears to be consistent with this proposed policy change: “If the issue addressed by a voluntary initiative constituted a legitimate risk to the public health and safety, the NRC can and would establish mandatory, legally-binding requirements to ensure that the public was adequately protected.”[33] In 1999, the

[33] Letter from Joseph E. Pollock, NEI, to David L. Skeen, NRC, dated August 15, 2013 (ADAMS Accession No. ML13234A022), page 3

view of an NEI representative during a workshop on DSI-13 was summarized by the NRC staff as follows: "The NEI representative who served as the session Chairman stated that NEI's position was that an industry initiative should never be a substitute for regulatory action that passes the adequate protection standard or passes a backfit test that justifies a substantial increase in overall protection. This is not to say that a voluntary industry initiative could not complement such actions."[34]

Countervailing considerations that should be evaluated are:

- Under this new policy, it may be necessary for the NRC to do a backwards look at existing Type 2 industry initiatives and determine if any of those issues are cost justified substantial safety enhancements. This would likely result in a modest increase in necessary rulemaking activities which could delay issuance of lower priority rules due to resource limitations.
- The new policy would not be consistent with how risk assessments are performed. As stated in the Commission's PRA Policy Statement, PRA evaluations in support of regulatory decisions should be as realistic as practicable. This includes allowing "credit" for plant features and procedures irrespective of whether there is a related regulatory requirement in place.
- The new policy appears to create an artificial and perhaps illogical distinction between a generic "industry initiative," versus an applicant/licensee plant-specific commitment which is not required by law, and therefore is also "voluntary" to the same extent as a generic industry initiative.
- The new policy may be viewed as reducing the flexibility of the decision maker, inasmuch as there would be only two choices under the NRC's control: adopt the generic requirement or do nothing.
- The rulemaking process, by design, is slower, more deliberative, and less susceptible to change than what could be put in place using an industry initiative. Some may view the delay and the greater difficulty of changing a regulation as undesirable from a safety perspective.
- The industry has commented that the new policy may reduce the incentive of the industry to participate in the development of solutions to issues or have less incentive to propose alternate approaches because no credit would be given to such industry initiatives in regulatory analysis, backfit analysis and/or Part 52 issue finality discussions supporting a new or changed generic regulatory requirement. The NRC will impose the generic requirement in all cases if it can be justified.
- This proposed policy is at odds with the PRA practice (and PRA policy statement) that PRA models be as realistic as practicable. PRA models include features in a plant that are not required by law as an accepted practice. Failing to credit the "as-built and operated plant" in any risk assessment would be contrary to the Commission's PRA policy statement. (Also, see RIS 2008-15)

[34] SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," dated March 2, 1999 (ADAMS Accession No. ML12265A505), Attachment page 3

Approach #3 – Maintain Status Quo on Voluntary Industry Initiatives

Under this approach, the SECY paper on NTTF Recommendation 1 will contain no recommendation for an improvement activity directed at any aspect of voluntary industry activities. This essentially leaves the current Commission policy and direction on voluntary industry actions unaffected and untouched by NTTF Recommendation 1. The discussion on Improvement Activity 3 would be removed entirely from the current draft of the SECY paper, and Enclosure 1 would contain a discussion of why the staff ultimately decided not to recommend an improvement activity in this area, even though the last White Paper included such a proposal for public comment.

The bases for selecting this alternative are:

- NTTF Recommendation 1 did not contain a specific recommendation on industry initiatives. In the instances where the NTTF noted problems with specific industry initiatives (SAMGs and hardened vents), the NRC is taking action such that there will no longer be reliance on those industry initiatives.
- The Recommendation 1 working group considered the importance of NRC action on voluntary industry initiatives to be low, when compared to most of the other potential improvement activities identified early by the working group. Industry stakeholders have commented that the NRC has not demonstrated systematic inadequacies with voluntary industry initiatives. Although minor discrepancies were identified in the special inspections following the Fukushima accident, the NRC staff has identified no systematic problem with the many industry voluntary initiatives that are in place.
- The NRC Reactor Oversight Process allows for some oversight of voluntary initiatives if desired (e.g., licensee commitments regarding shutdown risk) and evaluates the risk of licensee performance deficiencies even when not explicitly covered by a regulation. Plant-specific backfits can be pursued at facilities that are not implementing an initiative effectively. Therefore, there is less need for a formal policy statement, additional oversight, or revised implementing guidance.

Countervailing considerations that should be evaluated are:

- There would continue to be a lack of clear guidance to inspectors about what aspects of voluntary initiatives should be looked at and a lack of clarity about what regulatory action to take, if any, when a discrepancy with a voluntary initiative is found.
- NTTF Recommendation 1 specifically mentioned voluntary industry initiatives as a contributor to the NRC's "patchwork" approach to regulation.
- Special inspections regarding SAMGs and hardened vents revealed some inconsistencies in implementation and maintenance of these initiatives over time. There could be other safety-significant initiatives (e.g., shutdown risk measures) that also have not been consistently maintained.

Staff Conclusion:

During consideration of the pros and cons of the various approaches described above, the working group and the Steering Committee both had conflicting views on the best path forward. The staff ultimately selected Approach #1 and intends to enhance its effectiveness by developing a comprehensive oversight program for voluntary initiatives that is transparent to the public and may include reporting requirements for licensees. The staff believes that such an approach is preferable because some safety enhancements could be put in place more quickly and efficiently via industry initiatives than by the more resource-intensive and time-consuming rulemaking process. For example, industry proposed flexible mitigation strategies and equipment following the accident at Fukushima Dai-ichi and began work to implement them while the NRC was still working on mitigation strategies orders. The staff also believes that the proposed oversight program will ensure that any safety-significant voluntary industry initiatives relied upon by the NRC in lieu of issuing a regulation will be effectively implemented and maintained over time.

COMPARISON OF IMPROVEMENT ACTIVITIES TO NTTF RECOMMENDATION 1 AND RMTF POWER REACTOR RECOMMENDATIONS

The NRC staff studied in detail Recommendation 1 of the NTTF and interviewed members of that task force to ensure understanding of what had been proposed. The staff also followed the efforts of the RMTF and included a member of that task force on its inter-office working group that was tasked with developing a notation vote paper with options and a staff recommendation to disposition NTTF Recommendation 1 (SRM-SECY-11-0093).

The NRC staff has developed three proposed improvement activities to address NTTF Recommendation 1 and the related RMTF recommendations for power reactors. These improvement activities are intended to address the underlying intent of the recommendations, as understood by the staff, but do not fully implement every aspect of each of the recommendations. The staff's recommendations differ from the NTTF and RMTF for the following reasons:

- The staff has had more time to consider the regulatory framework issues raised by the NTTF, as compared with the limited 90-day period afforded the NTTF to consider those same issues

- The NRC has taken a number of post-Fukushima actions to improve safety, including issuing three Orders and initiating two rulemaking activities to address the areas of greatest potential risk, consistent with the NTTF recommendations

- The staff has had the benefit of the views of internal staff, as well as the public (including the nuclear power plant industry), and is cognizant of the concerns on resources and prioritization of issues

The following tables summarize how the three proposed improvement activities relate to NTTF Recommendation 1 and the related RMTF recommendations for nuclear power reactors. They also explain the NRC staff's rationale for not recommending full implementation of the NTTF or RMTF proposals.

Table 2: Comparison Of Staff-Proposed Improvement Activities To NTTF Recommendation 1

Recommendation	Relevant Improvement Activities	Remarks
1. Logical, consistent, coherent framework for adequate protection	1, 2, 3	Each of the three proposed improvement activities provides additional regulatory clarity, predictability, reliability, and efficiency over the current framework as currently implemented.

Table 2: Comparison Of Staff-Proposed Improvement Activities To NTTF Recommendation 1

Recommendation	Relevant Improvement Activities	Remarks
		Activity 1 would result in rules and orders currently considered to be "beyond design basis" to clearly specify well-defined performance goals, treatment requirements, documentation and change control requirements, and reporting requirements. Activity 2 would formalize by Commission Policy Statement and implementing guidance the defense-in-depth philosophy, elements and decision criteria to support regulatory decisions. Activity 3 would re-affirm the existing Commission policy that industry initiatives may not be used in lieu of NRC regulatory action where a question of adequate protection of public health and safety exists. It will also provide graded oversight of Type 2 industry initiatives.
1.1 Policy statement for risk-informed defense–in-depth for extended design basis (adequate protection)	2	Activity 2 directly supports risk-informed decisions by developing decision criteria to assess defense-in-depth adequacy. The staff does not propose defining adequate protection, or to treat defense-in-depth as relevant only to adequate protection.
1.2 Initiate rulemaking to implement a risk-informed defense-in-depth framework consistent with policy statement in 1.1	None	The staff is recommending a defense-in-depth Policy Statement and implementing guidance. A defense-in-depth regulation is not needed for transparency or consistent NRC decision-making if a Policy Statement and implementing guidance are adopted.

Table 2: Comparison Of Staff-Proposed Improvement Activities To NTTF Recommendation 1

Recommendation	Relevant Improvement Activities	Remarks
1.3 Modify Regulatory Analysis Guidelines to more effectively implement defense-in-depth in balance with risk-based guidelines	2, 3	The Regulatory Analysis Guidelines would be updated to include defense-in-depth criteria. The guidance would also be changed to strengthen the cost-benefit section regarding how Type 2 industry initiatives are credited.
1.4 Evaluate the insights IPE and IPEEE for generic or plant-specific requirements	None	This recommendation is not addressed by the staff's proposed improvement activities. The staff concluded that the low likelihood of identifying plant-specific design or operational safety concerns would not support the resources (staff and industry) that would be expended in this activity.
Voluntary safety initiatives by licensees should not take the place of needed regulatory requirements. (NTTF Report, pp. 19, 21)	3	Activity 3 partially addresses this NTTF comment by proposing that Type 2 industry initiatives not be credited in the baseline case as defined in the Regulatory Analysis Guidelines unless there is a high likelihood that the industry will effectively implement and maintain the initiative over time.
The current NRC regulatory approach (requirements for design-basis events, beyond design-basis events, and voluntary initiatives) has resulted in a "patchwork" of regulatory requirements and other safety initiatives.	1, 3	Design basis events, and especially design basis accidents, are acceptably addressed in the current regulatory structure and are well-understood by various stakeholders. Improvement Activity 1 addresses the NTTF observation regarding "beyond design-basis events" Improvement Activity 3 adds formal structure and NRC oversight to address the NTTF issue with voluntary industry initiatives.

Table 3: Comparison Of Staff-Proposed Improvement Activities To RMTF Power Reactor Recommendations

Recommendation	Relevant Improvement Activities	Remarks
PR-R-1 *OR-R-1(portion)* *Design-basis events and accidents should be reviewed and revised to integrate insights from operating history and modern methods such as PRA.* *NR-R-1(portion)* *Changes pursued for operating reactors (OR-R-1) should also consider applicability to new reactors.*	None The staff's proposed Recommendation 1 improvement activities differ from these RMTF recommendations.	The staff is proposing to retain the current approach for design-basis accidents because creating and implementing a new framework would generate additional regulatory complexity and costs but provide no clear safety benefit. Insights from operating history and PRA will be incorporated into Improvement Activity 1 as necessary when new design-basis extension events are identified. Licensees may submit individual risk-informed license amendment or exemption requests that are processed in the current framework. These requests may propose and demonstrate the acceptability of any proposed revisions to design-basis events and accidents found to be appropriate for a specific plant.
NR-R-1(portion) *GIV-R-1* *Promote adoption of risk-informed approaches for the selection of relevant scenarios (e.g., alternatives to the single failure criterion) for design-basis accidents*	None The staff's proposed Recommendation 1 improvement activities differ from these RMTF recommendations.	New reactor design basis events have been and will continue to be established by using risk-informed and performance-based approaches. For Generation IV reactors, NRC is working with DOE to apply risk-informed and performance-based approaches to determine design basis events applicable to the Next Generation Nuclear Plant design.
PR-R-2 *OR-R-2* *NR-R-2* *GIV-R-2* *Establish by rule a design-enhancement category of regulatory treatment for beyond-design-basis accidents.*	1 The staff's proposed Recommendation 1 Improvement	The staff is recommending a policy statement and internal staff guidance to formalize the *de facto* category of generic events traditionally considered to be beyond design basis. NRC already uses risk as one element of determining safety significance. A site specific approach

Table 3: Comparison Of Staff-Proposed Improvement Activities To RMTF Power Reactor Recommendations

Recommendation	**Relevant Improvement Activities**	**Remarks**
Category should use risk as a safety measure, be performance-based, provide for periodic updates, include consideration of costs, and be implemented on a site-specific basis	Activity 1 implements the intent of these RMTF recommendations.	(including periodic updates) is not recommended because of high costs and limited safety improvements that would result.
PR-R-3 *OR-R-3* *NR-R-3* *GIV-R-3* *Reassess methods for estimating frequency and magnitude of external hazards. Implement consistent process including deterministic and PRA methods. Risks from beyond-design-basis external hazards should be considered in the design-enhancement category*	1 (partial) The staff's proposed Recommendation 1 Improvement Activity 1 partially implements these RMTF recommendations. The Recommendation 1 working group did not fully consider all aspects of these RMTF recommendations. Consideration could be deferred to NTTF Rec. 2.1 and 2012 Appropriations Bill activities.	Other NTTF recommendations are being implemented that address this recommendation for power reactors. For example, NTTF 2.1 is reassessing seismic and external flooding hazards. The mitigation strategies order and related station blackout mitigation strategies rulemaking provide additional defense-in-depth for preventing and mitigating unspecified external events. The 2012 Appropriations Bill also requires the NRC to reassess external hazards. The ASME/ANS PRA standards development activity for external hazards, which the NRC participates in and endorses, provides methods for estimating frequency and magnitude of external hazards; an update of these standards is currently underway. Moreover, it is part of the ASME/ANS protocol to continually update their standards on a regular periodic basis.
PR-R-4 *OR-R-4* *NR-R-4*	None The	NTTF recommendation 2.2 will consider this recommendation for seismic and external flooding. Other external hazards will also be

Table 3: Comparison Of Staff-Proposed Improvement Activities To RMTF Power Reactor Recommendations

Recommendation	Relevant Improvement Activities	Remarks
GIV-R-4 *Establish a systematic program for collection, evaluation, and communication of external hazard information*	Recommendation 1 working group did not consider these RMTF recommendations which are not directly related to regulatory framework. Consideration could be deferred to NTTF Rec. 2.2 and 2012 Appropriations Bill activities.	included, consistent with the 2012 Appropriations Bill. In addition, this recommendation may be pursued regardless of the regulatory framework and could be integrated into Improvement Activity 1. The ASME/ANS PRA standards development activity for external hazards, which the NRC participates in and endorses, provides methods for collection and evaluation of external hazards (e.g., frequency, fragility analysis); an update of these standards is underway. Moreover, it is part of the ASME/ANS protocol to continually update their standards on a regular periodic basis.
PR-R-5 *OR-R-5* *NR-R-5* *GIV-R-5* *Apply risk-informed and performance-based defense-in-depth concepts in a more quantitative manner*	2 The staff's proposed Recommendation 1 Improvement Activity 2 would implement these RMTF recommendations.	Activity 2 would directly address this recommendation by defining defense-in-depth and associated attributes and criteria to facilitate regulatory decision-making.

Table 3: Comparison Of Staff-Proposed Improvement Activities To RMTF Power Reactor Recommendations

Recommendation	Relevant Improvement Activities	Remarks
PR-R-6 *OR-R-6* *NR-R-6* *GIV-R-6* *Develop and implement guidance for security regulatory activities using language in common with safety activities and harmonizes methods with risk assessment and the proposed risk-informed and performance-based defense-in-depth*	None The Recommendation 1 working group did not consider these RMTF recommendations.	The staff excluded security regulatory issues from the scope of the staff's activities for the disposition of NTTF Recommendation 1. These RMTF recommendations are being addressed separately by NSIR under the RMRF.

Partial List of Industry Initiatives

VOLUNTARY INDUSTRY INITIATIVES IDENTIFIED BY THE STAFF IN ITS EFFORTS TO DISPOSITION NTTF RECOMMENDATION 1

SECY-01-0121, "Industry Initiatives in the Regulatory Process," July 5, 2001 (ADAMS Accession No. ML011630126), identified three types of industry initiatives:

1. A Type 1 initiative is developed in response to an issue of potential safety concern that would complement regulatory actions within existing regulatory requirements. However, where it is determined that the safety concern involves the assurance of adequate protection, or other criteria described in Title 10, Section 50.109, of the Code of Federal Regulations (10 CFR 50.109), the NRC shall pursue rulemaking. In such a case, the Type 1 industry initiative may form the basis for an acceptable method of meeting the new regulation through endorsement in a regulatory guide.

2. A Type 2 initiative is developed in response to a potential safety concern that is a potential cost-beneficial safety enhancement outside existing regulatory requirements. Such industry initiatives may be used to provide safety enhancements without the need for regulatory action. However, where it is determined that the proposed industry initiative is not effective in addressing the safety concern, the NRC may pursue rulemaking in accordance with the criteria described in 10 CFR 50.109.

3. A Type 3 initiative is developed as an information-gathering mechanism, or a means to address issues of concern to the applicable industry group that are not potential safety concerns, do not involve adequate protection issues, are outside existing regulatory requirements, and are not likely to yield cost-beneficial safety enhancements. These voluntary industry initiatives may be used by the applicable industry group to address economic or efficiency issues.

The NRC staff identified a number of industry initiatives and classified each using the above taxonomy; these are presented in Table 4. Note that the distinction between the various types of initiatives is not always clear. Some of the Type 2 initiatives listed (underground piping, MOVs, Rosemount transmitters, etc.) do have an underlying regulatory requirement for the specific function served by the components.

Table 4: Partial List of Industry Initiatives

Description	Type*
Boron Corrosion • NRC issued a 10 CFR 50.54(f) request for information (GL 88-05), which stated: The principal concern is whether the affected plants continue to meet the requirements of General Design Criteria 14, 30, and 31 of Appendix A to Title 10 of the *Code of Federal Regulations* (CFR) Part 50 when the concentrated boric acid solution or boric acid crystals, formed by evaporation of water from the leaking reactor coolant, corrode the reactor coolant pressure boundary. Industry developed boric acid corrosion prevention programs to ensure compliance…	1
Guidelines for the management of materials issues • NEI 03-08, Rev. 2 (ADAMS Accession No. ML101050337)	1
Steam generator program • NEI 97-06 • SECY-00-0116: *As for the new NEI-97-06 steam generator industry initiative, it will result in voluntary and enforceable changes to plant technical specifications.* • SECY-00-0116: *This industry initiative will involve license amendments by all pressurized water reactor (PWR) licensees to change from deterministic to performance-based technical specifications. In response to the staff's ongoing regulatory development effort, the PWR industry focused its efforts on improving existing SG inspection guidance and developing additional guidelines on other programmatic elements related to SG tube integrity. The industry's efforts to improve industry guidance culminated in the NEI 97-06 industry initiative, developed through the NEI Nuclear Strategic Issues Advisory Committee, which establishes a framework for structuring and strengthening existing SG programs. This industry initiative discusses regulatory interfaces, licensee responsibilities, and a protocol for revising referenced guidelines. It also defines the performance criteria that licensees shall use to measure tube integrity. It should be noted that the final staff review of NEI-97-06 is still in progress.*	1

* The distinction between the various types of initiatives is not always clear. Some of the Type 2 initiatives listed (underground piping, MOVs, Rosemount transmitters, etc.) do have an underlying regulatory requirement for the specific function served by the components.

Table 4: Partial List of Industry Initiatives

Description	Type*
Boiling Water Reactor Vessel Internals Project • SECY-01-0121: *A Type 1 example of an existing program that complements existing regulatory requirements via an industry initiative is the Boiling Water Reactor Vessel and Internals Project (BWRVIP). This program, in which all U.S. BWR licensees participate, was instituted in 1994, initially to address the potential consequences of intergranular stress corrosion cracking (IGSCC) in the BWR core shroud. The project subsequently expanded in scope to address all BWR safety-related austenitic stainless steel and Alloy 600 components, the reactor vessel, and safety-related piping. This industry-led program developed, in safety-significance priority, approximately 50 generic industry guidelines for inspection scope and frequency, flaw evaluation, and mitigation and repair. All BWR owners committed to adhere to the program or inform the staff of any plant-specific deviations. Further, since the BWRVIP representatives agreed on which components are safety-related, actions taken to inspect, evaluate, and repair these components are covered by the individual licensees' quality assurance (QA) programs, as governed by Appendix B to 10 CFR Part 50.*	1
Dedication of Commercial Grade Items • Endorsed by NRC in a regulatory guide as an acceptable means, in whole or in part, of meeting a new or existing regulation.	1

* The distinction between the various types of initiatives is not always clear. Some of the Type 2 initiatives listed (underground piping, MOVs, Rosemount transmitters, etc.) do have an underlying regulatory requirement for the specific function served by the components.

Table 4: Partial List of Industry Initiatives

Description	**Type***
Low power/shutdown risk (or "Shutdown issues") • NUMARC 91-06 • Has not been endorsed by the NRC but has been recognized by the NRC as providing an acceptable means of addressing an NRC issue or concern. • SECY-00-0116: *In the case of shutdown risk, the staff had completed an analysis indicating that industry actions could be justified as a cost-beneficial safety enhancement; however, the Commission concluded that rulemaking should not proceed given the initiatives taken by the industry to maintain an acceptable level of risk during shutdown conditions. Licensee implementation of commitments in this area is not enforceable, but NRC monitoring provides a basis for determining if future regulatory action becomes necessary.* • SRM-SECY-00-0116: *This risk-significant issue is not explicitly required by existing regulations. The staff, using an older version of NUREG/BR-0058 which did not allow any credit for industry initiatives, found this issue to be valid for backfitting as a safety enhancement pursuant to 10 CFR 50.109. The rulemaking was discontinued since the Commission concluded that existing industry practices provide an adequate level of safety. The Commission also directed that NUREG/BR-0058 be updated to permit appropriate credit for industry initiatives. No enforcement would presently be appropriate.* • See also presentations about shutdown risk from Operating Experience Gateway internal web site: http://nrr10.nrc.gov/ope-info-gateway/shutdown-risk.html	2

* The distinction between the various types of initiatives is not always clear. Some of the Type 2 initiatives listed (underground piping, MOVs, Rosemount transmitters, etc.) do have an underlying regulatory requirement for the specific function served by the components.

Table 4: Partial List of Industry Initiatives

Description	**Type***
Severe Accident Management Guidelines • NEI 91-04, Revision 1 (ML072850981). Appendix E includes NRC staff comments on the draft formal industry position. • Has not been endorsed by the NRC but has been recognized by the NRC as providing an acceptable means of addressing an NRC issue or concern. • Temporary Instruction 2515/184 evaluated the status of Severe Accident Management Guidelines (SAMGs). See http://www.nrc.gov/NRR/OVERSIGHT/ASSESS/SAMGs.html • See also: Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants (August 8, 1985; 50 FR 32138). • See NTTF Recommendation 8. Also, for more information about the ongoing NRC activity "Onsite Emergency Response Capabilities," see Regulations.gov Docket ID NRC-2012-0031.	2
Hydrogen igniter backup power for BWRs and ice condensers • GSI-189 • Regulatory Analysis: ML051450060. The decision rationale on page 55 of the regulatory analysis for the proposed action to address generic safety issue 189 (ADAMS Accession No. ML051450060) explains that the decision to take no further regulatory action was based on the assumption that voluntary licensee actions would be implemented as described and that the NRC would revisit rulemaking in the future, if necessary. • Requirements based on mitigation strategies order (EA-12-049).	2

* The distinction between the various types of initiatives is not always clear. Some of the Type 2 initiatives listed (underground piping, MOVs, Rosemount transmitters, etc.) do have an underlying regulatory requirement for the specific function served by the components.

Table 4: Partial List of Industry Initiatives

Description	Type*
Industry Initiative on Underground Piping and Tanks Integrity • NEI 09-14 • NEI letter describing initiative: ML093350032 • NEI revision to the initiative: ML13079A318 • NRC Buried Piping Action Plan, Revision 3: ML13099A380 • See http://www.nrc.gov/reactors/operating/ops-experience/buried-piping-activities.html	2
•	
Heavy load lifts • NEI 08-05 ML082180666 • NRC safety evaluation: ML082410532 • NRC endorsement: RIS 2008-28 (ML082460291) • See also 2007 operating experience brief on this topic: http://nrr10.nrc.gov/rorp/docs/HeavyLoadsBrief200702.pdf • See also inspection guidance FY2007-03, Rev. 2	2
Motor Operated valves • Endorsed by NRC as providing an acceptable means of addressing an NRC issue or concern. • Joint Owners Group Motor-Operated Valve Periodic Verification Program • Established to address Generic Letter 96-05 • RIS 2011-13	2
Piping Erosion/Corrosion • NUMARC guidance located in Appendix A to NUREG-1344 • Generic Letter 89-08 • Endorsed by NRC as providing an acceptable means of addressing an NRC issue or concern.	2

* The distinction between the various types of initiatives is not always clear. Some of the Type 2 initiatives listed (underground piping, MOVs, Rosemount transmitters, etc.) do have an underlying regulatory requirement for the specific function served by the components.

Substandard Non-Safety-Related Molded Case Circuit Breakers • NUMARC 90-14 • Endorsed by NRC as providing an acceptable means of addressing an NRC issue or concern. • Generic Letter 88-10	2
Station Blackout (Diesel Reliability portion) • NSAC-108 • Endorsed by NRC as providing an acceptable means of addressing an NRC issue or concern. • Generic Letter 84-15 • USI-A-44 • Regulatory Guide 1.155	2
Safety culture initiative • NEI 09-07	2
Station Blackout (Diesel Reliability portion) • Endorsed by NRC as providing an acceptable means of addressing an NRC issue or concern.	2
Motor Operated valves • Endorsed by NRC as providing an acceptable means of addressing an NRC issue or concern. • Established to address Generic Letter 96-05	2
Piping Erosion/Corrosion • Endorsed by NRC as providing an acceptable means of addressing an NRC issue or concern.	2

* The distinction between the various types of initiatives is not always clear. Some of the Type 2 initiatives listed (underground piping, MOVs, Rosemount transmitters, etc.) do have an underlying regulatory requirement for the specific function served by the components.

Comprehensive Procurement Initiative • NUMARC 90-13 • Endorsed by NRC as providing an acceptable means of addressing an NRC issue or concern.	2
Oil Loss in Rosemount Transmitters • NUMARC 91-02 • Endorsed by NRC as providing an acceptable means of addressing an NRC issue or concern. • See resolution of generic safety issue 176: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0933/sec3/176r1.html	2
Substandard Non-Safety-Related Molded Case Circuit Breakers • NUMARC 90-14 • Endorsed by NRC as providing an acceptable means of addressing an NRC issue or concern.	2
Fraudulent Flanges • NUMARC 88-01 • Endorsed by NRC as providing an acceptable means of addressing an NRC issue or concern.	2
IPE/IPEEE commitments • GL 88-20	3
Groundwater Protection • Package: ML061910196 • Final: ML072610036	3
Data gathering rule Proposed rule to gather data for PRA 1996	3

* The distinction between the various types of initiatives is not always clear. Some of the Type 2 initiatives listed (underground piping, MOVs, Rosemount transmitters, etc.) do have an underlying regulatory requirement for the specific function served by the components.

Industry Consensus • Initiative taken to address industry, non-regulatory issue	3
Shortage of Qualified personnel • Initiative taken to address industry, non-regulatory issue	3
Fitness for Duty Data Collection • Initiative taken to address industry, non-regulatory issue	3
Reducing Automatic trips • Initiative taken to address industry, non-regulatory issue	3
Radiation Exposure Control • Initiative taken to address industry, non-regulatory issue	3
Personnel Access Data System • NEI-95-06 • Guideline to address industry, non-regulatory issue	3
ECCS Acceptance Criteria • Voluntary industry collection of data to ensure safety of current plants regarding previously-unconsidered phenomena. This data was collected voluntarily to eliminate the need for an NRC generic letter seeking information on the underlying matter. • See draft proposed rule: ML112520249. The data collection is discussed on page 15.	3
Air Operated Valve Program • See NEI letter dated 3/27/2001: ML010950310	3

* The distinction between the various types of initiatives is not always clear. Some of the Type 2 initiatives listed (underground piping, MOVs, Rosemount transmitters, etc.) do have an underlying regulatory requirement for the specific function served by the components.

ENCLOSURE 2: NRC STAFF RESPONSES TO PUBLIC COMMENTS ON WHITE PAPER DATED MAY 14, 2013

I. INTRODUCTION

This document presents the NRC staff's responses to written public comments received on a staff "White Paper," *NRC Staff Working Group Evaluation of Alternatives for the Disposition of Recommendation 1 of the Fukushima Near-Term Task Force Repor*t, dated May 14, 2013 (ADAMS Accession NO. ML13135A125). The staff posted the white paper on the regulations.gov website and on the NRC public website on May 15, 2013. Thereafter, the staff held a public meeting on June 5, 2013 to: (1) provide external stakeholders with the status of the NRC staff's progress on regulatory framework alternatives being evaluated to provide a recommended approach to the Commission regarding the Fukushima Near-Term Task Force (NTTF) Report Recommendation 1; (2) afford external stakeholders an opportunity to ask the NRC staff clarifying and amplifying questions on the staff's current thinking on disposition of the NTTF Recommendation 1 effort; and (3) provide an opportunity for external stakeholders and the NRC staff to exchange information on regulatory framework subject matter to facilitate more accurate and complete understanding by all parties. The public comment period on the white paper was opened on May 16, 2013, and closed August 15, 2013.

Although the staff previously issued versions of the White Paper for public comments on two occasions in October 2012 and February 2013, this comment response document does not address comments received on earlier versions of the White Paper. This is because substantial changes were made to the NRC staff's approach to resolving NTTF Recommendation 1 as a result of its internal deliberations and the input from interested stakeholders. As a result, many of the earlier comments would no longer be applicable as some have been incorporated and others refer to preliminary staff proposals that are no longer being put forward. A list of commenters on earlier versions of the staff's White Paper is set forth in Enclosure 4, "NRC Staff Outreach on Disposition of NTTF Recommendation 1."

II. OVERVIEW OF COMMENTERS AND COMMENTS ON MAY 14, 2013 WHITE PAPER

The staff received comment submissions from four commenters. One submission was received from the Nuclear Energy Institute (NEI), one was received from STARS Alliance LLC (representing seven nuclear power plants), and submissions were received from two individuals. One of those individuals, Mr. Stephen Maloney, submitted a revision to his first comment submission with additional information and corrections to his first comment submission. The NRC staff did not find any comments in Mr. Maloney's earlier document which were not provided in his second submission, so this comment response document only addresses the second submission. Table 1 presents information on the commenters who submitted comments on the May 14, 2013 White Paper.

Table 1.

Commenter	Affiliation	ADAMS Accession No.
Prasad Kadambi	Individual	ML13233A025
Joseph Pollock	NEI	ML13234A022
Stephen Maloney	Individual	ML13233A024
Stephen Maloney	Individual	ML13239A438
Scott Bauer	STARS Alliance LLC	ML13252A064

III. STAFF RESPONSES TO COMMENTS

Comments received by the NRC in the comment period which closed on August 15, 2013 fall into four general areas:

- General comments (e.g., scope, schedule, resources)
- Comments on Improvement Activity 1: creating a new category of events
- Comments on Improvement Activity 2: defining defense-in-depth
- Comments on Improvement Activity 3: voluntary industry initiatives

Accordingly, the comments and the staff's responses are organized into these four areas. In each area, comments that raise similar or identical matters are "binned" into a single comment summary, and an overall NRC response to the binned comments is provided.

A. General Comments

Comment: The current regulatory framework maintains nuclear safety and use of this existing process provides an acceptable approach to regulation while precluding an increase in costs associated with new regulations. Thus, no regulatory action is needed with respect to Recommendation 1. However, a long-term strategic objective to better define the regulatory framework and allow NRC to provide a more structured and predictable response to future issues that may involve beyond design basis considerations may be desirable. (NEI)

NRC staff response: No response necessary.

Comment: A generic categorization approach for design-basis extension events and requirements without plant specific probabilistic risk assessments (PRA), as recommended by the staff, would be the most appropriate course of action if the NRC proceeds with implementing changes to the NRC policies and processes related to NTTF Recommendation 1. A regulatory requirement for a site-specific PRA for currently operating reactors, for the sole purpose of searching for as yet unrealized cost-beneficial risk-reduction activities, would not provide benefits commensurate with the substantial cost of developing such regulatory compliant models." (STARS)

NRC staff response: No response necessary.

Comment: There is little safety benefit to be derived from the comprehensive changes recommended by the NTTF and in the staff's white paper. (NEI)

NRC staff response: The staff agrees that safety is not the main focus of the three improvement activities. The primary goals of the staff's proposed improvement activities are to enhance the logical, systematic and coherent character of the existing regulatory framework for nuclear power reactors – as recommended by the NTTF in Recommendation 1. The staff believes that the benefits of the three proposed improvement activities are primarily in the areas of regulatory efficiency and predictability, which may lead to increased public confidence in the NRC's regulatory activities for nuclear power reactors. The staff believes that there will be safety benefits in the future from consistent application of Improvement Activities 1 and 2, but these potential safety increases are not the staff's primary bases for recommending the three improvement activities. No changes in the staff's recommendations were made as a result of consideration of this comment.

Comment: Consistent and rigorous application of the NRC Regulatory Analysis Guidelines is the preferred solution to any perceived concerns with lack of transparency or objectivity in the NRC's current regulatory framework for power reactors. The existing NRC regulatory analysis guidelines provide appropriate and thorough considerations relative to criteria for beyond design basis regulatory thresholds. (NEI)

NRC staff response: The staff agrees with the comment to the extent that NRC's regulatory actions must reflect consistent and rigorous application of the NRC Regulatory Analysis Guidelines, NUREG/BR-0058 (currently, Revision 4). However, the staff disagrees with the comment's implicit argument that there are no other cost-effective improvements which the NRC could adopt to address perceived concerns with lack of transparency or objectivity in the NRC's current regulatory framework for power reactors. Based upon the plain words of Recommendation 1 as well as the discussion in the NTTF Report, one major aspect of the NTTF's concern was with the lack of a coherent, internally consistent, and readily explainable regulatory framework for nuclear power reactors.

After careful consideration, the staff believes that the three proposed improvement activities address NTTF Recommendation 1 in a cost-effective manner which minimizes undue diversion of NRC and licensee resources from more safety-significant activities. No changes in the staff's recommendations were made as a result of consideration of this comment.

Comment: The NRC should consider better integrating the NTTF Recommendation 1 effort with the work being done regarding NUREG-2150 and the Risk Management Regulatory Framework. (NEI)

NRC staff response: The staff agrees with the underlying premise of the comment, *viz*., that there should be a clear understanding within the NRC regarding the relationship between the staff's proposed disposition of NTTF Recommendation 1, and the staff's consideration of the recommendations in the Risk Management Task Force (RMTF) Report, NUREG-2150. The staff also has determined, as a result of the comment, that a clearer explanation of the relationship between Recommendation 1 disposition and the RMRF effort is needed.

Accordingly, the SECY paper and its enclosures describe the consideration of the RMTF Report as part of the disposition of NTTF Recommendation 1, and the relationship between the staff's proposed disposition of NTTF Recommendation 1, and the staff's consideration of NUREG-2150's recommended Risk Management Regulatory Framework (RMRF). That discussion makes clear that the staff considered the RMTF recommendations applicable to power reactors in developing the three improvement activities addressing NTTF Recommendation 1. The enclosures to SECY-2013-xxx provide tables showing the extent to which each portion of NTTF Recommendation 1 and each power reactor recommendation from the RMTF Report is addressed by the proposed regulatory framework improvement activities. No changes in the staff's recommendations were made as a result of consideration of this comment.

Comment: Recommendation 1 must also be evaluated in the context of the cumulative impacts of regulation. There exists a more immediate need to address regulatory considerations for post-Fukushima orders, rulemakings, and related guidance development. (NEI)

NRC staff response: The staff agrees, and has significantly changed its recommended improvement activities from what was set forth in the white paper, such that the implementation and ongoing costs are significantly lower than some of the options originally considered. The scope of the recommended improvement activities was reduced, in part, because the ongoing post-Fukushima efforts have and will result in safety improvements for nuclear power reactors. The staff has considered such actions and is making recommendations in an integrated manner with due consideration of cumulative impacts and the interrelationship among the various activities. Revised resource estimates are provided in the SECY for the final staff recommended improvements.

Comment: Improvement Activities 1 and 2 are interrelated and should be viewed in the context of a specified risk tolerance and risk management processes. Improvement Activities 1 and 2 would also benefit from exploring the correlated failure issue, measuring the relationship between as-built and as-designed, and instituting a policy to employ the "high confidence limit" throughout all design processes. (Maloney)

NRC staff response: The staff agrees that there are aspects of these two improvement activities, creating a new category of events and defining defense-in-depth, that are interrelated and that there may be synergies to be realized by considering them together. As noted above, the NRC is recommending these actions to the Commission. If the Commission approves both of these improvement activities, the NRC staff will consider how to best integrate them. As for the specific recommendations regarding correlated failures, as-built versus as-designed, and the high confidence limit, the NRC staff intends to fully engage interested stakeholders in the development of any improvement activities approved by the Commission, so that recommendations from interested stakeholders may be appropriately considered.

Comment: Improvement Activity 2 should be completed before embarking on Improvement Activity 1. NUREG-2150 offers the decision making structure and describes for each area of NRC's regulatory activity the description of how the structure could be implemented. The Appendices to NUREG-2150 go into considerable detail in describing state-of-the-art methods and tools. Hence, the NRC staff's immediate task should be to conceptualize, with appropriate input from stakeholders, the structure that accomplishes the above goals and objectives. This would go a long way toward accomplishing the NRC staffs stated goal in NRC-2012-0173-0017 for Improvement Activity 2. If resources are spent on Improvement Activity 1 prior to gaining agreement on a defense-in-depth framework, it is inevitable that inefficiencies, duplication and internal conflicts will arise. (Kadambi)

NRC staff response: The staff disagrees with the comment. The staff does not believe that there is any need to complete Activity 2 before beginning Activity 1, and the reasons presented by the comment do not appear to be valid. The development of a new category of plant events and accidents would not appear to be influenced by defense-in-depth considerations. It is true that defense-in-depth may play a role in selecting new events to populate the design-basis extension category. It might also be argued that the level of defense-in-depth that should be provided in addressing events in the new category should be included when the staff develops guidance on treatment requirements. The NRC staff notes that existing guidance regarding defense-in-depth will serve until such time as enhanced guidance results from Improvement Activity 2, at which time the guidance regarding defense-in-depth would be enhanced. More importantly, the concept of the new category does not depend, in any significant way, upon the characterization and development of decision criteria for defense-in-depth. The comment did not explain how defense-in-depth would constitute a fundamental part of the conceptualization for the new "design- basis extension" category. For these reasons, the staff does not believe that there is any particular sequence for accomplishing Activities 1 and 2 which provides distinct advantages, from either a resource expenditure (efficiency) or a conceptualization standpoint.

Comment: A PRA cannot adequately address (1) cascading failures arising from single point vulnerabilities that may or may not be known; (2) the prospect of serially correlated failures; or, (3) defects in design or construction. The NRC Staff's suggestions under Improvement Activity 2 are unlikely to be practical or achieve measurable benefits because the above, involving DID, cannot be addressed through a PRA, but can only be handled via advanced statistical methods. PRA models have limitations: (1) PRAs are not tested for accuracy or reliability; (2) PRAs do not routinely operate or present results at the high confidence limit; (3) PRAs are inferential engines that merely model the "as-designed" plant for an enumerated set of circumstances. "Top down" modeling methods would be more effective than PRA models. (Maloney)

NRC staff response: The staff believes that a plant-specific PRA need not be required in order to effectively address NTTF Recommendation 1. However, the staff believes that risk information from PRAs and other sources would be useful in informing the improvement activities to define a design basis extension category, to clarify the use of defense-in-depth in the regulatory process, and to determine which voluntary industry initiatives should be subject to NRC oversight. Should the Commission approve any or all of the recommended improvement activities, the NRC staff will work with interested stakeholders to ensure that information from PRA models is used with appropriate consideration of their limitations. No changes in the staff's recommendations were made as a result of consideration of this comment.

B. Comments on Improvement Activity 1: creating a new category of events

Comment: The Staff's estimate that there will be no additional costs to the industry for the approach described above is incorrect. While the new regulatory framework may address the so-called "patchwork" approach of regulations, there would likely be significant licensing changes, FSAR updates, program additions and changes, procedures, equipment requirements, change processes (beyond 10 CFR 50.59), training, etc. that would be associated with a new regulation [establishing a design basis extension category and treatment requirements]. (STARS)

NRC staff response: The staff disagrees with the comment. All of the changes proposed by the staff in Improvement Activity 1 are internal to the NRC; their implementation is not contingent upon any specific action by any external stakeholders. The staff believes that the comment may be referring to the costs to applicants and licensees necessary for compliance with new (future) design enhancement rulemakings. The staff recognizes that those costs exist, but the compliance costs of these rulemakings would be considered in the regulatory analysis and any necessary backfitting and Part 52 issue finality consideration associated with such rulemakings. The staff does not foresee a substantial additional increment in costs of compliance with such new (future) design-basis extension rulemakings that would be attributable solely to Improvement Activity 1. No changes in the staff's recommendations were made as a result of consideration of this comment.

Comment: In establishing a design-basis extension category, the NRC should address 6 elements:

1. *require all licensees to comply with contemporary safety requirements without regard to past SERs;*
2. *employ statistical sampling in inspection programs to assess alignment of as-built to as-designed specifications;*
3. *reexamine the issues considered under USI A-45 (Decay Heat Removal) with a special focus on sites sharing Fukushima risk factors;*
4. *employ high confidence limits for external event frequency and severity, and internal event frequency and failure rates;*
5. *notwithstanding the use of high confidence estimates, assume a minimal 2% dependent failure rate for systems considered to be "independent"; and*
6. *prioritize according to loss distribution effects relate to the protection of the public health and safety (mortality and morbidity) and economic consequences (third party damages).*

(Maloney)

NRC staff response: If the Commission approves Improvement Activity 1, then the NRC will seek stakeholder input in its development of a new category of plant events and accidents, and the associated decision criteria. The comment's proposal will be considered during that development process. No changes in the staff's recommendations were made as a result of consideration of this comment.

Comment: The NRC should define a set of key principles in order to guide future beyond design basis regulatory actions. An example set of key principles is presented in an attachment to one commenters' submission, and is supported by another commenter. The key principles in the commenter's Attachment are based on lessons learned from past and on-going beyond design basis regulatory activities, and includes a summary description of key principles addressing requirements for design, human performance, quality, programmatic controls, regulatory oversight, and processes for considering new information. (NEI, STARS)

NRC staff response: If the Commission approves Improvement Activity 1, then the NRC will seek stakeholder input in its development of a new category of plant events and accidents, and the associated decision criteria. The comment's proposal will be considered during that development process. No changes in the staff's recommendations were made as a result of consideration of these comments.

C. Comments on Improvement Activity 2: defining defense-in-depth

Comment: Developing defense-in-depth concepts for design is neither practical nor necessary. Defense-in-depth needs to be considered in measurable terms within the context of risk tolerance. The significance of "defense-in-depth" depends on site-specific risk relative to NRC's risk tolerance. The Commission should adopt a simpler approach to "defense-in-depth" that requires the potential for correlated failures impacting redundant safety systems to be shown on a statistical basis as less than 2% to 99% confidence, and to increase nonlinearly as an accident progresses. The Commission should impose conservatism in design while being receptive to licensee analysis demonstrating functional equivalence in a manner that can be measured. (Maloney)

NRC staff response: The staff does not agree with the comment's position that developing defense-in-depth concepts for design is neither practical nor necessary. The staff believes there would be value to more formally defining defense-in-depth and developing, at a high level, decision criteria for assessing its adequacy. A formal definition of the defense-in-depth concept for nuclear power reactors would provide greater clarity and predictability. The staff believes there is a reasonable likelihood of success in developing a formal definition, given the staff's determination that conceptual discussions of defense-in-depth seem to use the same language and concepts over many decades.

The staff believes that certain aspects of the defense-in-depth concept described in the comment might be incorporated into an acceptable approach for implementing defense-in-depth for nuclear power reactors. However, Improvement Activity 2 does not constitute a recommendation to adopt a specific defense-in-depth approach. Rather, if the Commission approves Improvement Activity 2, then the NRC will seek stakeholder input in its development of a definition of defense-in-depth and associate decision criteria. The comment's proposal will be considered during that development process. No changes in the staff's recommendations were made as a result of consideration of this comment.

Comment: The NRC's discussion under Improvement Activity 2 should be revised to reflect that defense-in-depth is a philosophy rather than a strategy, because it may cause confusion given past historical practice of basing defense-in-depth on a number of approaches rather than a single strategy and should reflect the principle that defense-in-depth should be commensurate with the importance to safety. (STARS)

NRC staff response: The staff agrees that different approaches and "importance to safety" need to be considered when addressing defense-in-depth. However, the staff does not believe that the discussion of Activity 2 needs to be changed or augmented as suggested by the comment. If Improvement Activity 2 is approved by the Commission, then the NRC will seek stakeholder input in its development of a definition of defense-in-depth and associated decision criteria. The comment's proposals will be considered during that development process, which is the appropriate time for detailed consideration of concepts and language. No changes in the staff's recommendations were made as a result of consideration of this comment.

Comment: Defense-in-depth should not involve a new layer of DID expectations that would be imposed on top of the existing regulatory framework. Defense-in-depth should be a structured process informed by risk considerations. The staff's proposed approach for DID could undermine the viability of PRA and risk-informed approaches and could induce instability and *unpredictability of outcomes due to the many layers of considerations, some with subjective inputs. (NEI)*

NRC staff response: The staff agrees that DID should not involve a new layer of DID expectations and agrees that it should be a structured process informed by risk considerations. The staff does not agree that its proposed Improvement Activity 2 undermines the viability of PRA and risk-informed approaches. The Commission's current risk informed approach considers DID, risk, and safety margins in an integrated fashion and the improvement activity would not change that. The development of proposed DID decision criteria will increase predictability. If Improvement Activity 2 is approved by the Commission, then the NRC will seek stakeholder input in its development of a definition of defense-in-depth and associate decision criteria. The comment's proposal will be considered during that development process. No changes in the staff's recommendations were made as a result of consideration of this comment.

Comment: Defense-in-depth should not be applied in a manner which overlaps or supersedes NRC's existing regulations and GDC. While defense-in-depth may be applied in conjunction with risk-informed considerations, it should continue to be a subjective process in cases where PRAs do not exist. Improvement Activity 2 should be implemented on a forward-looking basis, because the lack of a site-specific PRA for certain scenarios (including external hazards) would prevent licensee implementation on a retrospective basis, and the cost of a PRA performed solely to support a defense-in-depth decision, would not provide benefits commensurate with the cost of developing such PRA models. (STARS)

NRC staff response: The staff agrees that defense-in-depth should not be applied in a manner which overlaps or supersedes NRC's existing regulations and GDC as they exist today. However, under the staff's proposal to implement DID in a forward-looking manner, should existing regulations be amended in the future for reasons unrelated to DID, the NRC would employ DID decision criteria to re-evaluate any DID considerations implicit in those regulations. The staff notes that Improvement Activity 2 does not require the use of a plant-specific PRA nor does the staff recommend that a PRA be required, in part for the reason noted in the comment, *viz.*, that the cost of a PRA performed solely to support a defense-in-depth decision, would not provide benefits commensurate with the cost of developing such PRA models.

In any event, if Improvement Activity 2 is approved by the Commission, then the NRC will seek stakeholder input in its development of a definition of defense-in-depth and associated decision criteria, and the comment's proposal will be considered during that development process. No changes in the staff's recommendations were made as a result of consideration of this comment.

D. Comments on Improvement Activity 3: voluntary industry initiatives

Comment: There is no need for any NRC initiative regarding voluntary initiatives. The NRC has not identified any systematic, industry-wide problem that would suggest that the industry as a whole is not following through on its commitments to implement these voluntary safety enhancements. "Regulatory footprints" have generally been established for industry initiatives within the current framework, and a regulatory footprint on industry initiatives is not appropriate or necessary for items where there is no regulatory concern. Finally, the incentive for licensees to voluntarily pursue and implement safety enhancements would be significantly reduced or eliminated if the NRC were to impose a regulatory footprint on these activities. (NEI, STARS)

NRC staff response: The staff agrees with the principle, which seems to be reflected in the comment, that if the NRC determines that a matter is not *within the NRC's regulatory jurisdiction*, then an NRC "regulatory footprint" on an industry initiative addressing that matter is neither necessary nor appropriate. However, this type of industry initiative, which is what the NRC characterizes as a "Type 3" initiative, is *not* the focus of Improvement Activity 3.

Activity 3 is focused on what the NRC characterizes as "Type 2" industry initiatives, where the matter does not involve adequate protection and is within the NRC's regulatory jurisdiction, but the NRC declines to develop a "regulatory footprint" because of the Type 2 industry initiative. In these circumstances, the Commission has articulated the general principle that it is acceptable to rely on industry initiatives, as long as: (1) the industry initiative has the capability of adequately addressing the NRC's safety and/or regulatory concerns; and (2) there is a high likelihood that the industry initiative will be effectively implemented and maintained over time. Improvement Activity 3, in essence, is intended to strengthen the NRC's bases for relying on Type 2 industry initiatives, consistent with the Commission direction on this matter.

Improvement Activity 3 is premised in part on the staff's view that there will be greater NRC consistency and transparency if the NRC were to use a better tool to convey to internal NRC staff as well as to external stakeholders the current Commission guidance. The staff notes that, where there is no regulatory concern, the initiative would be a "type 3" initiative, which is not the focus of this improvement activity. Nor should Activity 3 have any significant adverse impact on licensee incentives regarding voluntary industry initiatives, as it is not a change in overall Commission policy.

The NRC staff agrees that there may be no evidence of widespread, systematic problems with industry initiatives. However, the NTTF's observations and subsequent deliberations have led the NRC staff to the conclusion that reliance on voluntary industry initiatives without some confidence that they are implemented and maintained over time is not consistent with the principles of good regulation. Improvement activity 3 seeks to clarify the Commission's policy on voluntary industry initiatives, gather additional information on whether selected voluntary industry initiatives have been effectively maintained, and optionally provide a regulatory basis requirement for monitoring changes to industry initiatives.

No changes in the staff's recommendations were made as a result of consideration of these comments.

Comment: Unless industry can regularly demonstrate in a measurable way that an industry initiative can be effective, the matters covered in the initiative should be the subject of NRC rules because rules are enforceable and allow for public interaction. The NRC should not rely upon industry initiatives until measures are in place to measure efficacy and reliability of a safety initiative. The NRC should accurately and reliably assess risk so as to conservatively measure the benefits in a repeatable way. If industry relies on a voluntary initiative, then information must be made publicly available by the industry or by the NRC. (Maloney)

NRC staff response: The staff agrees in part with the comment. It is the Commission's policy that actions necessary to provide a reasonable assurance of adequate protection of public health and safety may not rely on voluntary industry initiatives, and shall instead be issued as legally binding requirements. This would apply to the "Type 1" industry initiatives. At the other end of the spectrum from a safety standpoint are the "Type 3" industry initiatives, which do not involve safety issues and do not require demonstration of effectiveness. The “Type 2” initiatives are those that NRC recommend be further evaluated in terms of the likelihood that they will be effectively implemented and maintained over time by the licensees. For the more safety-significant Type 2 industry initiatives, the NRC staff is recommending that appropriate monitoring be put in place. This proposal is consistent with the individual’s comment regarding demonstration of the effectiveness of such industry initiatives, although the staff’s proposal would not apply to all Type 2 industry initiatives as proposed by the commenter. The NRC staff’s recommendation that this apply to safety-significant industry initiatives is consistent with other comments by this same individual that NRC should employ a risk management approach to regulation. As for the public availability of information regarding voluntary industry initiatives, the NRC staff notes that it is the Agency’s practice to discuss and deliberate on such topics in public meetings whenever practicable. No changes in the staff’s recommendations were made as a result of consideration of this comment.

Comment: The NRC staff should make greater use of standards development organizations and consensus standards when voluntary industry initiatives are being considered to address a potential safety issue. (Kadambi)

NRC staff response: The staff agrees in part with the comment. If a voluntary industry initiative includes use of a voluntary consensus standard developed by a standards development organization addressing the matter under consideration, then the NRC would consider that as a factor in favor of NRC reliance on the voluntary industry initiative, as opposed to developing an NRC regulatory requirement (*e.g.*, a “government-unique standard” under the National Technology Transfer and Advancement Act with respect to an NRC regulation).

The general principles governing reliance upon voluntary consensus standards as an alternative to a government unique standard is already reflected in the NRC’s rulemaking policies and procedures, and no fundamental change to those documents is needed. However, the staff will consider whether additional clarification on the consideration of industry voluntary initiatives utilizing voluntary consensus standards would be prudent and may pursue this outside of Improvement Activity 3, as this matter is not directly related to NTTF Recommendation 1 or Improvement Activity 3. No changes in the staff’s recommendations were made as a result of consideration of this comment.

ENCLOSURE 3 – A HISTORY OF DEFENSE-IN-DEPTH FOR COMMERCIAL NUCLEAR POWER PLANTS

[WORK IN PROGRESS]

BACKGROUND

Since the beginning of licensing nuclear facilities, the term "defense-in-depth" occurs frequently in the documented history of nuclear reactor safety with different positions regarding its definition and implementation. A variety of sources were identified, listed below, where defense-in-depth is discussed.

• Joint Committee on Atomic Energy Hearings[1] • Internal Study Group • ECCS Hearings • WASH-1250 • 10 CFR Part 60 • Post TMI Definitions and Examples • NUREG/CR-6042 • Commission Policy Statements • NUREG-1537 • MIT Speech by Chairman Jackson • Commission White Paper • Some Thoughts on Defense-in-Depth by Tom Kress • PSA '99 paper • ACRS letters • IAEA Documents (INSAG-3, 10, & 12, NP-T-2.2) • 10 CFR Part 50, Appendix R	• Joint ACNW/ACRS Subcommittee • A Risk-Informed Defense-in-Depth Framework for Existing and Advanced Reactors, Karl Fleming, Fred Silady • 10 CFR §50.69 • NEI 02-02 • Petition on Davis Besse • Remarks by Chairman Diaz • Digital Instrumentation and Controls (NUREG/CR-6303, RG 1.152, NUREG-0800 BTP HICB-91, NUREG-0800 SRP BTP 7-19, DI&C-ISG-02) • NUREG-1860 • INL NGNP report • RG 1.174 • NRC glossary • RMTF

A high level summary of these documents is provided below and a detailed summary provided in Appendix A.

The earliest definition of defense-in-depth appears to be in a 1967 paper submitted by Clifford Beck (Deputy Director of Regulation) to the Joint Committee on Atomic Energy. In summary, the paper defines three basic lines of defense dealing with "superior quality in design, construction and operation of basic reactor systems important to safety, accident prevention safety systems, consequences-limiting safety systems. The next reference to defense-in-depth occurs in the "Report to the Atomic Energy Commission on the Reactor Licensing Program," by the Internal Study Group in 1969. In the report, the Study Group endorses the defense-in-depth concept, but believes that the greatest emphasis should be placed on the first line of defense, i.e., on designing, constructing, testing and operating a plant so that it will perform during normal and abnormal conditions in a reliable and predictable manner. The third historical document is the testimony of the AEC Regulatory Staff at the Public Rulemaking Hearings on Interim Acceptance Criteria for Emergency Core Cooling Systems for Light Water Power Reactors, issued in 1971. The testimony also describes three lines of defense and states that the principal defense is through the prevention of accidents. The second line of defense includes protective systems and the third line is provided by installing engineered safety features to mitigate the consequences of postulated serious accidents. Another document that was in

[1] Much of this historical background is taken directly from a letter by J.N. Sorensen to the ACRS entitled "Historical Notes on Defense in Depth," dated October 15, 1997.

development at the same time the above testimony was prepared is WASH-1250 in 1973. This document states “the industry strives to protect the plant, the plant operators, and the health and safety of the public by application of a “defense-in-depth” design philosophy . . . A convenient method of describing this "defense-in-depth" is to discuss it in the broader concept of three levels of safety."

In the 1980s, the first instance of defense-in-depth associated with regulations appears in the Statements of Consideration for 10 CFR Part 60 (DATE). The Commission suggested that a course that would be "reasonable and practical" would be to adopt a defense-in-depth approach that would prescribe minimum performance standards for each of the major elements of the geologic repository.” In 1981, R.J. Breen, Deputy Director of EPRI's Nuclear Safety Analysis Center, published a paper titled "Defense-in-depth Approach to Safety in Light of the Three Mile Island Accident.” In the paper, Breen states that ". . . the principle of guarding against unwanted events by providing successive protective barriers is frequently called defense-in-depth." He defines three levels which he lists as preventing initiation of incidents, capability to detect and terminate incidents, and protecting the public.

The next instances where defense-in-depth is mentioned begins in the early 1990s. NUREG/CR-6042 (1994), "Perspectives on Reactor Safety," describes a one week course in reactor safety concepts. It describes key elements of defense-in-depth which are listed as accident prevention, safety systems, containment, accident management, and siting and emergency plans.

The term defense-in-depth occurs in three Commission Policy Statements: the Safety Goal Policy Statement, the Advanced Nuclear Power Plant Policy Statement, and the PRA Policy Statement. None of these documents offer a definition of defense-in-depth, except by example or implication. The Commission Safety Goal Policy Statement (1986) notes specific features (e.g., containment) as integral parts to defense-in-depth, and that understanding uncertainty is a key aspect of defense-in-depth. Additional views are provided by two Commissioners. The Commission Policy on Regulation of Advanced Reactors (1994/2008) notes that designs incorporate the defense-in-depth philosophy by maintaining multiple barriers against radiation release, and by reducing the potential for, and consequences of, severe accidents. The Commission PRA Policy Statement (1995) stipulates that “complete reliance for safety cannot be placed on any single element of the design, maintenance, or operation of a nuclear power plant." The statement goes on to note that “PRA technology will continue to support the NRC's defense-in-depth philosophy by allowing quantification of the levels of protection and by helping to identify and address weaknesses or overly conservative regulatory requirements.” It also notes that defense-in-depth is used by the NRC to provide redundancy as well as a multiple-barrier approach.

In 1996, NUREG-1537 (Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors) very briefly references defense-in-depth. It states, regarding describing “the principal architectural and engineering design criteria for the structures, systems and components that are required to ensure reactor facility safety and protection of the public,” that the “material presented should emphasize the safety and protective functions and related design features that help provide defense-in-depth against uncontrolled release of radioactive material.”

In 1997, in a talk at the MIT Nuclear Power Reactor Safety Course, Chairman Jackson notes that one element of the NRC safety philosophy is defense-in-depth and that “defense-in-depth ensures that successive measures are incorporated into the design and operating procedures . . . to compensate for potential failures . . .” In 1999, Chairman Jackson further elaborates on defense-in-depth in a white paper. She states that "defense-in-depth . . . employs successive compensatory measures to prevent accidents or mitigate damage . . . ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation . . . the net effect . . . of defense-in-depth . . . is that the facility . . . tends to be more tolerant of failures and external challenges."

ADD TOM KRESS THOUGHTS

For the 1999 PSA Conference, a paper by J.N. Sorenson, et. al., was presented entitled "On the Role of Defense in Depth in Risk-Informed Regulation." The authors note two different schools of thought. One is the structuralist model which asserts that defense-in-depth is embodied in the structure of the regulations and in the design of the facilities built to comply with those regulations. The second one is the rationalist model which asserts that defense-in-depth is the aggregate of provisions made to compensate for uncertainty and incompleteness in the knowledge of accident initiation and progression.

The ACRS has provided their insights on defense-in-depth over the years, and predominantly in two specific letters regarding reactors and nuclear materials.

- In a May 1999, letter to Chairman Shirley Jackson, the Committee states there are two different perceptions of defense-in-depth. One view (the structuralist view), defense-in-depth is considered to be the application of multiple and redundant measures to identify, prevent, or mitigate accidents to such a degree that the design meets the safety objectives. The other view (the rationalist view), sees the proper role of defense-in-depth in a risk-informed regulatory scheme as compensation for inadequacies, incompleteness, and omissions of risk analyses. The Committee states that the use of quantitative risk-assessment methods and the proper imposition of defense-in-depth measures would be facilitated considerably by the availability of risk-acceptance criteria applicable at a greater level of detail than the current ones.

- The Committee's views on nuclear materials is provided in a May 2000, letter to Chairman Richard Meserve. In this letter, the Committee states that the various compensatory measures taken for the purposes of defense-in-depth can be graded according to the risk posed by the activity, the contribution of each compensatory measure to risk reduction, the uncertainties in the risk assessment, and the need to build stakeholders trust.

For both reactors and nuclear materials, the Committee views defense-in-depth as a strategy to ensure public safety given the unquantified uncertainty in risk assessments, and that the extent of defense-in-depth should be related to the degree of uncertainty.

The International Nuclear Safety Advisory Group (INSAG) of the International Atomic Energy Agency (IAEA) has published several documents related to defense-in-depth (INSAG-3, 10 and 12 and NR-T-2.2):

- In 1988, INSAG-3 was published and explains defense-in-depth by stating that "All safety activities, whether organizational, behavioural or equipment related, are subject to layers of overlapping provisions, so that if a failure should occur it would be compensated for or corrected without causing harm to individuals or the public at large." The document then goes on to state the principle of defense-in-depth is "To compensate for potential human and mechanical failures, a defense in depth concept is implemented, centered on several levels of protection including successive barriers preventing the release of radioactive material to the environment. The concept includes protection of the barrier by averting damage to the plant and to the barriers themselves. It includes further measures to protect the public and the environment from harm in case these barriers are not fully effective."

- In 1996, INSAG-10 was published which restates the explanation and principle on defense-in-depth provided in INSAG-3. It further states that "Defense in depth consists in a hierarchical deployment of different levels of equipment and procedures in order to maintain the effectiveness of physical barriers placed between radioactive materials and workers, the public or the environment, in normal operation, anticipated operational occurrence and, for some barriers, in accident in the plant." The report goes on to state that "the strategy for defense in depth is twofold: first, to prevent accidents and, second, if prevention fails, to limit their potential consequences and prevent any evolution to more serious conditions. Accident prevention is the first priority. . ." Five levels of defense are defined such that if one level fails, the subsequent level comes into play.

- In 1999, INSAG-12 was published which is consistent with INSAG-3 and 10 on defense-in-depth; however, it further states that the strategy for defense-in-depth is twofold: first, to prevent accident and second, if prevention fails, to limit the potential consequences of accidents and to prevent their evolution to more serious conditions. It provides a definition and criteria for accident prevention and accident mitigation. INSAG-12 goes further than INSAG-10 in that it relates the five levels of defense-in-depth to the five operational states of nuclear power plants and classifies them either as accident prevention or accident mitigation.

- In 2009, IAEA published NP-T-2.2 which provides a technology-neutral safety approach to guide the design, safety assessment and licensing of innovative reactors. As part of the proposed approach, three "main pillars" are proposed, one of which is defense-in-depth which includes probabilistic considerations. The document references INSAG-10 in terms of the five levels, however, it also provides safety goals that are to be factored into the implementation of defense-in-depth. Quantitative Safety Goals targets are correlated to each level of defense-in-depth via a frequency consequence curve (the consequences being various accidents against acceptable frequencies). NP-T-2.2 also introduces the concept of a line of protection (LOP). A LOP is identified in the document for each safety function and for each level of defense-in-depth and that the LOPs provide the practical means of successfully achieving the objectives of the individual levels of defense.

The term defense-in-depth only appears in two places in the regulations: in 10 CFR Part 50, Appendix R and 10 CFR §50.69. In 10 CFR Part 50, Appendix R, the regulation states that the fire protection program shall extend the concept of defense-in-depth to fire protection in fire areas important to safety, with the objectives of dealing with prevention, detection and protection. 10 CFR §50.69 requires that the categorization process maintain defense-in-depth. In the FRN that published the rule (2004), defense-in-depth was discussed in several places. It provides criteria for when defense-in-depth is adequate (criteria that is similar to the principles stated in Revision 2 to RG 1.174). It is further stated in the FRN that the primary need for improving the implementation of defense-in-depth is guidance to determine how many measures are appropriate and how good these should be. Instead of merely relying on bottom-line risk estimates, defense-in-depth is invoked as a strategy to ensure public safety given there exists both unquantified and unquantifiable uncertainty in engineering analyses (both deterministic and risk assessments).

ADD SUBCOMMITTEE OF ACNW/ACRS AND PAPER BY FLEMING AND SALIDY

In 2002, NEI, in a white paper (NEI 02-02), describes a new and optional risk-informed, performance-based regulatory framework for commercial nuclear reactors which includes a discussion on "How to treat defense-in-depth in a risk-informed, performance-based regime." The paper provides principles for a risk-informed, performance-based regulatory framework where one principle is "The framework shall provide for defense-in-depth through requirements and processes that include design, construction, regulatory oversight and operating activities. Additional defense-in-depth shall be provided through the application of deterministic design and operational features for events that have a high degree of uncertainty with significant consequences to public health and safety." Guidance is provided for achieving its defined principle on defense-in-depth.

In 2003, a Petition was filed requesting that the NRC "immediately revoke the First Energy Nuclear Operating Company's (FENOC's or the licensee's) license to operate the Davis-Besse Nuclear Power Station, Unit 1 (Davis-Besse)." In the Director's Decision, it states that the NRC's approach to protecting public health and safety is based on the philosophy of defense-in-depth and defines six principles: (1) the application of conservative codes and standards, (2) the establishment of substantial safety margins; (3) high quality in the design, construction, and operation; (4) that equipment can fail and operators can make mistakes, thereby the need for redundancy; (5) requirement for a containment structure; and (6) requirement for comprehensive emergency plans and periodically exercised.

In 2004, Chairman Diaz gave a speech entitled "The Very Best-Laid Plans (the NRC's Defense-in Depth Philosophy)." In his remarks, he states that defense-in-depth "is really more than a philosophy: it is an action plan, an approach to ensuring protection. . . . It calls for, among other things, high quality design, fabrication, construction, inspection, and testing; plus multiple barriers to fission product release; plus redundancy and diversity in safety equipment; plus procedures and strategies; and lastly, emergency preparedness, which includes coordination with local authorities, sheltering, evacuation, and/or administration of prophylactics (for example, potassium iodide tablets). This approach addresses the expected as well as the unexpected . . ."

Over the years there are several documents (NUREG/CR-6303, 1994; Regulatory Guide 1.152, 1996; NUREG-0800, Branch Technical Position (BTP) HICB-19 1997; NUREG-0800, BTP 7-19, 2007; and DI&C-ISG-02, 2009.) addressing Digital Instrumentation and Control where defense-in-depth has been a key factor. In these documents, it is noted that "defense-in-depth is a principle of long standing for the design, construction and operation of nuclear reactors, and may be thought of as requiring a concentric arrangement of protective barriers or means, all of which must be breached before a hazardous material or dangerous energy can adversely affect human beings or the environment. The classic three physical barriers to radiation release in a reactor—cladding, reactor pressure vessel, and containment—are an example of defense-in-depth. These documents also define "echelons of defense" which are the control system, the reactor trip or scram system, the Engineered Safety Features actuation system (ESFAS), and the monitoring and indicator system.

In NUREG-1860, 2007, a proposed Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing is described where defense-in-depth is a key component. It addresses several questions: what should be the role of defense-in-depth, how should defense-in-depth be factored into the regulatory framework, what is the purpose of defense-in-depth, and how is defense-in-depth related to uncertainties. It states that "The ultimate purpose of defense-in-depth is to compensate for uncertainty (e.g., uncertainty due to lack of operational experience with new technologies and new design features, uncertainty in the in the type and magnitude of challenges to safety).” Defense-in-depth, in the NUREG, is defined as “defense-in-depth is an element of NRC’s safety philosophy that is used to address uncertainty by employing successive measure including safety margins to prevent and mitigate damage if a malfunction, accident or naturally caused event occurs at a nuclear facility.” The NUREG defines four objectives for defense-in-depth; defines a combined structuralist and rationalist approach to defense-in-depth; defines a set of six defense-in-depth principles with associated criteria; and defines probabilistic criteria for evaluating defense-in-depth sufficiency.

Idaho National Laboratory published INL/EXT-09-17139 in 2009 which documents a definition of defense-in-depth and the approach to be used to assure that its principles are satisfied for the NGNP project. It states that “defense-in-depth is a safety philosophy in which multiple lines of defense and conservative design and evaluation methods are applied to ensure the safety of the public. The philosophy is also intended to deliver a design that is tolerant to uncertainties in knowledge of plant behavior, component reliability, or operator performance that might compromise safety.” For NGNP, a defense-in-depth framework is proposed that defines three major elements: (1) Plant capability defense-in-depth, (2) Programmatic defense-in-depth, and (3) Risk-informed evaluation of defense-in-depth. For each of the above elements, principles and criteria are defined for each. As part of the risk-informed evaluation defense-in-depth element, a decision process with associated criteria is proposed. The criteria include probabilistic and deterministic criteria and also evaluates whether the uncertainties have been adequately addressed and if the defense-in-depth principles have been met.

Draft Guide (DG) 1285[2], provides guidance on the use of PRA findings and risk insights to support licensee requests for changes to a plant’s LB. In the RG, it provides an approach for implementing risk-informed decisionmaking which includes one principle that the proposed change is consistent with a defense-in-depth philosophy. The DG uses the definition developed by the Commission in the 1999 White Paper. It goes to state that there are two aspects to defense-in-depth. The first aspect is that there are three layers of defense against the consequences of an event at a nuclear facility. The three layers are (1) protection to prevent accidents from occurring, (2) mitigation of accidents if they occur, and (3) emergency preparedness to minimize the public health consequences of releases if they occur. The second major aspect of defense-in-depth is maintaining multiple barriers to the release of fission products. The RG provides three factors that need to be considered to determine that the proposed plant change is consistent with the three layers and the multiple-barrier philosophy. The three factors include (1) preserving balance among the three layers of defense-in-depth; (2) preserving multiple fission product barriers; and (3) other factors to consider when evaluating the impact of a change on defense-in-depth. These other factors include programmatic activities as compensatory measures; system redundancy, independence, and diversity; potential for common-cause failure (CCF); reliance on plant operators; and intent of the plant’s design criteria.

The glossary on the NRC Website defines defense-in-depth as “An approach to designing and operating nuclear facilities that prevents and mitigates accidents that release radiation or hazardous materials. The key is creating multiple independent and redundant layers of defense to compensate for potential human and mechanical failures so that no single layer, no matter how robust, is exclusively relied upon. Defense-in-depth includes the use of access controls, physical barriers, redundant and diverse key safety functions, and emergency response measures.”

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[2] DG-1285 is revision 3 to RG 1.174 which is to be published in November 2012.

In 2012, the Risk Management Task Force published its recommendation regarding a strategic vision and options for adopting a more comprehensive, 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. In the report, defense-in-depth plays a key role in their recommendation regarding a proposed Risk Management Regulatory Framework. The task force reviewed across the various arenas and notes that after decades of use, there is no clear definition or criteria on how to define adequate defense-in-depth protections; that the concept of defense-in-depth is not used consistently, and there is no guidance on how much defense-in-depth is sufficient; that the concept was developed and applied to compensate for the recognized lack of knowledge of nuclear reactor operations and the consequences of potential accidents. The RMTF characterizes defense-in-depth as follows: "Provide risk-informed and performance-based defense-in-depth protections to: (1) Ensure appropriate barriers, controls, and personnel to prevent, contain, and mitigate exposure to radioactive material according to the hazard present, the relevant scenarios, and the associated uncertainties – (a) each barrier is designed with sufficient safety margins to maintain its functionality for relevant scenarios and account for uncertainties, (b) systems that are needed to ensure a barrier's functionality are designed to ensure appropriate reliability for relevant scenarios, and (c) barriers and systems are subject to performance monitoring; and (2) ensure that the risks resulting from the failure of some or all of the established barriers and controls, including human errors, are maintained acceptably low."

DISCUSSION

Coming to an understanding of defense-in-depth, it is important to understand the importance of this "philosophy" or "process." That is, why defense-in-depth is essential to a regulatory structure that is designed to provide for adequate protection of the public health and safety. A major part of this understanding is also understanding the objective of defense-in-depth; that is, what is defense-in-depth attempting to accomplish. Additional aspects of understanding defense-in-depth involves defining an approach for accomplishing the objective, criteria for the approach, and criteria for ensuring adequate defense-in-depth has been achieved. These five "elements" of defense-in-depth, therefore, include:

- The need for defense-in-depth
- The objective of defense-in-depth (i.e., what is defense-in-depth attempting to accomplish)
- The approach or strategy used to achieve the goal of defense-in-depth
- The criteria used to implement the approach or strategy of defense-in-depth
- The criteria for determining whether there is adequate defense-in-depth

In reviewing the history on defense-in-depth and trying to understand the different perspectives, if indeed there are different perspectives, and there are actually common themes. There are common themes regarding specific issues, for example, uncertainties, accident prevention, accident mitigation, multiple barriers, redundancy, emergency preparedness. However, how these themes are classified differ. That is, while the actual views may be similar, whether the view is stating, for example, why is defense-in-depth needed or what is the objective of defense-in-depth, differs. Therefore, in reviewing the history, the views are summarized and grouped according to the above five elements, and discussed below.

The need for defense-in-depth

In reviewing the various sources regarding the first element of defense-in-depth, understanding why there is a need for defense-in-depth, the following statements are found:

- guard against unwanted events
- compensating for uncertainty in probabilistic analyses
- related to the issue of uncertainty
- the aggregate of provisions made to compensate for uncertainty and incompleteness in the knowledge of accident initiation and progression
- compensation for inadequacies, incompleteness, and omissions of risk analyses
- a strategy to ensure public safety given the unquantified uncertainty in risk assessments
- a strategy to ensure public safety given there exists both unquantified and unquantifiable uncertainty in engineering analyses (both deterministic and risk assessments)
- application of deterministic design and operational features for events that have a high degree of uncertainty
- ultimate purpose is to compensate for uncertainty (e.g., uncertainty due to lack of operational experience with new technologies and new design features, uncertainty in the type and magnitude of challenges to safety)
- an element of NRC's safety philosophy that is used to address uncertainty
- a safety philosophy intended to deliver a design that is tolerant to uncertainties in knowledge of plant behavior, component reliability, or operator performance that might compromise safety
- to compensate for the recognized lack of knowledge of nuclear reactor operations and the consequences of potential accidents

There does appear to be a general consensus regarding why defense-in-depth is needed. There is a common recognition that there is a lack of knowledge (or uncertainty) with regard to the design, construction, maintenance and operation of the facility. In answering the first question of why there is a need for defense-in-depth, it is to address the uncertainties in the design, construction, maintenance and operation of the nuclear facility. EXPAND DISCUSSION

The objective of defense-in-depth

In reviewing the various sources regarding the next element of defense-in-depth, understanding what is its objective; that is, what is DID attempting to accomplish, the following statements are found:

- to protect the plant, the plant operators, and the health and safety of the public
- guarding against unwanted events
- ensure the protection of public health and safety

- reducing the potential for, and consequences of, severe accidents
- to increase the degree of confidence in the results of the PRA or other analyses supporting the conclusion that adequate safety has been achieved
- the probability of accidents must be acceptably low
- to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility
- if a failure should occur it would be compensated for or corrected without causing harm to individuals or the public at large
- preventing the release of radioactive material to the environment
- averting damage to the plant
- the facility or system in question tends to be more tolerant of failures and external challenges
- to provide several levels or echelons of defense to challenges to plant safety, such that failures in equipment and human error will not result in an undue threat to public safety
- to designing and operating nuclear facilities that prevents and mitigates accidents that release radiation or hazardous materials
- to prevent, contain, and mitigate exposure to radioactive material

There also appears to be a general consensus regarding the objective of defense-in-depth. There is a common recognition that because there is a lack of knowledge (or uncertainty) with regard to the design, construction, maintenance and operation of the facility, the objective of defense-in-depth is to avert damage to the plant thereby ensuring the protection of public health and safety while maintaining an acceptably low probability of accidents. EXPAND DISCUSSION

The approach or strategy used to achieve the goal of defense-in-depth

BRING IN CONCEPT OF A BLENDED STRUCTURALIST AND RATIONALIST STRATEGY/APPROACH

In reviewing the various sources regarding the approach or strategy to achieve the goal of defense-in-depth, the following statements are found:

- three basic lines of defense: (1) superior quality in design, construction and operation, (2) accident prevention safety systems, and (3) consequences-limiting safety systems
- the greatest emphasis should be placed on the first line of defense, i.e., on designing, constructing, testing and operating a plant so that it will perform during normal and abnormal conditions in a reliable and predictable manner
- The principal defense is through the prevention of accidents

- three lines of defense: (1) prevention of accidents, (2) protective systems are provided to take corrective actions, and (3) engineered safety features to mitigate the consequences of postulated serious accidents

- multiple barrier approach

- three successive protective barriers: (1) preventing initiation of incidents (conservative design margins, etc.), (2) capability to detect and terminate incidents, and (3) Protecting the public.

- The key elements are accident prevention, safety systems, containment, accident management, and siting and emergency plans.

- emphasize features such as containment, siting in less populated areas, and emergency planning as integral parts of the defense-in-depth concept associated with its accident prevention and mitigation philosophy

- maintaining multiple barriers against radiation release, and by reducing the potential for, and consequences of, severe accidents

- explains defense in depth by stating that "All safety activities, whether organizational, behavioural or equipment related, are subject to layers of overlapping provisions, so that if a failure should occur it would be compensated for or corrected without causing harm to individuals or the public at large

- Depth ensures that successive measures are incorporated into the design and operating procedures for nuclear installations

- the strategy for defense in depth is two fold: first, to prevent accidents and, second, if prevention fails, to limit their potential consequences and prevent any evolution to more serious conditions. Accident prevention is the first priority. . ."

- Five levels of defense are defined such that if one level fails, the subsequent level comes into play: (1) Prevention of abnormal operation and system failures; (2)Control of abnormal operation and detection of failures; (3) Control of accident within the design basis; (4) Control of severe conditions including prevention of accident progression and mitigation of the consequences of a severe accident; and (5) Mitigation of the radiological consequences of significant external releases of radioactive materials

- the principle of defense in depth is implemented primarily by means of a series of barriers which would in principle never be jeopardized, and which must be violated in turn before harm can occur to people or the environment

- three layers of defense against the consequences of an event at a nuclear facility. The three layers are (1) protection to prevent accidents from occurring, (2) mitigation of accidents if they occur, and (3) emergency preparedness to minimize the public health consequences of releases if they occur

- COMPLETE

The above are just a list of some of the statements regarding the approaches or strategies that have been defined for defense-in-depth. There is a similar concept that can be found, which is there are basic protections which involve, at a high level, prevention of accidents and mitigation of accidents. Prevention of accident can be defined as preventing the occurrence of an event to preventing the progression of an accident sequence. Mitigation of an accident can be defined from ending the progression of a severe accident, containing the effects of a severe accident, to mitigating the consequences of a severe accident. This approach or strategy is similar to the concept of multiple barriers which are achieving the same goal. EXPAND DISCUSSION

The criteria used to implement the approach or strategy of defense-in-depth

In reviewing the various sources regarding the criteria to implement the approach or strategy to achieve the goal of defense-in-depth, the following statements are found:

- The keys to achievement of this objective are quality and quality assurance, independently and concurrently. The work must be done well and then checked well, in order for the chance for errors and flaws to be reduced to an acceptable level

- redundant elements, provision for periodic in-service testing, and other features to enhance performance and reliability

- Extensive and comprehensive quality assurance programs are required and used to assure the integrity of each line of defense and to maintain the different lines as nearly independent as practicable.

- provide multiple barriers to the escape of radioactive material, from whatever cause, and to withstand the occurrences of natural forces . . . without compromising these barriers

- selection of proper materials, quality controls in fabrication of components, rigorous systems of inspection and testing, appropriate techniques and controls in workmanship.

  The requirement of high standards of engineering practice in design for critical components and systems

- Regularly scheduled equipment checks and maintenance programs; prompt and thorough investigation and correction of abnormal events, failures or malfunctions.

  The requirements of sound and well defined principles of good management in operation; a competent and well-trained staff, clearly assigned duties, written procedures, checks and balances in the procedures for revisions, periodic internal audits of operations, etc.

- redundancy in controls and shutdown devices; emergency power from independent sources -sometimes in triplicate -and emergency cooling systems

- containment building itself, building spray and washdown system, building cooling system . . ., and an internal filter-collection system

- The structuralist model asserts that defense in depth is embodied in the structure of the regulations and in the design of the facilities built to comply with those regulations.

- provide for defense-in-depth through requirements and processes that include design, construction, regulatory oversight and operating activities. Additional defense-in-depth shall be provided through the application of deterministic design and operational features for events that have a high degree of uncertainty with significant consequences to public health and safety

- programmatic activities as compensatory measures; system redundancy, independence, and diversity; potential for common-cause failure (CCF); reliance on plant operators; and intent of the plant's design criteria.

- no key safety functions will depend on a single element (i.e., SSC or action) of design, construction, maintenance or operation. The key safety functions include (1) control of reactivity, (2) removal of decay heat, and the functionality of physical barriers to prevent the release of radioactive materials.

- appropriate safety margins are provided

- containment functional capability

The above are just a list of some of the statements regarding the criteria for implementing the approaches or strategies that have been defined for defense-in-depth. There are very similar criteria that include, for example, quality assurance, redundancy, independence, oversight, containment, emergency planning. EXPAND DISCUSSION

The criteria for determining whether there is adequate defense-in-depth

In reviewing the various sources regarding the criteria to whether adequate defense-in-depth has been achieved, the following statements are found:

- Risk insights can make the elements of defense-in-depth more clear by quantifying them to the extent practicable

- Decisions on the adequacy of or the necessity for elements of defense should reflect risk insights gained through identification of the individual performance of each defense system in relation to overall performance

- In order to assure a proper balance between accident prevention and accident mitigation, the mean frequency of containment failure in the event of a severe core damage accident should be less than 1 in 100 severe core damage accidents

- Severe core-damage accident should not be expected, on average, to occur . . .; Containment performance . . . such that severe accidents . . . are not expected to occur . . .; The goal for offsite consequences should be expected to be met after conservative consideration of the uncertainties . . ."

- the rationalist is: (1) establish quantitative acceptance criteria, such as the quantitative health objectives, core damage frequency and large early release frequency, (2) analyze the system using PRA methods to establish that the acceptance criteria are met, and (3) evaluate the uncertainties in the analysis, especially those due to model incompleteness, and determine what steps should be taken to compensate for those uncertainties

- The various compensatory measures taken for the purposes of defense in depth can be graded according to the risk posed by the activity, the contribution of each compensatory measure to risk reduction, the uncertainties in the risk assessment, and the need to build stakeholders trust.

- The ultimate objective is that any credible accident sequence, even considering the failures of lines of protection for the different levels of defense in depth, remain under the overall frequency consequence curve.

- Defense-in-depth is adequate if the overall redundancy and diversity among the plant's systems and barriers is sufficient to ensure the risk acceptance guidelines discussed in . . . . are met

- Assessing the adequacy via a process that uses a PRA to assess the acceptability of uncertainties and uses identified options (such as increasing performance monitoring) to determine the acceptability of the uncertainties or refine the design

The above are just a list of some of the statements regarding the criteria for determining whether adequate defense-in-depth has been achieved. In looking at the various criteria, each proposes a process to be used; some rely strictly on probabilistic criteria, others deterministic criteria and other used a combined deterministic and probabilistic criteria. EXPAND DISCUSSION

SUMMARY

The RMTF notes that "After decades of use, there is no clear definition or criteria on how to define adequate defense-in-depth protections." While there is no clear definition or criteria, there are very similar concepts, strategies and criteria. The RMTF furthers notes that "the concept of defense-in-depth has served the NRC and the regulated industries well and continues to be valuable today. However, it is not used consistently, and there is no guidance on how much defense-in-depth is sufficient." Again, while it has not been used consistently, certain consistencies can be found, and there has been some high level guidance which can be used to develop more detailed guidance. The RMTF concluded that "clarifying what the U.S. Nuclear Regulatory Commission (NRC) means by defense-in-depth is a necessary part of the development of a holistic strategic vision."

RECOMMENDATION

The staff recommends that the Commission take the following actions:

- The staff develop a policy statement on defense-in-depth for Commission approval. This statement would state the objective and need for defense-in-depth, along with the strategy to be used for accomplishing defense-in-depth.

- The staff develop guidance on defense-in-depth that would include criteria for implementing the strategy for achieving defense-in-depth and a process with associated criteria for determining whether adequate defense-in-depth has been achieved.

- The staff develop the rulemaking package for Commission approval for requiring the development of a full-scope Level 3 PRA that would be used, at a minimum, to address implementation and adequacy of DID.

APPENDIX A

HISTORICAL BACKGROUND SUMMARY ON DEFENSE-IN-DEPTH

A summary of the variety of positions regarding defense-in-depth is provided in the Appendix. The documents summarized include:

• Joint Committee on Atomic Energy Hearings[3] • Internal Study Group • ECCS Hearings • WASH-1250 • 10 CFR Part 60 • Post TMI Definitions and Examples • NUREG/CR-6042 • Commission Policy Statements • NUREG-1537 • MIT Speech by Chairman Jackson • Commission White Paper • Some Thoughts on Defense-in-Depth by Tom Kress • PSA '99 paper • ACRS letters • IAEA Documents (INSAG-3, 10, & 12, NP-T-2.2) • 10 CFR Part 50, Appendix R	• Joint ACNW/ACRS Subcommittee • A Risk-Informed Defense-in-Depth Framework for Existing and Advanced Reactors, Karl Fleming, Fred Silady • 10 CFR §50.69 • NEI 02-02 • Petition on Davis Besse • Remarks by Chairman Diaz • Digital Instrumentation and Controls (NUREG/CR-6303, RG 1.152, NUREG-0800 BTP HICB-91, NUREG-0800 SRP BTP 7-19, DI&C-ISG-02) • NUREG-1860 • INL NGNP report • RG 1.174 • NRC glossary • RMTF

The following provides excerpts from the above documents that were found to contain discussions related to defense-in-depth.

Joint Committee on Atomic Energy Hearings, 1967

The earliest definition of defense-in-depth appears to be in an April 1967 paper submitted by Clifford Beck (Deputy Director of Regulation) to the Joint Committee on Atomic Energy. In summary, the paper states:

> "For safety, three basic lines of defense are built into the physical systems of nuclear power reactor facilities,
>
> 1. The first and most important line of safety protection is the achievement of superior quality in design, construction and operation of basic reactor systems important to safety, which insures a very low probability of accidents. . . . Emphasis on this objective is reflected in:
>
>   The stress placed on selection of proper materials, quality controls in fabrication of components, rigorous systems of inspection and testing, appropriate techniques and controls in workmanship.
>
>   The requirement of high standards of engineering practice in design for critical components and systems. For example, the principles of fail-safe design, redundancy and backup, defense-in-depth, and extra margins of safety at key points are employed. The principle of defense-in-depth is illustrated by the successive barriers provided

[3] Much of this historical background is taken directly from a letter by J.N. Sorensen to the ACRS entitled "Historical Notes on Defense in Depth," dated October 15, 1997.

against the escape of fission products: (1) the ceramic uranium oxide fuel matrix has a very high retention capacity. .; (2) the fuel pins are sheathed in impervious claddings of stainless steel or zirconium; (3) the fuel core is enclosed in a high-integrity, pressure-tested primary coolant system. ., (4) a high-integrity pressureand-leak-tested containment building entirely surrounds each reactor structure.

Regularly scheduled equipment checks and maintenance programs; prompt and thorough investigation and correction of abnormal events, failures or malfunctions.

The requirements of sound and well defined principles of good management in operation; a competent and well-trained staff, clearly assigned duties, written procedures, checks and balances in the procedures for revisions, periodic internal audits of operations, etc.

2. The second line of defense consists of the accident prevention safety systems which are designed into the facility. These systems are intended to prevent mishaps and perturbations from escalating into major accidents. Included are such devices as redundancy in controls and shutdown devices; emergency power from independent sources -sometimes in triplicate -and emergency cooling systems.

3. The third line of defense consists of consequences-limiting safety systems. These systems are designed to confine or minimize the escape of fission products to the environment in case accidents should occur with the release of fission products from the fuel and the primary system. These include the containment building itself, building spray and washdown system, building cooling system . . ., and an internal filter-collection system.

Three related elements in the system of protection consist of the means for ensuring the effectiveness of these three basic lines of defense in the physical facility.

1. A major element is systematic analysis and evaluation of the proposed reactor design .. up to and including the so-called "maximum credible accident."

2. The system of numerous independent reviews by experts in the safety analysis and evaluation of a proposed facility by licensee experts and consultants, by the regulatory staff, the ACRS, the Atomic Safety and Licensing Boards, and the Commission .

3. A system of surveillance and inspection is the final element mentioned here. During construction and after the reactor becomes operative, surveillance is maintained by means of periodic inspections, periodic reports from the company, examination of operating records, and investigation of facility irregularities."

Internal Study Group, 1969

Another reference to defense-in-depth occurs in the "Report to the Atomic Energy Commission on the Reactor Licensing Program," by the Internal Study Group, June 1969. This study was initiated by the AEC in June 1968 to help assure that procedures keep pace with the rapid expansion of the nuclear industry. The study group members were appointed from the AEC staff, the ACRS, and the Atomic Safety and Licensing Board Panel. The report states:

"The achievement of an adequate level of safety for nuclear power plants is generally recognized to require defense-in-depth in the design of the plant and its additional engineered safety features. The degree of emphasis on defense-in-depth in the nuclear field is new to the power industry.

In seeking reliability of safety systems, there has been much attention in the nuclear field to redundancy, diversity, and quality control. As a result of the evolution of designs, and the large number of new orders for nuclear plants, questions have been raised regarding the proper balance among back-up systems with respect to the requirements of basic plant design.

The Study Group endorses the defense-in-depth concept, but believes that the greatest emphasis should be placed on the first line of defense, i.e., on designing, constructing, testing and operating a plant so that it will perform during normal and abnormal conditions in a reliable and predictable manner,"

ECCS Hearings, 1971

The third historical document of interest is the testimony of the AEC Regulatory Staff at the Public Rulemaking Hearings on Interim Acceptance Criteria for Emergency Core Cooling Systems for Light Water Power Reactors, issued December 28, 1971. The introduction to this document includes a subsection titled "Defense-in-depth." The testimony states,

"The safety goal, therefore, is the prevention of exposure of people to this radioactivity. This goal can be achieved with a high degree of assurance, though not perfectly, by use of the concept of defense-in-depth. The principal defense is through the prevention of accidents. All structures, systems, and components important to safety must be designed, built, and operated so that the probability of an accident occurring is very small. The keys to achievement of this objective are quality and quality assurance, independently and concurrently. The work must be done well and then checked well, in order for the chance for errors and flaws to be reduced to an acceptable level.

However, excellent the design and execution, and however comprehensive the quality assurance, they must be acknowledged to be imperfect. As a second line of defense, protective systems are provided to take corrective actions as required should deviations from expected behavior occur, despite all that is done to prevent them. The protective systems include redundant elements, provision for periodic in-service testing, and other features to enhance performance and reliability.

Yet another defense -the third line -is provided by installing engineered safety features to mitigate the consequences of postulated serious accidents, in spite of the fact that these accidents are highly unlikely because of the first two lines of defense. Analogously to protective systems, engineered safety features are furnished with redundant elements, separate sources of energy an fluids, protection against natural phenomena and manmade accidents, and other similar elements to ensure their correct functioning in the unlikely event they are called upon.

The three separate lines of the defense-in-depth provided for power reactors are considered appropriate to reduce to an acceptable value the probability and potential consequences of radioactive releases. Extensive and comprehensive quality assurance programs are required and used to assure the integrity of each line of defense and to maintain the different lines as nearly independent as practicable."

The same introductory section includes a subsection titled "Probability and Margins." That subsection states,

> ". . . the ECCS is part of the third line of defense, in the defense-in-depth concept used to ensure reactor safety. The design basis for ECCS is the postulated spectrum of LOCAs, for which the ECCS is required to provide protection for the public. This is consistent with defense-in-depth, and we believe the provision of such protection, with this design basis, to be proper."

In addition, in a subsection titled "Conclusions," it states:

> "Quality in the design, manufacture, installation and operation of the primary system is a necessary part of the defense-in-depth."

WASH-1250, 1973

Another document that was in development at the same time the above testimony was prepared is WASH-1250, "The Safety of Nuclear Power Reactors (Light Water Cooled) and Related Facilities." This document was completed in 1973.

The first chapter, "Description of Light Water Reactor Power Plants and Related Facilities," states that

"While differences in detail exist among PWR plants and among BWR plants, the basic features of each type are much the same. All are massive and complex structures, designed and built to provide multiple barriers to the escape of radioactive material, from whatever cause, and to withstand the occurrences of natural forces . . . without compromising these barriers. The term "defense-in-depth is not introduced at that point.

Chapter 2, titled "Basic Philosophy and Practices for Assuring Safety," states that

> "the basic philosophy underlying the AEC Rules of Procedure and Regulatory Standards, and underlying industrial practices . . . is frequently called a 'defense-in-depth' philosophy." The discussion goes on to note that "Previous mention has been made of the use of multiple barriers against the escape of radioactivity . . . Of equal importance, however, is the need to assure that these barriers will not be jeopardized by off-normal occurrences . . . In this regard, the industry strives to protect the plant, the plant operators, and the health and safety of the public by application of a "defense-in-depth" design philosophy, as required within the variation allowed by the regulatory envelope of rules, procedures, criteria and standards. A convenient method of describing this "defense-in-depth" is to discuss it in the broader concept of three levels of safety."

10 CFR Part 60, Statements of Consideration

The term "defense-in-depth" does appear in the statements of Consideration for 10 CFR Part 60. In this case, defense-in-depth appears to be defined in terms of multiple barriers (as much systematic as physical), and the concept of balance is introduced. Specifically, the SOC for the final rule (48 FR 28194-28299), contain the statement:

> "The Commission suggested that a course that would be "reasonable and practical" would be to adopt a "defense-in-depth" approach that would prescribe minimum performance standards for each of the major elements of the geologic repository, in addition to prescribing the EPA standard as a single overall performance standard. There was general acceptance of the Commission's multiple barrier approach, with its identification of two major engineered barriers (waste package and underground facility) in addition to the natural barrier provided by the geologic setting."

Later the SOC state "There is nothing inconsistent between the multiple barrier, defense-in-depth approach and a unitary EPA standard."

Post-TMI Definitions and Examples, 1981

R.J. Breen, Deputy Director of EPRI's Nuclear Safety Analysis Center, published a paper titled "Defense-in-depth Approach to Safety in Light of the Three Mile Island Accident (Nuclear Safety, Vol. 22, No.5, Sept.-Oct. 1981). Breen refers to defense-in-depth as a "concept," and states that ". . . the principle of guarding against unwanted events by providing successive protective barriers is frequently called "defense-in-depth." Breen acknowledges that there are various ways of describing the application of defense-in-depth, and then chooses a "fairly common three level description emphasizing functions," which he lists as:

1. Preventing initiation of incidents (conservative design margins, etc.)
2. Capability to detect and terminate incidents
3. Protecting the public.

Breen then goes on to pose the question, to what extent can defense-in-depth be quantified? He notes that one of the functions of PRA, when the technology is more fully developed, is to help quantify defense-in-depth. Until that time arrives, when confronted with a long list of possible safety enhancements, the problem is to determine which activities make the greatest contribution to safety. He mentions that NRC used a point system in NUREG-660, and then goes on to describe a ranking system developed by NSAC and the Atomic Industrial Forum. The system was based on (1) the number of important accident sequences affected, (2) the likelihood that the specified action can be implemented and will reduce risk, (3) a downside assessment (hazards or risks that may result from implementing a proposed action), and (4) the time required to implement the proposed action.

NUREG/CR-6042 , Perspectives on Reactor Safety, 1994

NUREG/CR-6042, "Perspectives on Reactor Safety," by F. E. Haskin (University of New Mexico) and A. L. Campbell (Sandia National Laboratory), 1994, which describes a one week course in reactor safety concepts offered by the NRC Technical Training Center introduces defense-in-depth by listing ". ,the key elements of an overall safety strategy that began to emerge in the early 1950s and has become known as defense-in-depth." The key elements listed are accident prevention, safety systems, containment, accident management, and siting and emergency plans.

NRC Commission Policy Statements, 1986, 1994 (2008), 1995

The term occurs in three Commission Policy Statements: the Safety Goal Policy Statement, the Advanced Nuclear Power Plant Policy Statement (2008), and the PRA Policy Statement. None of these documents offer a definition of defense-in-depth, except by example or implication.

Commission policy on Safety Goals (1986) contains the following statements:

> “The Commission recognizes the importance of mitigating the consequences of a core-melt accident and continues to emphasize features such as containment, siting in less populated areas, and emergency planning as integral parts of the defense-in-depth concept associated with its accident prevention and mitigation philosophy.”

> “. . . the probabilistic results should also be reasonably balanced and supported through use of deterministic arguments. In this way, judgements can be made by the decisionmaker

about the degree of confidence to be given to these estimates and assumptions. This is a key part of the process of determining the degree of regulatory conservatism that may be warranted for particular decisions. This defense-in-depth approach is expected to continue to ensure the protection of public health and safety."

"A defense-in-depth approach has been mandated in order to prevent accidents from happening and to mitigate their consequences. Siting in less populated areas is emphasized. Furthermore, emergency response capabilities are mandated to provide additional defense-in-depth protection to the surrounding population."

Additional views offered by Commissioners:

". . .the Commission should have developed a policy on the relative emphasis to be given to accident prevention and accident mitigation. Such guidance is necessary to ensure that the principle of defense-in-depth is maintained."

"In order to assure a proper balance between accident prevention and accident mitigation, the mean frequency of containment failure in the event of a severe core damage accident should be less than 1 in 100 severe core damage accidents."

". . . a containment performance objective is an element of ensuring that the principle of defense-in-depth is maintained."

"Consistent with the Commission's long-standing defense-in-depth philosophy, both core-melt and containment performance criteria should therefore be clearly stated parts of the Commission's safety goals."

". . .this pudding lacks a theme. Meaningful assurance to the public; substantive guidance to the NRC staff; the regulatory path to the future of the industry—all these should be provided by plainly stating that, consistent with the Commission's "defense-in-depth" philosophy:

(1) Severe core-damage accident should not be expected, on average, to occur . . .
(2) Containment performance . . . such that severe accidents . . . are not expected to occur . . .
(3) The goal for offsite consequences should be expected to be met after conservative consideration of the uncertainties . . ."

Commission policy on Regulation of Advanced Reactors (1994/2008) contains the following statement:

" Designs that incorporate the defense-in-depth philosophy by maintaining multiple barriers against radiation release, and by reducing the potential for, and consequences of, severe accidents."

Commission policy on PRA (1995) contain the following statements:

In response to public comments regarding the role of PRA, the NRC response stated that "It is not the Commission's intent to replace traditional defense-in-depth concepts with PRA. . . "

In response to public comments on PRA methodology, the NRC response stated that "Deterministic-based regulations have been successful in protecting the public health and safety and PRA techniques are most valuable when the serve to focus the traditional, deterministic-based, regulations and support he defense-in-depth philosophy."

In the discussion on deterministic and probabilities approaches to regulation, regarding the defense-in-depth philosophy, the NRC states "In the defense-in-depth philosophy, the Commission recognizes that complete reliance for safety cannot be placed on any single element of the design, maintenance, or operation of a nuclear power plant. Thus, the expanded use of PRA technology will continue to support the NRC's defense-in-depth philosophy by allowing quantification of the levels of protection and by helping to identify and address weaknesses or overly conservative regulatory requirements applicable to the nuclear industry. Defense-in-depth is a philosophy used by NRC to provide redundancy for facilities with "active" safety systems, e.g., a commercial nuclear power, as well as the philosophy of a multiple-barrier approach against fission product releases. Such barrier principles are mandated by the Nuclear Water Policy Act of 1982, which provides redundancy for a geologic repository to contain and isolate nuclear waste from the human environment."

The policy statement itself states that "the use of PRA technology should . . . complement the NRC's deterministic approach and support the "NRC's traditional defense-in-depth philosophy."

NUREG-1537, Part 1, 1996

NUREG-1537 (Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors) very briefly references defense-in-depth. It states, regarding describing "the principal architectural and engineering design criteria for the structures, systems and components that are required to ensure reactor facility safety and protection of the public," that the "material presented should emphasize the safety and protective functions and related design features that help provide defense-in-depth against uncontrolled release of radioactive material."

Chairman Jackson MIT Speech, 1997

Chairman Jackson, in a talk at the MIT Nuclear Power Reactor Safety Course, notes that "the NRC safety philosophy is . . . comprises several closely interrelated elements . . . The elements are: defense-in-depth, licensee responsibility, safety culture, regulatory effectiveness, and accountability to the public. Defense-in-Depth ensures that successive measures are incorporated into the design and operating procedures for nuclear installations to compensate for potential failures in protection or safety measures, wherever such failures could lead to serious public or national security consequences."

Some Thoughts on Defense-in-Depth by Tom Kress, 1997

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The techniques and tools for determining risk were not well developed and risk measures were unavailable to the regulator. NRC developed a regulatory philosophy that it called defense-in-depth which can be viewed as providing balance among three "levels" of protection: preventing the initiation of accidents, stopping (or limiting) the progression of an accident, and providing for evacuation in the event of accidental release of fission products. Each of the three levels are to be implemented by providing multiple independent provisions to accomplish the desired function.

Regarding the three elements, the first (DID prevention) is implemented through provisions that include such things as quality in construction, QA, inspections and maintenance, testing, redundant and diverse emergency power supplies. The second element includes such concepts as multiple physical barriers, redundant and diverse shutdown systems. The third element includes provisions for siting and the plans for evacuation and sheltering. This implementation of DID results in about everything the NRC does is part of DID and become difficult to separate out just those things that would be considered purely DID requirements.

All aspects of DID are reflected in the PRA. The first level is reflected in the initiating event frequencies of the various accident sequences, the second level in the conditional CDF, CCFP and LERF, and the third level in the final conditional risk measure on early and late fatalities as well as on land contamination. The PRA results can be considered a measure of the effectiveness of the overall implementation of DID. Moreover, use of DID would be a means to reduce both the risk and the uncertainty DID is a philosophy that guides the regulatory process and the DID provision and requirements are implicit and scattered throughout the entirety of the regulatory activities and regulations. These already spell out the necessary and sufficiency conditions.

Regarding the need for a policy statement, for the first and third level, there appears to be little need or basis for further clarification. The second level, which is most closely related to deisgn and hardware issues, further clarification may be needed, particularly on what constitutes appropriate regulatory balance between CDF and CCFP.

Rational approach for developing a policy statement would be:

- Presume the current regulations and requirements for level 1 and level 3 elements are sufficient.
- Establish “N+1” as a DID principle.
- Establish risk acceptance criteria on CDF and CCFP that takes into account the uncertainties.
- Establish (via expert judgment) and appropriate regulatory balance between CDF and CCFP (or LERF).
- Mandate that certain Level 2 DID features be required (e.g., redundant and diverse shutdown systems, ECCS and long-term cooling, containment)
- Mandate that the containment design must accoodateall severe accident loads and not fail by virtue of only its volume, strength, and natural heat transfer properties..

Commission White paper, 1999

Chairman Jackson has also recently provided her thoughts on defense-in-depth in a March 1999 White Paper. In it, she states that “The concept of defense-in-depth has always been and will continue to be a fundamental tenet of regulatory practice in the nuclear field, particularly regarding nuclear facilities. Risk insights can make the elements of defense-in-depth more clear by quantifying them to the extent practicable. Although the uncertainties associated with the importance of some elements of defense may be substantial, the fact that these elements and uncertainties have been quantified can aid in determining how much defense makes regulatory sense. Decisions on the adequacy of or the necessity for elements of defense should reflect risk insights gained through identification of the individual performance of each defense system in relation to overall performance.” She goes on to state that “Defense-in-depth is an element of the NRC's Safety Philosophy that employs successive compensatory measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges."

PSA Paper, 1999

For the 1999 PSA Conference, a paper by J.N. Sorenson, et. al., was presented entitled "On the Role of Defense in Depth in Risk-Informed Regulation." The authors note that there are "two different schools of thought (models) on the scope and nature of defense in depth. The models came to be labeled 'structuralist' and 'rationalist.'" The paper provides a discussion of the two models:

> "The structuralist model asserts that defense in depth is embodied in the structure of the regulations and in the design of the facilities built to comply with those regulations. The requirements for defense in depth are derived by repeated application of the question, "What if this barrier or safety feature fails?" The results of that process are documented in the regulations themselves, specifically in Title 10, Code of Federal Regulations. In this model, the necessary and sufficient conditions are those that can be derived from Title 10: It is also a characteristic of this model that balance must be preserved among the high-level lines of defense, e.g., preventing accident initiators, terminating accident sequences quickly, and mitigating accidents that are not successfully terminated. One result is that certain provisions for safety, for example reactor containment and emergency planning, must be made regardless of our assessment of the probability that they may be required. Accident prevention alone is not relied upon to achieve an adequate level of protection.
>
> The rationalist model asserts that defense in depth is the aggregate of provisions made to compensate for uncertainty and incompleteness in our knowledge of accident initiation and progression. This model is made practical by the development of the ability to quantify risk and estimate uncertainty using probabilistic risk assessment techniques. The process envisioned by the rationalist is: (1) establish quantitative acceptance criteria, such as the quantitative health objectives, core damage frequency and large early release frequency, (2) analyze the system using PRA methods to establish that the acceptance criteria are met, and (3) evaluate the uncertainties in the analysis, especially those due to model incompleteness, and determine what steps should be taken to compensate for those uncertainties. In this model, the purpose of defense in depth is to increase the degree of confidence in the results of the PRA or other analyses supporting the conclusion that adequate safety has been achieved.
>
> The underlying philosophy here is that the probability of accidents must be acceptably low. Provisions made to achieve sufficiently low accident probabilities are defense in depth. It should be noted that defense in depth may be manifested in safety goals and acceptance criteria which are input to the design process. In choosing goals for core damage frequency and conditional containment failure probability, for example, a judgment is made on the balance between prevention and mitigation.
>
> What distinguishes the rationalist model from the structural model is the degree to which it depends on establishing quantitative acceptance criteria, and then carrying formal analyses, including analysis of uncertainties, as far as the analytical methodology permits. The exercise of engineering judgment, to determine the kind and extent of defense in depth measures, occurs after the capabilities of the analyses have been exhausted."

The authors propose two options:

1. defense in depth as a supplement to risk analysis (the rationalist view)
2. a high-level structural view and a low-level rationalist view.

> "Option (1) requires a significant change in the regulatory structure. The place of defense in depth in the regulatory hierarchy would have to change. The PRA policy statement could no longer relegate PRA to a position of supporting defense in depth. Defense in depth would become an element of the overall safety analysis.
>
> Option (2) is to a large degree compatible with the current regulatory structure. The structuralist model of defense in depth would be retained as the high-level safety philosophy, but the rationalist model would be used at lower levels in the safety hierarchy."

The authors view "Option (2) as a pragmatic approach to reconciling defense in depth with risk-informed regulation. However, "the rationalist model, Option (1), will ultimately provide the strongest theoretical foundation for risk-informed regulation."

ACRS Letters, 1999, 2000

The ACRS has provided their insights on defense-in-depth over the years, and predominantly in two specific letters regarding reactors and nuclear materials. The Committee's views on reactors is provided in a May 19, 1999, letter to Chairman Shirley Jackson entitled "The Role of Defense in Depth in a Risk-Informed Regulatory System." In this letter, the Committee discusses the appropriate relationship and balance between probabilistic risk assessment and defense in depth in the context of risk-informed regulation. The Committee states:

> "Improved capability to analyze nuclear power plants as integrated systems is leading us to reconsider the role of defense in depth. Defense in depth can still provide needed safety assurance in areas not treated or poorly treated by modem analyses or when results of the analyses are quite uncertain. To avoid conflict between the useful elements of defense in depth and the benefits that can be derived from quantitative risk assessment methods, constraints of necessity and sufficiency must be imposed on the application of defense in depth and these must somehow be related to the uncertainties associated with our ability to assess the risk.
>
> We believe that two different perceptions of defense in depth are prominent. In one view (the "structuralist" view. . .), defense in depth is considered to be the application of multiple and redundant measures to identify, prevent, or mitigate accidents to such a degree that the design meets the safety objectives. This is the general view taken by the plant designers. The other view (the "rationalist"), sees the proper role of defense in depth in a risk-informed regulatory scheme as compensation for inadequacies, incompleteness, and omissions of risk analyses. We choose here to refer to the inadequacies, incompleteness, and omissions collectively as uncertainties. Defense-in-depth measures are those that are applied to the design or operation of a plant in order to reduce the uncertainties in the determination of the overall regulatory objectives to acceptable levels. Ideally then, there would be an inverse correlation between the uncertainty in the results of risk assessments and the extent to which defense in depth is applied. For those uncertainties that can be directly evaluated, this inverse correlation between defense in depth and the uncertainty should be manifest in a sophisticated PRA uncertainty analysis.
>
> When defense in depth is applied, a justification is needed that is as quantitative as possible of both the necessity and sufficiency of the defense-in-depth measures. Unless defense-in-

depth measures are justified in terms of necessity and sufficiency, the full benefits of risk-informed regulation cannot be realized.

The use of quantitative risk-assessment methods and the proper imposition of defense-in-depth measures would be facilitated considerably by the availability of risk-acceptance criteria applicable at a greater level of detail than those we now have. Development of the additional risk-acceptance criteria would have to take into consideration safety objectives embodied in the existing regulations. . . . Setting such acceptance values is a policy role, very much like setting safety goal values. The uncertainties that are intended to be compensated for by defense in depth include all uncertainties (epistemic and aleatory). Not all of these are directly assessed in a normal PRA uncertainty analysis. Therefore, when acceptance values are placed on uncertainty, these would have to appropriately incorporate consideration of the additional uncertainties not subject to direct quantification by the PRA. These considerations would have to be determined by judgment and expert opinion. As a practical matter, we suggest that the acceptance values be placed on only those epistemic uncertainties quantifiable by the PRA but that these be set sufficiently low to accommodate the unquantified aleatory uncertainties.

When acceptance values have been chosen as policy for the regulatory objectives and their associated uncertainties, it would be possible to develop objective limits on the amount of defense in depth required for those design and operational elements that are subject to evaluation by PRA. . .

The balance between core damage frequency (CDF) and conditional containment failure probability (CCFP) can serve as an example of this defense-in-depth concept. . . In our view, three acceptance criteria must be satisfied -one each on CDF, LERF, and the epistemic uncertainty associated with LERF. . . We believe this concept of defense in depth can provide a rational way to develop sufficiency limits wherever the defense-in-depth measures can be directly evaluated by PRA. We acknowledge however, that considerable judgment will have to be exercised to set limits on uncertainty, especially uncertainties not quantified by the PRA."

The Committee's views on nuclear materials is provided in a May 25, 2000, letter to Chairman Richard Meserve entitled "Use of Defense in Depth in Risk-Informing NMSS Activities." In this letter, the Committee provided their review of the use of defense in depth in risk informing the activities of NMSS. The Committee states:

1. The various compensatory measures taken for the purposes of defense in depth can be graded according to the risk posed by the activity, the contribution of each compensatory measure to risk reduction, the uncertainties in the risk assessment, and the need to build stakeholders trust.

2. The treatment of defense in depth for transportation, storage, processing and fabrication should be similar to its treatment for reactors. Defense in depth for industrial and medical applications can be minimal and addressed on the basis of actuarial information.

3. Defense in depth for protecting the public and the environment from high-level waste (HLW) repositories is both a technical and a policy issue. It is important that a reasonable balance be achieved in the contribution of the various compensatory measures to the reduction of risk. The staff should develop options on how to achieve the desired balance. The opinions of experts and other stakeholders should be sought

regarding the appropriateness of each option.

4. Since the balancing of compensatory measures to achieve defense in depth depends on the acceptability of the risk posed by the facility or activity, risk-acceptance criteria should be developed for all NMSS-regulated activities.

The Committee further states:

> We agree that there is a need for a common understanding of defense in depth as it relates to a risk-informed regulatory system and that a good working definition is provided in the Commission's White Paper on Risk-Informed and Performance-Based Regulation (Reference 1): Defense-in-Depth is an element of the NRC's safety philosophy that employs successive compensatory measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility.
>
> . . . The primary need for improving the implementation of defense in depth in a risk-informed regulatory system is guidance to determine how many compensatory measures are appropriate and how good these should be. To address this need, we believe that the following guiding principles are important:
>
> - Defense in depth is invoked primarily as a strategy to ensure public safety given the unquantified uncertainty in risk assessments. The nature and extent of compensatory measures should be related, in part, to the degree of uncertainty.
> - The nature and extent of compensatory measures should depend on the degree of risk posed by the licensed activity.
> - How good each compensatory measure should be is, to a large extent, a value judgment and, thus, a matter of policy.

With regard to nuclear reactors, the Committee states:

> ". . . It is the CDF distribution that should determine if additional compensatory measures are needed due to inadequate models. In general, the more such measures are added, the more this distribution shifts to lower frequency values. What CDF distribution is acceptable is a matter of policy. As noted above, the current regulatory system for reactors has evolved without the benefit of these probability distributions. Consequently, the structuralist approach to defense in depth was employed that involves placing compensatory measures on important safety cornerstones to satisfy acceptance criteria for defined design-basis accidents that represent the range of important accident sequences."

With regard to nuclear materials, the Committee states:

> "The issue of defense in depth and the suggested guiding principles have to be considered somewhat differently when it comes to nuclear materials. For example, there is much less experience in the application of PRA methods to nuclear materials than for nuclear reactors. Although materials systems are not as complex as those for reactors in terms of the assessment of risk, there is greater diversity in materials licensed activities. Perhaps the biggest difference relates to the basic differences in the safety issues between reactors and nuclear waste disposal, especially with regard to HLW repositories. The principal concern in the safety of such repositories is not a catastrophic release of radiation resulting from an accident, but rather the loss through contamination of a valuable life-supporting resource

such as ground water or land use. Both can be pathways for radiation exposure to humans. On the other hand, both lend themselves to simple interdiction and intervention measures for the protection of public health and safety. Therefore, the concept of defense in depth for repositories should be targeted more towards protecting resources where there are high uncertainties due to the very long time involved. Although the accident perspective is somewhat important during pre-closure operations, it is not the dominant safety issue in the area of nuclear waste. Pre-closure operations do, however, lend themselves to using risk assessment methods similar to those applied to reactor facilities.

With respect to the issue of the diversity of nuclear materials, SECY-99-100 categorizes nuclear materials into four groups. The four groups are abbreviated here as nuclear material activities involving: (1) disposal, (2) transportation and storage, (3) processing and fabrication, and (4) industrial and medical applications.

For disposal (Group 1), the reactor example suggests an approach for considering the effectiveness of protective barriers. For waste disposal facilities, defense in depth is implemented through the use of multiple barriers. For transportation and processing facilities (Groups 2 and 3), PRA methods similar to those applied to reactors can be used and defense in depth can be treated as it is for reactors. For industrial and medical applications (Group 4), we believe that sufficient data exist for many of these nuclear materials activities so that the uncertainties in estimating risks are relatively small. For Group 4 materials, defense in depth can be minimal and can be addressed on the basis of actuarial information, an advantage not available to the same extent for Groups 1-3."

The Committee goes on to state:

"Implementation of regulations within a risk-informed framework, including the use of defense in depth, requires the establishment of risk-acceptance criteria for each regulated activity. In most cases, a facility (or a proposed design) already exists with compensatory measures in place. The questions then become (1) Are these measures sufficient for the facility or design to meet the risk-acceptance criteria? (2) Do the measures compensate sufficiently for uncertainties in their assessment? (3) Will the measures gain stakeholder acceptance? Answering these questions is the most difficult aspect of the appropriate utilization of defense in depth in a risk-informed regulatory framework and is the key to establishing limits of necessity and sufficiency.

. . . For nuclear materials applications, including HLW repositories, we recommend the following pragmatic approach for selecting compensatory measures:

1. The contribution that each individual safety system makes in achieving the risk acceptance criterion should be determined by risk assessment with quantified uncertainty distributions.

2. The adequacy of the risk-assessment models should be evaluated quantitatively where possible and qualitatively in all aspects.

3. Whether the appropriate balance has been achieved can be judged through the opinions of experts and of other stakeholders and is ultimately a policy issue.

4. Policy options should be formulated on how the appropriate balance can be achieved. The impact of each option on building stakeholder trust should be evaluated.

IAEA Documents, 1988, 1996, 1999, 2009

INSAG -3. 1988

The International Nuclear Safety Advisory Group in INSAG-3, "Basic Safety Principles for Nuclear Power Plants," IAEA, 1988, explains defense in depth by stating that "All safety activities, whether organizational, behavioural or equipment related, are subject to layers of overlapping provisions, so that if a failure should occur it would be compensated for or corrected without causing harm to individuals or the public at large. This idea of multiple levels of protection is the central feature of defence in depth, and it is repeatedly used in the specific safety principles that follow."

The document then goes on to state the principle of defense-in-depth is "To compensate for potential human and mechanical failures, a defense in depth concept is implemented, centered on several levels of protection including successive barriers preventing the release of radioactive material to the environment. The concept includes protection of the barrier by averting damage to the plant and to the barriers themselves. It includes further measures to protect the public and the environment from harm in case these barriers are not fully effective."

INSAG-10, 1996

The International Nuclear Safety Advisory Group in INSAG-10, "Defense in Depth in Nuclear Safety," IAEA, 1996, restates the explanation on defense in depth provided in INSAG-3. It further states that "Defense in depth consists in a hierarchical deployment of different levels of equipment and procedures in order to maintain the effectiveness of physical barriers placed between radioactive materials and workers, the public or the environment, in normal operation, anticipated operational occurrence and, for some barriers, in accident in the plant." The report states the objectives of defense in depth are to "compensate for potential human and component failures, maintain the effectiveness of barriers by averting damage to the plant and to the barrier themselves, and protect the public and environment from harm in the event that these barriers are not fully effective." It goes on to state that "the strategy for defense in depth is twofold: first, to prevent accidents and, second, if prevention fails, to limit their potential consequences and prevent any evolution to more serious conditions. Accident prevention is the first priority. . ."

Five levels of defense are defined such that if one level fails, the subsequent level comes into play. The objectives of the five levels are as follows:

1. Prevention of abnormal operation and system failures
2. Control of abnormal operation and detection of failures
3. Control of accident within the design basis
4. Control of severe conditions including prevention of accident progression and mitigation of the consequences of a severe accident
5. Mitigation of the radiological consequences of significant external releases of radioactive materials.

With respect to the above levels, the report states that "the general objective of defense in depth is to ensure that a single failure, whether equipment failure or human failure, at one level of defense, and even combinations of failures at more than one level of defense, would not propagate to jeopardize defense in depth at subsequent levels." Moreover, for each of the levels, further explanation is provided along with examples of how to implement. The report also states that "For the effective implementation of defense in depth, some basic prerequisites apply to all measures at Levels 1 to 5. These prerequisites . . . are appropriate conservatism, quality assurance and safety culture." The goal for each prerequisite is provided in the report.

INSAG-12, 1999

INSAG-12, "Basic Safety Principles for Nuclear Power Plants," provides a logical framework for understanding the underlying objectives and principles of nuclear safety, and the way in which its aspects are interrelated. Defense in depth is discussed as a fundamental principle. These statements regarding defense in depth, while similar, are slightly different than in INSAG-3 or 10. In this report, defense in depth is a principle "to compensate for potential human and mechanical failures, a defense in depth concept is implemented, centered on several levels of protection including successive barriers preventing the release of radioactive material to the environment. The concept includes protection of the barriers by averting damage to the plant and to the barriers themselves. It includes further measures to protect the public and the environment from harm in case these barriers are not fully effective." The report goes on to state the "the principle of defense in depth is implemented primarily by means of a series of barriers which would in principle never be jeopardized, and which must be violated in turn before harm can occur to people or the environment. These barriers are physical, providing for the confinement of radioactive material at successive locations. The barriers may serve operational and safety purposes, or may serve safety purposes only. Power operation is only allowed if this multibarrier system is not jeopardized and is capable of functioning as designed." This report also states that the strategy for defense in depth is twofold: first, to prevent accident and second, if prevention fails, to limit the potential consequences of accidents and to prevent their evolution to more serious conditions." It provides a definition and criteria for accident prevention and accident mitigation. Moreover, it also uses the same five levels presented in INSAG-10. It is also consistent with INSAG-10 in stating "the existence of several levels of defense in depth is never justification for continued operation in the absence of one level." INSAG-12 goes further than INSAG-10 in that it relates the five levels of defense in depth to the five operational states of nuclear power plants and classifies them either as accident prevention or accident mitigation as follows:

Accident prevention –

- Level 1 (Prevention of abnormal operation and failure) – normal operation
- Level 2 (Control of abnormal operation and detection of failures) – anticipated operational occurrences
- Level 3 (Control of accidents below the severity level postulated in the design basis) – design basis and complex operating states

Accident mitigation –

- Level 4 (Control of severe plant conditions, including prevention of accident progression, and mitigation of the consequences of severe accidents, including confinement protection) – severe accidents beyond the design basis
- Level 5 (Mitigation of radiological consequences of significant releases of radioactive materials) – post-severe accident situation

IAEA NP-T-2.2, 2009

NP-T-2.2, "Proposal for a Technology-Neutral Safety Approach for New Reactor Designs," provides a technology-neutral safety approach to guide the design, safety assessment and licensing of innovative reactors. As part of the proposed approach, three "main pillars" are proposed, one of which defense in depth which includes probabilistic considerations. The document references INSAG-10 in terms of the five levels, however, it also provides safety goals that are to be factored into the implementation of defense in depth. Quantitative Safety Goals targets are correlated to each level of defense in depth via a frequency consequence curve (the consequences being various accidents against acceptable frequencies). For example, normal operational occurrences are accommodated only within the first level of defense in depth and result in no consequences, as the aim of this level is to prevent deviations from normal operation and to prevent system failures. The second level of defense in depth assures, by detecting and intercepting deviations from normal operational states, that the consequences of events above a frequency of 10-2/yr (i.e., anticipated operational occurrences) are within the success criteria of this second level of defense. Similar approach is followed for the remaining three levels. "The ultimate objective is that any credible accident sequence, even considering the failures of lines of protection for the different levels of defense in depth, remain under the overall frequency consequence curve."

NP-T-2.2 also introduced the concept of a line of protection (LOP). A LOP is identified in the document for each safety function and for each level of defense in depth. "It is an effective defense against a given mechanism or event that has the potential to impair a fundamental safety function. It is used for any set of inherent characteristics, equipment, system (active or passive), etc., that is part of the plant safety architecture, the objective of which is to accomplish the mission needed to achieve a given safety function. For a given event, and against a given safety function, the LOPs provide the practical means of successfully achieving the objectives of the individual levels of defense."

10 CFR Part 50, Appendix R, 2000

The term defense-in-depth only appears in the regulations in Title 10 of the Code of Federal Regulations Part 50, Appendix R ("Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979"), where it appears once. The specific statement occurs in Section II.A, General Requirements, Fire Protection Program, which states in part,

> "The fire protection program shall extend the concept of defense-in-depth to fire protection in fire areas important to safety, with the following objectives:
>
> - To prevent fires from starting;
> - To detect rapidly, control, and extinguish promptly those fires that do occur;
> - To provide protection for systems, structures and components important to safety so that a fire that is not promptly extinguished will not prevent the safe shutdown of the plant."

In June 2000, the NRC amended Appendix R to remove the requirement that fire barrier penetration seal materials be noncombustible, and to make other minor changes. As part of the rule change, a public comment was received which related to defense-in-depth:

> "By providing for the acceptance of combustible penetration seals, the NRC is reducing the level of defense-in-depth without fully analyzing the risks associated with accelerated burn-through of seals from the combination of these widely documented factors."

Joint ACNW/ACRS Subcommittee, January 13/14, 2000

EDIT TO SHOW THOUGHTS ARE FROM PRESENTERS

Defense-in-depth: Perspective for Risk-Informing 10 CFR 50, Tom King, Gary Holahan

DID philosophy included in reactor regulations, in licensing and licensee amendment process, and in reactor oversight process. DID includes multilayer protection from fission products; for example, ceramic fuel pellets, metal cladding, reactor vessel and piping, containment, exclusion area, low population zone and evacuation plan, and population center distance. GDCs provide for DID; for example, 1-5, 10-18, 20-29, 30-46, 50-57, and 60-64. Reactor oversight process cornerstones are a DID concept.

Should develop a working definition of DID that establishes an approach in risk-informing 10 CFR part 50. It should provide for multiple lines of defense, balance between prevention and mitigation, and provide for a framework to address uncertainties in accident scenarios. It should consist of two parts: fundamental elements that should be provided in all cases, and implementation elements that may vary depending on uncertainty and reliability and risk goals. The fundamental elements should build upon the cornerstone concept, assure for prevention and mitigation, and assure balance between prevention and mitigation to achieve an overall level of safety consistent with CDF and LERF goals. The implementation elements would use redundancy, diversity, QA, EQ, IST, safety margins, etc in a variable manner, as necessary, to achieve reliability and risk goals and balance of prevention and mitigation.

Design Defense-in-Depth in a Risk-Based Regulatory System with Imperfect PRA, Tom Kress

DID is a design and operational strategy for dealing with uncertainty in risk assessment. However, there are two concerns: does not constitute a precise definition in terms of risk assessment, a definition or criteria does not exist that allow for placing limits on DID.

DID philosophy consist of four principles: prevent accident from starting (initiation), stop accident at early stages before they progress to unacceptable consequences (intervention), provide for mitigating the release of the hazard vector (mitigation) and provide sufficient instrumentation to diagnose the type and progress of any accident (diagnosis). Base on the principles, definition of DID is "design DID is a strategy of providing design features to achieve acceptable risk (in view of the uncertainties) by the appropriate allocation of the risk reduction to both prevention and mitigation."

To put limits on DID, you must have risk acceptance criteria that you desire to allocate (preferable expressed in terms of confidence levels), and where quantifiable uncertainty should come out of the PRA, unquantifiable uncertainty should be estimated by expert opinion, and the acceptance criteria should include both uncertainties. Moreover, allocation is a value judgment in that we need criteria for how much we value prevention versus mitigation. Allocation could depend on the level of inherent hazard (the more hazardous the activity the more we should value prevention), depend on the extent of uncertainty in the risk assessment, depend on how much the uncertainty is unquantifiable, may want to minimize uncertainty, and may be based on the "loss function" of decision theory.

<u>Defense-in-Depth</u>, Robert Bernero

DID can be viewed by addressing six questions:

1. What is defense-in-depth? "DID is an element of NRC's Safety Philosophy that employs successive compensatory measure to prevent accident or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. The DID philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance or operation of a nuclear facility. The net effect of incorporating DID into design, construction, maintenance, and operation is that the facility or system in questions tends to be more tolerating of failures and external challenges." DID is not a formula for adequate protection; it is part of the safety philosophy, a strategy for safety analysis.

2. Is there an overarching philosophy of defense-in-depth? Yes, as a strategy of safety analysis. DID prevent undue reliance on single occurrence, design feature, barrier, or performance model. It is not a formula for acceptability, DID may not be enough defense. It is risk-informed achieving a sufficient margin of safety, neither too close nor too far from the unacceptable.

3. Are current safety goals and objectives clear for general use? No, not for general use. The span of protection includes public safety, worker safety, patient safety, environmental protection. The range of authorize practices include reactors, fuel cycle facilities, industrial and medical uses, exempt distribution, and transportation.

4. What is the role of DID in risk-informed regulation of nuclear reactors? Does not apply to routine releases. It is the basis for evaluating areas of heavy reliance in accident analysis; for example, seismic safety, RPV rupture, SG tube rupture, human action. It is a graded defense with graded goals.

5. What is the role of DID in risk-informed regulation of radioactive material processes and uses? May sometimes apply to routine releases, for example, exempt products. It needs graded goals for graded defenses. It needs to be thought through considering potential consequences, potential barriers, potential actions, and balanced chose of defense. It has "knotty" problems, for example, patient safety and medical QA.

6. What is the role of DID in risk-informed regulation of radioactive disposal? It definitely applies to release barriers. One fundamental basis of acceptability is the TSPA with proper uncertainty analysis. There is apparent confusion since DID analysis is a form of uncertainty analysis. Part 63 proposal is a sound approach to DID, develop the body of information for the exercise of judgment. You need graded goals for graded uncertainties; for example, clearly acceptable, acceptable, clearly tolerable, tolerable, life-threatening, unacceptable.

<u>On the Quantification of Defense-in-Depth</u>, John Garrick

The key to using PRA and probabilistic performance assessment (PPA) to determine whether we are getting our money's worth from multiple levels of defense and whether we need more or less is (1) understanding the role that the individual safety systems play in providing protection against the release of radiation to the environment, and (2) the effect of the individual systems acting in concert. The approach NEED TO COMPLETE

Defense-in-Depth for Risk-Informed Performance-Based Regulation: A Provisional NMSS Perspective, Norman Eisenberg

NMSS motivations for defense-in-depth – NMSS framework requires reexamination of regulatory approaches including DID and DID is addressed in various parts of the framework and in risk-informed activities (e.g., Part 63, ISA).

Several factors affect implementation of DID in NMSS; for example, nature of licensees and activities regulated, NMSS regulators systems with less hazard than nuclear power reactors.

Both a structuralist and rationalist approach to DID is defined. Regarding the structuralist, the need for and extent of DID is related to the system structure. For the rationalist approach, the need for and extent of DID is related to the residual uncertainties in the system.

There are two type of residual uncertainty. Type 1 (Best available risk assessment) involves a system for which a fairly complete risk analysis or safety analysis has been performed, so residual uncertainty relates to the confidence or lack of confidence in the analysis; i.e., the analysis does not represent all uncertainty because the state of knowledge is incomplete. Type 2 (Limited risk assessment) involves a system for which the risk or safety analysis is somehow limited (e.g., by not being complete, or not quantifying certain types of uncertainty). Details are provided describing the differences in the limitations of Type 1 versus Type 2.

NMSS safety philosophy is three-fold: (1) goal is reasonable assurance of protecting public health and safety, etc. (2) design concept assist in achieving this goal; for example, safety margin, DID, diversity, redundancy, etc. and (3) DID is a risk management method.

Suggestions are provided for describing the concept of margin in a probabilistic context.

There are differences between DID and margin:

- Margin relates to the “cushion” between required performance and expected performance
- DID relates to the characteristic of the system to (1) not rely on any single element of the system and (2) be more robust to challenges
- Margin describes expected performance of a system versus the safety limit; DID describe the ability of the system to compensate for unanticipated performance, which results from limitations on knowledge
- Margin and DID are orthogonal, so DID can be added without increasing margin
- Increasing margin in a system that relies on a single component, does not necessarily increase DID.
- DID assures that if any component fails, the rest of the system compensates, so consequences are not unacceptable.

Point is made that two different systems with the same reliability can have different DID characteristics.

Process is proposed for determining the amount of DID that is needed by examining the potential consequences posed by a system against the uncertainty in the performance of the system.

Conclusions on DID are provided which include:

- DID is related to, but different from, other design concepts such as safety margin, redundancy, and diversity.
- DID is not necessarily equivalent to meeting a safety goal or the margin associated with meeting the goal.
- DID can be implemented in a risk-informed, performance-based regulatory context as a system requirement, rather than as a set of subsystem requirements.
- DID can be used to address residual uncertainties concerning the performance of a safety system.
- The need for DID depends on the degree of residual uncertainty and the degree of hazard (i.e., consequences).

Several issues needing resolution were identified:

- How to measure the degree of DID?
- How to measure the degree of uncertainty in performance of the safety system, encompassing quantified and unquantified uncertainty?
- How to measure the degree of potential hazard (i.e., consequences) posed by a system?
- How to use current state of knowledge to make reasonable tests for a system to have sufficient DID, which allows for incomplete knowledge?
- How to explain to stakeholders the flexibility inherent in a risk-informed, performance-based approach to DID, which also provides reasonable assurance of safety?

A Risk-Informed Defense-in-Depth Framework for Existing and Advanced Reactors, Karl Fleming, Fred Silady, July 2002

This paper provides a review of the current definitions (at that time), offers solutions to the technical issues identified from the review, and proposes a general definition that can be used for any reactor concept.

The paper notes that over time the definition of DID has evolved from a simple set of strategies to apply multiple lines of defense to a more comprehensive set of cornerstones, strategies and tactics to protect the public health and safety. Based on the various definitions, the paper classifies the definitions as either design DID, process DID or scenario DID. Design DID focuses on strategies implemented during the design phase including the selection of inherent features, definition of reactor specific safety functions, and passive and active engineered safety features that together with the inherent features support the maintenance of radionuclide barriers. Process DID sets requirements and criteria for decision s that ar made in the life cycle of the plant that contribute to plant safety and is the focus of may regulatory decisions to support licensing and regulations of nuclear power. Scenario DID provides a framework for the evaluation of safety using appropriate combinations of deterministic and probabilistic approaches and serves as the “referee” in determining how well the design and process DID decisions are implemented.

The paper provides insights regarding the need to incorporate risk insights into the definitions of DID. A summary of these insights include:
- Risk is dominated by events beyond design basis
- Events beyond the design basis are not always rare
- Radionuclide barriers are not independent

- Containments mitigate some events beyond design basis
- Containments are rarely an independent barrier
- Common cause failures are important for redundant active systems

NEED TO COMPLETE

10 CFR 50.69, 2004

In November, 2004, the final rule on "Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors," (10 CFR §50.69) was published. In the Federal Register Notice announcing the final rule, defense-in-depth is discussed in several places.

As part of the background discussion, it states in the FRN that:

> "Defense-in-depth is an element of the NRC's safety philosophy that employs successive measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. Defense-in-depth is a philosophy used by the NRC to provide redundancy as well as the philosophy of a multiple barrier approach against fission product releases. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges."
>
> "The primary need for improving the implementation of defense-in-depth in a risk-informed regulatory system is guidance to determine how many measures are appropriate and how good these should be. Instead of merely relying on bottom-line risk estimates, defense-in-depth is invoked as a strategy to ensure public safety given there exists both unquantified and unquantifiable uncertainty in engineering analyses (both deterministic and risk assessments).
>
> Risk insights can make the elements of defense-in-depth clearer by quantifying them to the extent practicable. Although the uncertainties associated with the importance of some elements of defense may be substantial, the fact that these elements and uncertainties have been quantified can aid in determining how much defense is appropriate from a regulatory perspective. Decisions on the adequacy of, or the necessity for, elements of defense should reflect risk insights gained through identification of the individual performance of each defense system in relation to overall performance."

As part of the final rule regarding the basis for reduction in scope with regard to Appendix J containment leakage testing:

> "Because it is likely that most CIVs will be categorized as RISC–3, the licensee or applicant must evaluate the proposed change in the treatment of RISC–3 CIVs to ensure that defense-in-depth is maintained by ensuring with reasonable confidence that the RISC–3 CIVs are capable of performing their safety related functions under design basis conditions. Although the licensee or applicant is allowed flexibility in addressing this issue, the rule requires that the licensee or applicant ensure with reasonable confidence the capability of RISC–3 CIVs to perform their safety functions to maintain defense-in-depth as discussed in RG 1.174."

10 CFR §50.69(c)(1)(iii) requires that the categorization process maintain defense-in-depth. In the FRN, it states that to

> "satisfy this requirement, when categorizing SSCs as low safety significant, the IDP must demonstrate that defense-in-depth is maintained. Defense-in-depth is adequate if the overall redundancy and diversity among the plant's systems and barriers is sufficient to ensure the risk acceptance guidelines discussed in Section V.4.4 are met, and that:
>
> - Reasonable balance is preserved among prevention of core damage, prevention of containment failure or bypass, and mitigation of consequences of an offsite release.
> - System redundancy, independence, and diversity is preserved commensurate with the expected frequency of challenges, consequences of failure of the system, and associated uncertainties in determining these parameters.
> - There is no over-reliance on programmatic activities and operator actions to compensate for weaknesses in the plant design.
> - Potential for common cause failures is taken into account.
>
> The Commission's position is that the containment and its systems are important in the preservation of defense-in-depth (in terms of both large early and large late releases). Therefore, as part of meeting the defense-in-depth principle, a licensee should demonstrate that the function of the containment as a barrier (including fission product retention and removal) is not significantly degraded when SSCs that support the functions are moved to RISC–3 (e.g., containment isolation or containment heat removal systems). The concepts used to address defense-in-depth for functions required to prevent core damage may also be useful in addressing issues related to those SSCs that are required to preserve long-term containment integrity. Where a licensee categorizes containment isolation valves or penetrations as RISC–3, the licensee should address the impact of the change in treatment to ensure that defense-in-depth continues to be satisfied."

NEI 02-02. 2002

NEI formed a "New Plant Regulatory Framework Task Force" which was charged with developing a new and optional risk-informed, performance-based regulatory framework for commercial nuclear reactors, focusing mainly on technical and operational requirements. The results of this task force is documented in a white paper, NEI 02-02, entitled "A Risk-Informed, Performance-Based Regulatory Framework for Power Reactors," date May 2002. The paper includes a discussion on "How to treat defense-in-depth in a risk-informed, performance-based regime."

The paper provides principles for a risk-informed, performance-based regulatory framework where one principle is "The framework shall provide for defense-in-depth through requirements and processes that include design, construction, regulatory oversight and operating activities. Additional defense-in-depth shall be provided through the application of deterministic design and operational features for events that have a high degree of uncertainty with significant consequences to public health and safety." The paper does provide the guidance for achieving its defined principle on defense-in-depth. The guidance involves a series of iterative steps:

1. The first step is to complete the initial design.

2. The second step is to perform a risk assessment of the design that includes a PRA. At this point, the design may be modified to meet risk acceptance criteria (which would need to be defined) and in internal industry and licensee guidelines. As a result of any modifications to the design, the PRA would be revised to reflect the changes.

The next series of steps involves addressing the uncertainties. The paper states that "the defense-in-depth opportunities are considered to compensate for unacceptable risk uncertainty." These steps are "based on the cornerstones established in the reactor oversight process that encompass design, construction, regulatory oversight and operational activities."

3. The third step involves identifying key uncertainties.

4. The forth step is to perform an assessment regarding the acceptability of the identified uncertainties. If it is determined that the uncertainties are acceptable, then the design may be considered final. However, if it is determined that the uncertainties are not considered acceptable, then "four discrete defense-in-depth options" are defined.

5. The fifth step defines the four options as:
   - Define risk management activity
   - Increase performance monitoring
   - Add safety margin
   - Add redundancy or diversity

6. The sixth re-evaluates the acceptability of the uncertainties. If determined acceptable, then the design can be considered final; however, it determined unacceptable, then the design and PRA are revisited.

Petition on Davis-Besse, 2003

By letter dated February 3, 2003, Congressman Dennis Kucinich, Representative for the 10th Congressional District of the State of Ohio in the United States House of Representatives, filed a Petition requesting that the NRC "immediately revoke the FirstEnergy Nuclear Operating Company's (FENOC's or the licensee's) license to operate the Davis-Besse Nuclear Power Station, Unit 1 (Davis-Besse)." In the Director's Decision, it is stated that

> "The NRC's approach to protecting public health and safety is based on the philosophy of "defense-in-depth." Briefly stated, this philosophy
>
> 1. requires the application of conservative codes and standards to establish substantial safety margins in the design of nuclear plants;
>
> 2. requires high quality in the design, construction, and operation of nuclear plants to reduce the likelihood of malfunctions, and promotes the use of automatic safety system actuation features;
>
> 3. recognizes that equipment can fail and operators can make mistakes and, therefore, requires redundancy in safety systems and components to reduce the chance that malfunctions or mistakes will lead to accidents that release fission products from the fuel;

4. recognizes that, in spite of these precautions, serious fuel-damage accidents may not be completely prevented and, therefore, requires containment structures and safety features to prevent the release of fission products; and

5. further requires that comprehensive emergency plans be prepared and periodically exercised to assure that actions can and will be taken to notify and protect citizens in the vicinity of a nuclear facility."

Remarks of Nils J. Diaz, Chairman, U.S. Nuclear Regulatory Commission, 2004

On June 3, 2004, at the 3rd Annual Homeland Security Summit Session on "The Best-Laid Plans: A Case Study in Preparedness Planning," Chairman Diaz gave a speech entitled "The Very Best-Laid Plans (the NRC's Defense-in Depth Philosophy)." In his remarks, he states that defense-in-depth "is really more than a philosophy: it is an action plan, an approach to ensuring protection. The concept of "defense-in-depth" is a centerpiece of our approach to ensuring public health and safety, and it goes beyond pieces of equipment. It calls for, among other things, high quality design, fabrication, construction, inspection, and testing; plus multiple barriers to fission product release; plus redundancy and diversity in safety equipment; plus procedures and strategies; and lastly, emergency preparedness, which includes coordination with local authorities, sheltering, evacuation, and/or administration of prophylactics (for example, potassium iodide tablets). This approach addresses the expected as well as the unexpected; it actually accommodates the possibility of failures. . . . The events of 9/11 brought to this country a new recognition of the importance of physical security and emergency preparedness in the world of 21st century America. . . What the post-9/11 review of security issues highlighted is how tightly interconnected are reactor safety, security and emergency preparedness. Many of the same issues are involved in avoiding and mitigating reactor accidents as in preventing and mitigating acts of terrorism. . . The fact is that nuclear reactor design requirements for structures to withstand severe external events (hurricanes, tornadoes, and floods), and for safety systems to include redundant emergency core cooling, redundant and diverse heat removal, fire protection features, and station blackout capabilities, provide built-in means of dealing with attempted terrorist attacks. Existing emergency operating procedures and enhanced severe accident management guidelines are well suited for mitigating the effects of accidents or intentional attacks on nuclear power plants. . . . Further, the studies confirm that even in the unlikely event of a radiological release due to terrorist use of a large aircraft, NRC's emergency planning basis remains valid. Defense-in-depth provides the time needed to use the right protective strategies. . . . The analyses, conclusions, and insights that I just presented for nuclear power plants also apply to spent fuel pools, since they are also well engineered and protected structures, and are amenable to simple and effective mitigative actions, if needed. . . . Defense-in-depth works for nuclear facilities. It is definitely a case study in total preparedness planning."

Digital Instrumentation and Controls, 1994, 1996, 1997, 2007, 2009

There are several documents that discuss this issue. These include NUREG/CR-6303 (Method for Performing Diversity and Defense-in-Depth Analyses of Reactor Protection Systems) dated December 1994; Regulatory Guide 1.152 (criteria for Digital Computers in Safety Systems of Nuclear Power Plants), dated January 1996; NUREG-0800, Branch Technical Position (BTP) HICB-19 (Guidance for Evaluation of Defense-in-depth and Diversity in Digital Computer-Based Instrumentation and Control Systems), dated June 1997; NUREG-0800, Standard Review Plan (SRP), BTP 7-19 (Guidance for Evaluation of Defense-in-depth and Diversity in Digital

Computer-Based Instrumentation and Control Systems), dated March 2007; and DI&C-ISG-02 (Digital Instrumentation and Controls), dated June 2009.

NUREG/CR-6303, 1994

In NUREG/CR-6303, entitled "Method for Performing Diversity and Defense-in-depth Analyses of Reactor Protection Systems, states that "Defense-in-depth is a principle of long standing for the design, construction and operation of nuclear reactors, and may be thought of as requiring a concentric arrangement of protective barriers or means, all of which must be breached before a hazardous material or dangerous energy can adversely affect human beings or the environment. The classic three physical barriers to radiation release in a reactor—cladding, reactor pressure vessel, and containment—are an example of defense-in-depth.

"Echelons of defense" are specific applications of the principle of defense-in-depth to the arrangement of instrumentation and control systems attached to a nuclear reactor for the purpose of operating the reactor or shutting it down and cooling it. Specifically, the echelons are the control system, the reactor trip or scram system, the Engineered Safety Features actuation system (ESFAS), and the monitoring and indicator system. The echelons may be considered to be concentrically arranged in that when the control system fails, the reactor trip system shuts down reactivity; when both the control system and the reactor trip system fail, the ESFAS continues to support the physical barriers to radiological release by cooling the fuel, thus allowing time for other measures to be taken by reactor operators to reduce reactivity. All four echelons depend upon sensors to determine when to perform their functions, and a serious safety concern is to ensure that no more than one echelon is disabled by a common sensor failure or its direct consequences.

REGULATORY GUIDE 1.152, 1996

This Regulatory Guide (RG) describes a method acceptable to the NRC staff for complying with the Commission's regulations for promoting high functional reliability and design quality for the use of digital computers in safety systems of nuclear power plants. In this RG, it notes the staff concern regarding the potential to propagate a common cause failure of redundant equipment and the software programming errors can defeat the redundancy achieved by the hardware architectural structure. Because of this concern, the RG states that "the NRC staff has placed significant emphasis on defense-in-depth against propagation of common cause failures within and between functions." In addition, it states that "the principle of defense-in-depth is to provide several levels or echelons of defense to challenges to plant safety, such that failures in equipment and human error will not result in an undue threat to public safety. A detailed defense-in-depth study and failure mode and effect analysis or an analysis of abnormal conditions or events should be made to address common cause failure."

NUREG-0800, BTP HICB-19, 1997

One of the main objectives of this BTP is "verify that adequate defense-in-depth has been provided in a design to meet the criteria established by the NRC's requirements." In the BTP, it provides the same four echelons of defense as listed in NUREG/CR-6303; however, associated acceptance guidelines are provided:

- "Control system – The control echelon consists of that non-safety equipment which routinely prevents reactor excursions toward unsafe regimes of operation, and is used for normal operation of the reactor.

- RTS – the reactor trip echelon consists of that safety equipment designed to reduce reactivity rapidly in response to an uncontrolled excursion.

- ESFAS – The ESFAS echelon consists of that safety equipment which removes heat or otherwise assists in maintaining the integrity of the three physical barriers to radioactive release (cladding, vessel, and containment).

- Monitoring and indicators – The monitoring and indication echelon consists of sensors, displays, data communications systems, and manual controls required for operators to respond to reactor events."

<u>NUREG-0800, BTP 7-19, 2007</u>

In the BTP, one of the main objectives is the same as noted in BTP HICB-19. The same four defense echelons are also defined in this BTP. The BTP also provides a four-point position that requires a D3 (diversity and defense-in-depth) assessment:

"Point 1 The applicant/licensee should assess the D3 of the proposed I&C system to demonstrate that vulnerabilities to common-cause failures have been adequately addressed.

Point 2 In performing the assessment, the vendor or applicant/licensee should analyze each postulated common-cause failure for each event that is evaluated in the accident analysis section of the safety analysis report (SAR) using best-estimate or SAR Chapter 15 analysis methods. The vendor or applicant/licensee should demonstrate adequate diversity within the design for each of these events.

Point 3 If a postulated common-cause failure could disable a safety function, a diverse means, with a documented basis that the diverse means is unlikely to be subject to the same common-cause failure, should be required to perform either the same function as the safety system function that is vulnerable to common-cause failure or a different function that provides adequate protection. The diverse or different function may be performed by a non-safety system if the system is of sufficient quality to perform the necessary function under the associated event conditions.

Point 4 A set of displays and controls located in the main control room should be provided for manual system-level actuation of critical safety functions and for monitoring of parameters that support safety functions. The displays and controls should be independent and diverse from the computer-based safety systems identified in Points 1 and 3."

<u>DI&C-ISG-02, 2009</u>

This Interim Staff Guidance (ISG) provides acceptable methods for implementing diversity and defense-in-depth (D3) in digital I&C system designs. With regard to specifics, this ISG is consistent with the BTP 7-19 and NUREG/CR-6303.

NUREG-1860, 2007

The comprehensive examination of defense-in-depth can be found In NUREG-1860, "Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing" (also known as the technology-neutral framework, or framework). Iit addresses several questions: what should be the role of defense-in-depth, how should defense-in-depth be factored into the regulatory framework, what is the purpose of defense-in-depth, and how is defense-in-depth related to uncertainties? It states that "The ultimate purpose of defense-in-depth is to compensate for uncertainty (e.g., uncertainty due to lack of operational experience with new technologies and new design features, uncertainty in the in the type and magnitude of challenges to safety)." Defense-in-depth, in the NUREG, is defined as "defense-in-depth is an element of NRC's safety philosophy that is used to address uncertainty by employing successive measure including safety margins to prevent and mitigate damage if a malfunction, accident or naturally caused event occurs at a nuclear facility." The Framework defines four objectives for defense-in-depth:

- "compensate for uncertainties, including events and event sequences which are unexpected because their existence remained unknown during the design phase,
- compensate for potential adverse equipment performance, as well as human actions of commission (intentional adverse acts are part of this) as well as omission,
- maintain the effectiveness of barriers and protective systems by ensuring multiple, generally independent and separate, means of accomplishing their functions, and
- protect the public and environment if these barriers are not fully effective.

The first objective emphasizes the importance of providing some means to counterbalance unexpected challenges. The second objective addresses uncertainty in equipment and human actions. It encompasses equipment design and fabrication errors, as well as both deliberate acts meant to compromise safety, and errors or inadequacy in carrying out procedures meant to ensure safety. The third objective addresses the uncertainty in the performance of the systems, structures, and components (SSCs) that constitute the barriers to radionuclide release, as well as in the SSCs whose function is to protect those barriers. The final objective emphasizes the concept of layers of protection, in that it addresses the need for additional measures should the barriers to radionuclide release fail after all."

The Framework approach incorporates both deterministic and probabilistic elements.

"The two principal deterministic defense-in-depth elements of the approach are

1. Ensuring the implementation of all of the five protective strategies. . . The protective strategies were selected based on engineering judgment, as a minimal set to provide protection for lines of defense against accident and exposure of the public and environment to radioactive material.
2. Ensuring that the defense-in-depth principles . . . are followed to develop licensing potential requirements. . . the defense-in-depth principles are established by examining the different kinds of uncertainties to be treated, and incorporating successful past practices and lessons learned related to defense-in-depth.

The probabilistic elements of the approach consist of

1. Using the PRA, to the extent possible, to search for and identify unexpected scenarios, including their associated uncertainties.

2. To subsequently establish adequate defense-in-depth measures, including safety margins, to compensate for those scenarios and their uncertainties which are quantified in the PRA model. . ."

The process chosen in the Framework to initially identify and define the requirements and regulations is to define safety fundamentals using a defense-in-depth approach, in the form of protective strategies that, if met, will ensure the protection of the public health and safety with a high degree of confidence. The protective strategies provide defense-in-depth that offer multiple layers of protection of public health and safety. The five protective strategies and their objectives are:

1. "The **Physical Protection** objective is to protect workers and the public against intentional acts (e.g., attack, sabotage, and theft) that could compromise the safety of the plant or lead to radiological release.

2. The **Stable Operation** objective is to limit the frequency of events that can upset plant stability and challenge safety functions, during all plant operating states, i.e., full power, shutdown, and transitional states.

3. The **Protective Systems** objective is to ensure that the systems that mitigate initiating events are adequately designed, and perform adequately, in terms of reliability and capability, to satisfy the design assumptions on accident prevention and mitigation during all states of reactor operation. Human actions to assist these systems and protect the barriers are included here.

4. The **Barrier Integrity** objective is to ensure that there are adequate barriers to protect the public from accidental radionuclide releases from all sources. Adequate functional barriers need to be maintained to protect the public and workers from radiation associated with normal operation and shutdown modes and to limit the consequences of reactor accidents if they do occur. Barriers can include physical barriers as well as the physical and chemical form of the material that can inhibit its transport if physical barriers are breeched.

5. The **Protective Actions** objective is to ensure that adequate protection of the public health and safety in a radiological emergency can be achieved should radionuclides penetrate the barriers designed to contain them. Measures include emergency procedures, accident management, and emergency preparedness."

The Framework also defines a set of six defense-in-depth principles with associated criteria that are evaluated against the requirements for each protective strategy. The principles defined in the Framework include:

- "**Measures against intentional as well as inadvertent events are provided**. -- This principle ensures that defense-in-depth measures are applied not just against random failures of SSCs or human errors, but also against acts of sabotage, theft of nuclear materials, armed intrusion, and external attack. Such measures can be incorporated in the design of the plant, be part of operating practices, and include the capability to respond to intrusion or attack.

- **The design provides accident prevention and mitigation capability**. -- This principle ensures an apportionment in the plant's capabilities between limiting disturbances to the plant and mitigating them, should they occur. This apportionment is present in both the design and operation of the plant. It is not meant to imply an equal apportionment of capabilities. Some of the protective strategies (stable operation, protective systems) are more preventive, while others (protective actions, and to some extent barrier integrity) are more mitigative. Physical protection clearly falls into both areas. By requiring that all of the strategies have to be incorporated into plant design and operation, the presence and availability of both preventive and mitigative features is ensured.

- **Accomplishment of key safety functions is not dependent upon a single element of design, construction, maintenance or operation**. -- This principle ensures that redundancy, diversity, and independence in SSCs and actions are incorporated in the plant design and operation, so that no key safety functions will depend on a single element (i.e., SSC or action) of design, construction, maintenance or operation. The key safety functions include (1) control of reactivity, (2) removal of decay heat, and the functionality of physical barriers to prevent the release of radioactive materials.

- **Uncertainties in SSCs and human performance are accounted for in the safety analysis and appropriate safety margins are provided**. -- This principle ensures that when risk and reliability goals are set, at the high level and the supporting intermediate levels, the design and operational means of achieving these goals account for the quantifiable uncertainties, and provide some measure of protection against the ones that cannot be quantified as well.

- **The plant design has containment functional capability to prevent an unacceptable release of radioactive material to the public**. -- This principle ensures that regardless of the features incorporated in the plant to prevent an unacceptable release of radioactive material from the fuel and the reactor coolant system (RCS), there are additional means to prevent an unacceptable release to the public should such a release occur that has the potential to exceed the dose acceptance criteria. The purpose of this principle is to protect against unknown phenomena and threats, i.e., to compensate for completeness uncertainty affecting the magnitude of the source term.

- **Plants are sited at locations that facilitate the protection of public health and safety**. -- This principle ensures that the location of regulated facilities facilitates the protection of public health and safety by considering population densities and the proximity of natural and human-made hazards in the siting of plants. Physical protection aspects associated with security concerns are additional considerations in selecting the site. Siting factors and criteria are important in ensuring that radiological doses from normal operation and postulated accidents will be acceptably low, that natural phenomena and potential human made hazards will be accounted for in the design of the plant, that site characteristics are such that adequate security measures to protect the plant can be developed, and that physical characteristics unique to the proposed site that could pose a significant impediment to developing emergency plans are identified."

INL NGNP, 2009

Idaho national Laboratory published INL/EXT-09-17139, "Next Generation Nuclear Plant Defense-in-Depth Approach," in December 2009. The report documents a definition of defense-in-depth and the approach to be used to assure that its principles are satisfied for the NGNP project. It states the "defense-in-depth is a safety philosophy in which multiple lines of defense and conservative design and evaluation methods are applied to ensure the safety of the public. The philosophy is also intended to deliver a design that is tolerant to uncertainties in knowledge of plant behavior, component reliability, or operator performance that might compromise safety." For NGNP, a defense-in-depth framework is proposed that defines three major elements:

1. "Plant capability defense-in-depth that reflects the decision made by the designer in the selection of functions, structures, systems and components for the design that ensure defense-in-depth in the physical plant.

2. Programmatic defense-in-depth that reflects the decisions made regarding the processes of manufacturing, constructing, operating, maintaining, testing, and inspecting the plant and the processes undertaken that ensure plant safety throughout the lifetime of the plant.

3. Risk-informed evaluation of defense-in-depth that reflects the development and evaluation of strategies that manage the risks of accidents, including the strategies of accident prevention and mitigation. This aspect provides the framework for performing deterministic and probabilistic safety evaluations, which help determine how well the other two defense-in-depth elements have been implemented."

For each of the above elements, principles and criteria are defined for each. For example, for plant capability defense-in-depth, it includes "the use of multiple barriers, diverse and redundant means to perform safety functions to protect the barriers, conservative design principles and safety margins, site selection, and other physical and tangible elements of the design that use multiple lines of defense and conservative design approaches to protect the public."

As part of the risk-informed evaluation defense-in-depth element, a decision process with associated criteria is proposed. It evaluates whether the developed frequency-consequence curve has been met in conjunction with determining if there is adequate prevention and mitigation and adequate safety margins. It further evaluates whether the uncertainties have been adequately addressed and if the defense-in-depth principles have been met. If the above have each been adequately addressed, then it is determined that there is adequate treatment of defense-in-depth. If at any point in the decision process that one of the decisions have not been adequately addressed, then plant defense-in-depth capabilities and the programmatic assurance are each enhanced and the entire decision criteria are re-evaluated.

RG 1.174, 2012

RG 1.174, Revision 2, dated May 2011, provides guidance on the use of PRA findings and risk insights to support licensee requests for changes to a plant's LB, as in requests for license amendments and technical specification. In the RG, it provides an approach for "implementing risk-informed decisionmaking, LB changes are expected to meet a set of key principles. Some of these principles are written in terms typically used in traditional engineering decisions (e.g., defense-in-depth). While written in these terms, it should be understood that risk analysis techniques can be, and are encouraged to be, used to help ensure and show that these principles are met." One principle states "The proposed change is consistent with a defense-in-depth philosophy."

In response to a Commission SRM, RG 1.174 is being revised to better address defense-in-depth. Draft Guide 1285 states:

> "The engineering evaluation should evaluate whether the impact of the proposed LB change (individual and cumulative) is consistent with the defense-in-depth philosophy. In this regard, the intent of this principle is to ensure that the philosophy of defense-in-depth is

maintained, not to prevent changes in the way defense-in-depth is achieved. Defense in depth is an element of the NRC's safety philosophy that employs successive compensatory measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges.

At a high level, there are three layers of defense against the consequences of an event at a nuclear facility. The three layers are (1) protection to prevent accidents from occurring, (2) mitigation of accidents if they occur, and (3) emergency preparedness to minimize the public health consequences of releases if they occur. An important element of the three layers is that a reasonable balance should be preserved among them. Another major aspect of defense-in-depth is maintaining multiple barriers to the release of fission products. While it could be reasoned that multiple fission product barriers represent one approach to implementing the three high-level layers of defense-in-depth, the use of barriers is so fundamental to this philosophy that it warrants its own discussion."

DG 1285 provides a discussion on the three high-level layers of defense-in-depth, followed by a discussion of fission product barriers. A discussion is also provided of some factors that licensees should consider when assessing whether a proposed change to the plant is consistent with the three layers and the multiple-barrier philosophy.

"Preserving Balance Among the Three Layers of Defense-in-Depth

A reasonable balance of these layers (i.e., preventing accidents, mitigating accidents, and emergency preparedness) helps to ensure an apportionment of the plant's capabilities between limiting disturbances to the plant and mitigating their consequences. "Balance" is not meant to imply an equal apportionment of capabilities. A reasonable balance is preserved if the proposed plant change does not significantly reduce the effectiveness of a layer that exists in the plant design before the proposed change. The NRC recognizes that there may be aspects of a plant's design that may cause one of the three layers to be adversely affected. For these situations, the balance between the other two layers becomes especially important when evaluating the impact of a proposed change to the LB and its impact on defense-in-depth.

Preserving Multiple Fission Product Barriers

The plant's LB includes fission product barriers and engineered structures, systems, and components (SSCs) that support or maintain those barriers. These barriers, as exemplified by current reactors, are generally considered to be the fuel elements' cladding, the reactor coolant system pressure boundary, and the containment systems and structure. Adverse conditions created during reactor accidents (e.g., high temperature, high pressure) can challenge the integrity of barriers. Consequently, the concept of multiple barriers provides for separate means to contain and mitigate fission products. The intent of preserving multiple barriers may be adversely affected if the proposed plant change reduces the effectiveness of any of the barriers. The licensee should evaluate the impact of the proposed change on the fission product barriers and supporting systems and consider any cause and effect relationship between the barrier and the aspect of the plant proposed to be changed.

Factors To Consider When Evaluating the Impact of a Change on Defense-in-Depth

When evaluating the impact of a proposed plant change on the three high-level layers (Section 2.1.1.1 above) and the multiple fission product barriers (Section 2.1.1.2 above) of defense-in-depth, the licensee should consider the following factors:

- programmatic activities as compensatory measures;
- system redundancy, independence, and diversity;
- potential for common-cause failure (CCF);
- reliance on plant operators; and
- intent of the plant's design criteria.

These factors are not meant to be a comprehensive list, but are intended to help the licensee assess how the proposed change could affect one of the three layers of defense or one of the multiple barriers."

DG 1285 provides a discussion explaining each of the above factors including examples for additional clarification. This discussion from DG 1285 is not repeated.

NRC Glossary, 2012

The glossary on the NRC Website defines defense-in-depth as "An approach to designing and operating nuclear facilities that prevents and mitigates accidents that release radiation or hazardous materials. The key is creating multiple independent and redundant layers of defense to compensate for potential human and mechanical failures so that no single layer, no matter how robust, is exclusively relied upon. Defense-in-depth includes the use of access controls, physical barriers, redundant and diverse key safety functions, and emergency response measures."

Proposed Risk Management Regulatory Framework, 2012

At the request of Chairman Gregory B. Jaczko, a task force headed by Commissioner George Apostolakis was assembled whose charter was to develop a strategic vision and options for adopting a more comprehensive, 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. In the report, defense-in-depth plays a key role in their recommendation regarding a proposed Risk Management Regulatory Framework. The task force reviewed across the various arenas and notes:

- "After decades of use, there is no clear definition or criteria on how to define adequate defense-in-depth protections.

- the concept of defense-in-depth has served the NRC and the regulated industries well and continues to be valuable today. However, it is not used consistently, and there is no guidance on how much defense-in-depth is sufficient.

- The term "defense-in-depth" has been used since the 1960s in the context of ensuring nuclear reactor safety. The concept was developed and applied to compensate for the recognized lack of knowledge of nuclear reactor operations and the consequences of potential accidents.

- The Risk Management Task Force (RMTF) has reviewed a number of documents[4] that historically have helped to shape the characterization of defense-in-depth. Since the characterizations provided in these documents are not completely consistent and are focused on operating power reactors, the RMTF concluded that clarifying what the U.S. Nuclear Regulatory Commission (NRC) means by defense-in-depth is a necessary part of the development of a holistic strategic vision."

The RMTF characterizes defense-in-depth as follows:

"Provide risk-informed and performance-based defense-in-depth protections to:

- Ensure appropriate barriers, controls, and personnel to prevent, contain, and mitigate exposure to radioactive material according to the hazard present, the relevant scenarios, and the associated uncertainties.
  - Each barrier is designed with sufficient safety margins to maintain its functionality for relevant scenarios and account for uncertainties.
  - Systems that are needed to ensure a barrier's functionality are designed to ensure appropriate reliability for relevant scenarios.
  - Barriers and systems are subject to performance monitoring.

  and
- Ensure that the risks resulting from the failure of some or all of the established barriers and controls, including human errors, are maintained acceptably low."

[4] The documents reviewed by the RMTF include (1) Safety," INSAG-10, A Report by the International Nuclear Safety Advisory Group, 1996; (2) Idaho National Laboratory, "Next Generation Nuclear Plant Defense-in-Depth Approach," INL/EXT-0917139, December 2009; (3) U.S. Nuclear Regulatory Commission, Staff Requirements Memorandum Regarding SECY-98-44, "White Paper on Risk-Informed and Performance-Based Regulation," March 1, 1999, Agencywide Documents Access and Management System (ADAMS) Accession No. ML003753601; (4) U.S. Nuclear Regulatory Commission, "Risk-Informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Reactors," 10 CFR 50.69, Published in the Federal Register on November 22, 2004 (69 FR 68008); and U.S. Nuclear Regulatory Commission, "Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing," NUREG-1860, Volume 1, December 2007, ADAMS Accession No. ML080440170.

ENCLOSURE 4: NRC STAFF OUTREACH ON DISPOSITION OF NTTF RECOMMENDATION 1

Public Meetings:

June 20, 2012 Public meeting to discuss the status of Fukushima Near-Term Task Force Recommendation 1

- Meeting notice (ADAMS Accession No. ML12152A014)
- Press release (ADAMS Accession No. ML12159A179)
- Presentation slides (ADAMS Accession No. ML12198A035)
- Meeting summary (ADAMS Accession No. ML12195A152)

Public Comments

Comment Number	Name	Affiliation	Date Received	ADAMS Accession no.
Note 1	Adrian Heymer	Nuclear Energy Institute	7/16/2012	ML12207A185

Note 1: This letter, addressing Recommendation 1, was received even though a formal comment period was not provided. However, the letter was considered during the NRC staff development of the recommended improvement activities.

November 8, 2012 Public meeting to discuss the status of Fukushima Near-Term Task Force Recommendation 1

- Meeting notice (ADAMS Accession No. ML12296A052)
- Press release (ADAMS Accession No. ML12306A188)
- Option summary (ADAMS Accession No. ML12296A096)
- Presentation slides (ADAMS Accession No. ML12314A039)
- Meeting summary (ADAMS Accession No. ML12320A254)

Public Comments

Comment Number	Name	Affiliation	Date Received	ADAMS Accession no.
Note 1	unknown		11/08/2012	ML12320A254
1	Paul Sicard		11/13/2012	ML12324A275
2	Ed Burns	Westinghouse	12/10/2012	ML12348A033
3	Jack Stringfellow	Pressurized Water Reactor Owners Group	12/12/2012	ML12354A405
4	Prasad Kadambi		12/12/2012	ML12354A406
5	Biff Bradley	Nuclear Energy Institute	12/13/2012	ML12355A369

Note 1: This comment was made verbally at the November 8, 2012 public meeting and reflected in the meeting minutes.

June 5, 2013

Public meeting to discuss the status of Fukushima Near-Term Task Force Recommendation 1

- Meeting notice (ADAMS Accession No. ML13126A004)
- Press release (ADAMS Accession No. ML13142A442)
- 02/2013 white paper (ADAMS Accession No. ML13053A108
- 05/2013 white Paper (ADAMS Accession No. ML13135A125)
- Presentation slides (ADAMS Accession No. ML13156A370)
- Meeting summary (ADAMS Accession No. ML13171A005)

Public Comments

Comment Number	Name	Affiliation	Date Received	ADAMS Accession no.
Note 1	Joseph Pollock	Nuclear Energy Institute	4/30/2013	ML131260106
Note 2	Ed Burns	Westinghouse	6/5/2013	ML13171A005
Note 2	Prasad Kadambi		6/5/2013	ML13171A005
Note 2	Steven Dolly	Platts	6/5/2013	ML13171A005
Note 2	Ed Lyman	UCS	6/5/2013	ML13171A005
Note 3	Stephen Maloney		8/11/2013	ML13233A024
6	Stephen Maloney		8/13/2013	ML13239A438
7	Prasad Kadambi		8/11/2013	ML13233A025
8	Joseph Pollock	Nuclear Energy Institute	8/15/2013	ML13234A022
9	Scott Bauer	STARS Alliance LLC	8/30/2013	ML13252A064

Note 1: This letter was received outside of the formal comment period, but was treated as a comment and considered during the NRC staff development of the recommended improvement activities.

Note 2: This comment was made verbally at the June 20, 2013 public meeting and reflected in the meeting minutes.

Note 3: This comment submission was superseded by comment submission 6, which was received two days after this comment submission.